IDEAS TO IMPROVE MEDICARE OVERSIGHT TO REDUCE WASTE, FRAUD AND ABUSE

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HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

APRIL 30, 2014

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IDEAS TO IMPROVE MEDICARE OVERSIGHT TO REDUCE WASTE, FRAUD AND ABUSE

WEDNESDAY, APRIL 30, 2014

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to call, at 1:58 p.m., in Room 1100, Longworth House Office Building, Hon. Kevin Brady [Chairman of the Subcommittee] presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
Wednesday, April 23, 2014
No. HL–11

CONTACT: (202) 225–3625

Chairman Brady Announces Hearing on Ideas to Improve Medicare Oversight to Reduce Waste, Fraud and Abuse

House Ways and Means Health Subcommittee Chairman Kevin Brady (R–TX) today announced that the Subcommittee on Health will hold a hearing on Medicare waste, fraud, and abuse, with a focus on the policies that address these problems. This hearing will allow the Subcommittee to hear directly from the U.S. Office of the Inspector General at the Department of Health and Human Services (OIG–HHS), the U.S. Government Accountability Office (GAO), and the Centers for Medicare and Medicaid Services' Center for Program Integrity (CPI) about the different recommendations and approaches to curb abuses within Medicare. The Subcommittee will hear testimony from Gloria Jarmon, Deputy Inspector General for Audit Services at OIG–HHS; Kathleen King, Director, Health Care at GAO; and Dr. Shantanu Agrawal, Deputy Administrator and Director of CPI. **The hearing will take place on Wednesday, April 30, 2014, in 1100 Longworth House Office Building, beginning at 2:00 p.m.**

In view of the limited time available to hear from the witnesses, oral testimony at this hearing will be from the invited witnesses only. However, any individual or organization not scheduled for an appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

According to the 2014 March Medicare Payment Advisory Commission (MedPAC), the Medicare program paid out approximately $574 billion each year to more than 1.5 million doctors, hospitals and medical suppliers, and citing a GAO report estimates that about $44 billion a year is lost to fraudulent activity within the system. There are many methods utilized by perpetrators of fraud, including false billing and identity theft.

CMS has primary responsibility for paying providers appropriately for furnishing services to beneficiaries and preventing fraud, waste, and abuse. The agency partners with numerous entities to carrying out these important functions, including contracts with:

- Medicare Administrative Contractors (MACs) perform prepayment medical reviews to ensure services provided to Medicare beneficiaries are covered and medically necessary, among other activities;
- Zone Program Integrity Contractors (ZPICs), located in seven zones throughout the country, are auditors that perform a wide range of medical review, data analysis, and evidence-based policy auditing activities;
- Recovery Audit Contractors (RACs) aim to reduce Medicare improper payments through the detection and collection of overpayments, the identification of underpayments, and the implementation of actions that will prevent future improper payments. Many of these activities involve data-mining activities based on billing information. Most of the data analysis is done after Medicare has made payment, but some work is now also being done before on a prepayment basis. The Affordable Care Act established RACs for Medicare Part C and Part D and for Medicaid.

The OIG–HHS and GAO monitor efforts by CMS and its contractors to evaluate performance and identify vulnerabilities. OIG–HHS and GAO reports, often requested by Members of the Committee, provide valuable insight and information to assist the Congress in oversight of the Medicare program.

The Federal Government devotes significant resources and employs numerous entities to curb inappropriate and excessive payments. While significant improvements in fraud detection have been made, such as enhanced screening of certain provider types before Medicare pays them, the most recent Comprehensive Error Rate Testing (CERT) contractor report to Congress shows additional improvements can and should be made. The report states that the payment error rate for the Medicare program was 8.5 percent for FY2012, the most recent data available, representing $29.6 billion in payment errors. This hearing will give Members the opportunity to assess if resources are being used efficiently and identify how to improve a system in need of transparency and upgrade.

In announcing the hearing, Chairman Brady stated, **"It is very clear that problems with Medicare waste, fraud, and abuse persist. The Medicare trust fund is already headed toward insolvency and every dollar of fraud is a dollar not dedicated to providing quality care for our Nation's seniors. It's a double whammy for seniors, threatening their access to necessary care while also hitting their pocketbook. More action, stronger oversight, and true transparency is needed. This hearing will find areas of improvement by looking honestly and thoroughly at the problem. We must move beyond the unacceptable status quo and work to enact bipartisan bills to strengthen anti-fraud programs to protect the Medicare program for generations to come."**

FOCUS OF THE HEARING:

The hearing will focus on the different agencies roles and missions in curbing the fraud, waste, and abuse within the Medicare program.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "Hearings." Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Wednesday, May 14, 2014**. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721 or (202) 225–3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone, and fax numbers of each witness.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TDD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://www.waysandmeans.house.gov/*.

Chairman BRADY. This Subcommittee will come to order. Good afternoon, everyone.

Every dollar lost to Medicare fraud is a dollar stolen from America's elderly and every dollar lost to improper payments, intentional or not, robs from the solvency of this important program. Today's hearing will examine the issue of Medicare fraud. This is a bipartisan concern shared by our seniors, the Medicare program and lawmakers on this Committee.

The Office of Inspector General, which is testifying here today, cites that nearly $50 billion is lost to improper Medicare payments each year. That is an alarming amount. I am most alarmed by how often I open the Houston Chronicle back home to find stunning investigations of Medicare fraud that runs into tens of millions of dollars, involving doctors, ambulance companies, mental health clinics and even patient advocates, those who are tasked with protecting the sick and elderly.

Last Friday brought news of a 13-count indictment of providers in Florida and the Houston area for allegedly billing Medicare for services that were not needed and providing kickbacks for patient referrals. Last Wednesday was the sentencing of a Houston-area woman after her 2013 conviction for defrauding Medicare. These stories are all too frequent in communities around the Nation.

To make matters worse, in the past year, the Office of Inspector General has documented evidence that Medicare has paid for services to those who are deceased, in prison, and not entitled to benefits, all this while Medicare's main trust fund is on a crash course with insolvency in a short 12 years.

President George W. Bush established the Federal Medicare Fraud Strike Force in 2007 that changed to a much more aggressive approach to Medicare fraud, and it is starting to bear fruit. In response, the Centers for Medicare and Medicaid have taken strides to address this growing problem. The agency has used its authority to impose a temporary moratorium on the enrollment of certain providers in high-risk areas, including preventing new ambulance companies from billing Medicare in my home State of Texas; however, more must be done to protect our seniors and taxpayers.

While a moratorium on new providers may very well prevent unscrupulous providers from entering the program, it doesn't stop those who have already enrolled and are improperly billing. More must be done to move from the outdated pay-and-chase approach to a new 21st century approach that stops improper payments before they go out the door.

I am also concerned about the CMS lack of leadership and interest in problems that are especially embarrassing for the Medicare program. Preventing payments for services to those who are dead or are in jail involves a straightforward fix, yet it is still a problem, regrettably still a topic for discussion at this hearing. And that is the focus of this hearing, not merely identifying the fraud and abuses, but identifying what can be done using new technologies and successful strategies to prevent and deter fraud in the future.

First, I commend my colleagues on this Committee, Members on both sides of the aisle, who have introduced bills to make commonsense changes. For example, my colleagues and fellow Texans, Mr. Johnson and Mr. Doggett, have been working on a legislative fix for nearly a decade to take Social Security numbers off of Medicare cards. And you see bipartisan efforts throughout this Subcommittee. It is frustrating that such a simple fix has yet to happen. I look forward to the day when I can tell my seniors in my district that they no longer must worry about having their Social Security number compromised simply by carrying the Medicare card they need to access their health care.

Second, we are interested in hearing recommendations from the OIG and the Government Accountability Office. These watchdog entities have identified vulnerabilities and proposed solutions in the areas of improper payments, and CMS oversight of claims paying and fraud fighting contractors. Many of these recommended fixes support bills that Members of Congress on this Committee are championing.

Third, we will hear from CMS about its program integrity efforts. While we are interested to hear what the agency has done, we are perhaps more interested in what it plans to do going forward.

The written statements from our witnesses make clear that much work is left to be done. Lawmakers have ideas, OIG and GAO have made recommendations, and CMS has its plans. So let's identify the ideas and solve our problems and get to work now to put them in place. It is not important who comes up with these ideas on fighting fraud, waste and abuse. What is important is that we act on these good ideas. It is my intent that we move forward on a bipartisan basis, working with CMS, to protect our seniors, bolster the Medicare trust fund, and ensure appropriate use of taxpayer funds.

Before I recognize the Ranking Member, Dr. McDermott, for the purposes of an opening statement, I ask unanimous consent that all Members' written statements be included in the record. Without objection, so ordered. I now recognize our Ranking Member, Dr. McDermott, for his opening statement.

Mr. MCDERMOTT. Thank you, Mr. Chairman. I want to commend the chairman for having this hearing. I think the controlling of costs as we move forward in health care is going to be the toughest issue we face. This administration has been serious about combating fraud, waste and abuse. The joint effort of Attorney General Holder and Secretary Sebelius through the Health Care Fraud Prevention and Enforcement Action Team, so-called HEAT, there have been measurable results. The team has recovered in excess of $4 billion every single year since 2011. That is real money.

There was a time when a hearing on Medicare fraud such as this would have focused solely on the dollar amounts recouped at the back end after the fraud had been perpetrated, and any money that could have been recouped would have been long spent. Then came the Affordable Care Act, which gave regulators additional new powers to prevent fraud rather than just reactively address it, powers such as expanded payment suspension authority and the requirements to effectively police who gets into the Medicare program, ensuring Medicare participation is reserved for scrupulous providers and suppliers.

So now when we talk about our fraud prevention efforts, we speak a different language than even 5 years ago. We speak of payment suspensions in greater numbers, we speak of high risk or moderate risk providers and suppliers, we are talking about fingerprinting owners of the high risk providers and suppliers, we speak of the fraud prevention system and the predictive analytics designed to monitor for potential fraud on a real-time basis.

Notwithstanding all the efforts that have been made at transforming Medicare and Medicaid into programs that hold participating providers and suppliers accountable, as the chairman has said, much more work needs to be done.

With alternative delivery system models, what does fraud, waste and abuse really look like? With the expanded waiver authority that essentially granted Federal agencies the ability to issue wide-open waivers, what new fraud schemes will emerge?

So our important work in this area is not done. Much more work remains. I know the GAO will continue to play an important role in helping us with our oversight responsibilities, and the OIG and CMS will use their expanded authorities to root out the fraud, waste and abuse to preserve the Medicare and Medicaid programs for the future.

I look forward to working with the chairman on a bipartisan basis on these issues. I yield back the balance of my time.

Chairman BRADY. Thank you, Doctor.

Today we will hear from three distinguished witnesses: Gloria Jarmon, Deputy Inspector General for audit services at the Office of Inspector General, the Department of Health and Human Services; Kathleen King, Director of Health at the Government Accountability Office; and Dr. Shantanu Agrawal, Deputy Administrator at CMS and Director of Center for Program Integrity.

We have reserved 5 minutes for each of the opening statements and we will explore the testimony further during questions. Ms. Jarmon, you are recognized.

STATEMENT OF GLORIA L. JARMON, DEPUTY INSPECTOR GENERAL FOR AUDIT SERVICES, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. JARMON. Good afternoon, Chairman Brady, Ranking Member McDermott, and other distinguished Members of the Subcommittee. Thank you for the opportunity to discuss OIG's work related to Medicare oversight and reducing fraud, waste and abuse. We have a lot of work in this area. Today my statement focuses on our recent work related to improper Medicare payments and billings and oversight of Medicare contractors.

CMS needs to continue to take steps to reduce improper Medicare payments and improve its oversight of the various Medicare contractors. Improper Medicare payments cost taxpayers and beneficiaries about $50 billion a year. In recent work, OIG has identified millions in improper payments made on behalf of persons not entitled to Medicare, such as incarcerated, unlawfully present, deceased, or entitlement-terminated individuals. While some progress has been made by CMS in these areas, it needs more accurate and timely information to trigger payment edits and better procedures to detect and recoup these improper payments.

OIG has also uncovered a stream prescribing patterns for hundreds of general care physicians and questionable billings by thousands of retail pharmacies. Medicare also paid millions for prescriptions from unauthorized prescribers, such as massage therapists and athletic trainers. This is especially concerning in light of OIG's increasing investigations into drug diversion. Verification of prescriber authority edits and enhanced monitoring are necessary to safeguard Medicare Part D and ensure patient safety.

Recently we have also reported improper payments to hospitals of millions of dollars related to vulnerabilities we identified as part of our nationwide hospital compliance reviews. In addition, we found that Medicare could have saved about $638 million over just a 2-year period by establishing a hospital transfer-of-payment policy for hospice transfers and strengthening billing requirements. OIG has made specific recommendations to reduce these and other improper payments, but those steps alone will not adequately safeguard Medicare.

CMS must continue its efforts to improve its oversight of Medicare contractors. CMS relies on contractors to administer various parts of Medicare, including claims payment, identification and recoupment of overpayments and benefit integrity functions. Our work has identified vulnerabilities associated with CMS's oversight of contractors.

First, CMS has not fully leveraged data to improve oversight. Part C and Part D plans report fraud and abuse data on merely a voluntary basis. CMS does not mandate such reporting. Under this system, we found that less than half of the Part D plans have actually reported fraud data, and reporting varies significantly from plan to plan. In addition, CMS has made limited use of the data it has received in overseeing Part C plans and has not fully used reported fraud and abuse data for monitoring Part D. As a result, CMS is still missing opportunities to discover and alert plans and law enforcement to emerging fraud and abuse schemes.

Second, we have found that while CMS's performance reviews of Medicare Administrative Contractors, or MACs, were extensive, they were not always timely. If the performance reviews are not performed—completed and performed timely, the information they contain may not be available to support future contracting decisions.

To improve contractor oversight, we have made several recommendations to CMS that are included in our compendium of priority recommendations on our Web site.

While my testimony focuses on our work to help CMS improve program operations, I would like to make a request that would help

OIG better meet our growing oversight responsibilities. OIG is responsible for oversight of about $0.25 of every Federal dollar spent, but our mission is challenged by declining resources at a time when our oversight responsibilities are increasing.

By the end of this fiscal year, OIG expects to reduce Medicare and Medicaid oversight by about 20 percent. During the same time, 2012 to 2014, outlays for Medicare are expected to grow by about 20 percent. To ensure that we can continue to provide needed oversight as these programs expand, we ask for the Committee's support of our 2015 budget request.

In summary, we remain very committed to carrying out our responsibilities in the area of improving Medicare oversight to reduce waste, fraud and abuse as comprehensively and effectively as possible with the tools and resources we have available.

Thank you for your interest and support. I would be happy to answer your questions.

[The prepared statement of Ms. Jarmon follows:]

Testimony of:
Gloria L. Jarmon
Deputy Inspector General for Audit Services
Office of Inspector General
U.S. Department of Health and Human Services

Hearing:
"Ideas to Improve Medicare Oversight
To Reduce Waste, Fraud, and Abuse"

House Committee on Ways and Means
Subcommittee on Health

April 30, 2014
1100 Longworth House Office Building
2:00 PM

Testimony of:
Gloria L. Jarmon
Deputy Inspector General for Audit Services
Office of Inspector General
U.S. Department of Health and Human Services
Hearing Title: "Ideas to Improve Medicare Oversight to Reduce Waste, Fraud, and Abuse"
House Ways and Means Committee
Subcommittee on Health

Good afternoon, Chairman Brady, Ranking Member McDermott, and other distinguished Members of the Subcommittee. Thank you for the opportunity to testify about the U.S. Department of Health and Human Services (the Department) Office of Inspector General's work to improve Medicare oversight to reduce waste, fraud, and abuse. Fighting waste, fraud, and abuse in Medicare and other Department programs is a top priority. We use a range of tools in this fight, including audits, evaluations, investigations, enforcement authorities, and educational outreach.

The key takeaway from my testimony today is that more action is needed from the Centers for Medicare & Medicaid Services (CMS), its contractors, and the Department to reduce improper Medicare payments and billings and improve oversight of its Medicare contractors. Reducing improper payments and improving the oversight of contractors are two of the Department's top management and performance challenges and are critical to reducing Medicare waste, fraud, and abuse.

CMS Should Further Reduce Improper Medicare Payments

Improper Medicare payments cost taxpayers and beneficiaries about $50 billion a year. For fiscal year (FY) 2013, the Department reported improper payment information for eight programs that the Office of Management and Budget deemed susceptible to significant improper payments. Three of these programs were Medicare related: Medicare Fee-for-Service (Fee-for-Service), Medicare Advantage (Part C), and the Medicare Prescription Drug Benefits Program (Part D). In its FY 2013 Agency Financial Report,[1] the Department reported $36 billion in improper payments for Medicare Fee-for-Service, $11.8 billion for Part C, and $2.1 billion for Part D.

The Department has achieved some success in reducing improper payment rates.[2] In the FY 2013 Agency Financial Report, the Department reported reductions in rates for five of the Department's programs, including Part C. However, the Department reported increases in gross improper payment rates for Fee-for-Service (from 8.5 percent in FY 2012 to 10.1 percent in

[1] *Department of Health and Human Services FY 2013 Agency Financial Report,* available at http://www.hhs.gov/afr/2013-hhs-agency-financial-report.pdf.

[2] *U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for Fiscal Year 2013*, A-17-14-52000, April 15, 2014, available at http://oig.hhs.gov/oas/reports/other/171452000.asp.

FY 2013) and Part D (from 3.1 percent in FY 2012 to 3.7 percent in FY 2013). By having a Fee-for-Service improper payment rate that exceeded 10 percent, the Department did not comply with one of the requirements of the Improper Payments Information Act of 2002, as amended.[3]

Our recent audits and evaluations have identified opportunities to reduce improper payments throughout the Department, including three areas critical to Medicare program integrity: payments made on behalf of ineligible beneficiaries, payments for prescription drugs, and payments to hospitals.

Reducing Improper Medicare Payments on Behalf of Ineligible Beneficiaries

We have uncovered improper Medicare payments on behalf of unlawfully present, incarcerated, entitlement-terminated, and deceased beneficiaries. Obtaining more accurate and timely information that would trigger payment edits would help Medicare avoid these improper payments.

Unlawfully Present Beneficiaries. Medicare benefits are not allowable for services provided to unlawfully present beneficiaries.[4] Although CMS has procedures to identify these beneficiaries, CMS did not always prevent and detect improper payments:

- For Fee-for-Service – CMS prevented improper payments when it received unlawful presence information before the Medicare contractor processed a claim. However, when the information was not timely, CMS's controls were not adequate to detect and recoup the improper payment. We identified more than $91 million in improper payments.

- Part C – CMS did not have policies and procedures to notify the Part C plans of the unlawful-presence information in its data systems. As a result, Part C plans could neither prevent unlawfully present beneficiaries from enrolling nor could the Part C plans disenroll beneficiaries whose unlawful-presence status changed after they had enrolled. We identified more than $26 million in improper payments.[5]

[3] The IPIA has been amended by the IPERA as well as the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA; P.L. No. 112-248).

[4] Federal health care benefits are generally allowable when provided to a beneficiary who is either a U.S. citizen or a U.S. national or to an alien who is lawfully present in the United States. But when the alien beneficiary is not lawfully present in the United States (unlawfully present), Federal health care benefits are not allowable.

[5] *Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 Through 2012*, A-07-13-01125, April 23, 2013, available at http://oig.hhs.gov/oas/reports/region7/71301125.asp.

- Part D – CMS also lacked policies and internal controls to identify and disenroll unlawfully present beneficiaries and to automatically reject prescription drug event (PDE) records associated with those beneficiaries. We identified more than $29 million in gross drug costs related to unlawfully present Part D beneficiaries.[6]

Incarcerated Beneficiaries. With certain exceptions, prisons (instead of Medicare) pay for the health care of incarcerated individuals who are otherwise eligible for Medicare. However, CMS does not always receive timely updates regarding incarceration information before Medicare contractors pay providers on behalf of incarcerated beneficiaries. In these instances, CMS's controls were not adequate to detect and recoup the improper payment. We identified more than $33 million in improper Fee-for-Service payments.[7]

Entitlement-Terminated Beneficiaries. We identified more than $18 million of improper Fee-for-Service payments made on behalf of beneficiaries whose entitlement to Medicare had been terminated.[8] These improper payments occurred because CMS's data systems did not always indicate that a beneficiary's entitlement had been terminated until after a claim had been processed. In addition, CMS did not have policies and procedures to review such information after payment that would have flagged improper payments that could not be detected before payment. Consequently, CMS had not notified the Medicare contractors to recoup any of the improper payments that we identified.

Deceased Beneficiaries. We have identified millions in Medicare payments made on behalf of deceased beneficiaries. Although CMS has safeguards to prevent and recover these payments, it inappropriately paid $23 million in 2011 for deceased beneficiaries. Most of these improper payments occurred despite CMS having accurate information on beneficiaries' date of death. Eleven percent of these improper payments occurred because dates of death were either missing from CMS's Enrollment Database or were incorrect.[9]

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[6] *Medicare Improperly Paid Millions of Dollars for Prescription Drugs Provided to Unlawfully Present Beneficiaries During 2009 Through 2011*, A-07-12-06038, October 30, 2013, available at http://oig.hhs.gov/oas/reports/region7/71206038.asp.

[7] *Medicare Improperly Paid Providers Millions of Dollars for Unlawfully Present Beneficiaries Who Received Services During 2009 Through 2011*, A-07-12-01116, January 23, 2013, available at http://oig.hhs.gov/oas/reports/region7/71201116.asp. *Medicare Improperly Paid Providers Millions of Dollars for Incarcerated Beneficiaries Who Received Services During 2009 Through 2011*, A-07-12-01113, January 23, 2013, available at http://oig.hhs.gov/oas/reports/region7/71201113.asp.

[8] *Medicare Improperly Paid Providers Millions of Dollars for Entitlement-Terminated Beneficiaries Who Received Services During 2010 Through 2012*, A-07-13-01127, April 7, 2014, available at http://oig.hhs.gov/oas/reports/region7/71301127.asp.

[9] *Medicare Payments Made on Behalf of Deceased Beneficiaries in 2011,* OEI-04-12-00130, October 30, 2013, available at http://oig.hhs.gov/oei/reports/oei-04-12-00130.asp.

Key recommendations to CMS include:

- Implement policies and procedures to detect and recoup improper payments made to unlawfully present and incarcerated beneficiaries.

- Prevent enrollment in Part D of unlawfully present beneficiaries, disenroll any currently enrolled unlawfully present beneficiaries, and automatically reject PDE records submitted by Part D plans for prescription drugs provided to this population.

- Identify and recoup improper payments made on behalf of entitlement-terminated beneficiaries and establish policies and procedures to prevent additional improper payments.

- Improve existing safeguards to prevent payments to deceased beneficiaries.

Reducing Improper Medicare Payments for Prescription Drugs

We have extensively examined CMS's monitoring and oversight of the Part D program and the effectiveness of controls to ensure appropriate payment and patient safety. Our work has found limitations in program safeguards that leave Part D vulnerable to waste, fraud, and abuse and Medicare patients vulnerable to potentially harmful prescribing.

Notably, we found that Medicare paid millions of dollars for prescriptions from unauthorized prescribers, such as massage therapists and athletic trainers.[10] We also estimated that Part D paid $25 million for Schedule II drugs billed as refills in 2009.[11] Such drugs may cause severe psychological or physical dependence if abused, and Federal law prohibits the refilling of these prescriptions.[12]

We have also uncovered extreme prescribing patterns by hundreds of general-care physicians, who prescribed, for example, extremely high numbers of prescriptions per beneficiary or ordered extremely high percentages of Schedule II or III drugs.[13] In addition, thousands of retail

[10] *Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority*, OEI-02-09-00608, June 21, 2013, available at http://oig.hhs.gov/oei/reports/oei-02-09-00608.asp.

[11] Drugs and other substances that are considered controlled substances under the Controlled Substances Act are divided into five schedules. Drugs are placed on a certain schedule on the basis of having a medically accepted use in treatment in the United States, their potential for abuse, and the likelihood that dependence will result from that abuse. Schedule II drugs are those with a high potential for abuse, potentially leading to severe psychological or physical dependence. http://www.justice.gov/dea/druginfo/ds.shtml.

[12] *Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills*, OEI-02-09-00605, September 26, 2012, available at http://oig.hhs.gov/oei/reports/oei-02-09-00605.asp.

[13] *Prescribers With Questionable Patterns In Medicare Part D*, OEI-02-09-00603, June 20, 2013, available at http://oig.hhs.gov/oei/reports/oei-02-09-00603.asp.

pharmacies demonstrated extremely high billing for at least one of the eight measures of questionable billing we developed. For example, many pharmacies billed extremely high dollar amounts or numbers of prescriptions per beneficiary or per prescriber. Such pharmacies could have been billing for drugs that were not medically necessary or that were not provided to beneficiaries.[14]

These vulnerabilities are even more concerning in light of our increasing number of investigations into drug diversion, particularly for high-cost, noncontrolled, name-brand prescription drugs such as respiratory, antipsychotic, and HIV/AIDS medications. The serious and growing problem of prescription drug abuse lends a greater urgency to efforts to address drug diversion and improve monitoring and oversight of Part D.[15]

Key recommendations include:

- Require Part D plans to verify that prescribers have the authority to prescribe drugs. Monitor Part D plans to ensure that they validate prescriber numbers for Schedule II drugs and exclude Schedule II refills when calculating payments to Part D plans.

- Instruct the Medicare contractor to expand its analysis of prescribers and provide Part D plans with additional guidance on monitoring prescribing patterns.

- Strengthen the Medicare contractor's monitoring of pharmacies and its ability to identify for further review pharmacies with questionable billing patterns.

Reducing Improper Medicare Payments to Hospitals

Since 2010, OIG has issued approximately 100 reports to hospitals across the Nation recommending that the hospitals collectively return about $60 million in overpayments to the Federal Government and take corrective action to address the vulnerabilities we identified. These hospital reviews uncovered systemic hospital billing and payment issues related to canceled elective surgeries, early hospital discharges to hospice care, and improper payments for mechanical ventilation, to name a few. In separate audits of these three areas, we found:

- Medicare could save about $600 million over a 2-year period by applying a hospital transfer payment policy for early discharges to hospice care. Many of the hospital discharges to hospice care that we reviewed were early discharges that would have received per diem payments, rather than full payments, if there had been a hospital transfer payment policy.[16]

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[14] *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 9, 2012, available at http://oig.hhs.gov/oei/reports/oei-02-09-00600.asp.

[15] See *Spotlight on Drug Diversion*, available at http://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp.

[16] *Medicare Could Save Millions by Implementing a Hospital Transfer Payment Policy for Early Discharges to Hospice Care*, A-01-12-00507, May 28, 2013, available at http://oig.hhs.gov/oas/reports/region1/11200507.asp.

- Medicare could save about $38 million over a 2-year period by ensuring that inpatient admissions related to short-stay hospital claims involving canceled elective surgeries satisfy the Medicare requirement that the admissions be reasonable and necessary. [17]

- Hospital claims sometimes included incorrect procedure codes when beneficiaries had received fewer than 96 hours of mechanical ventilation. These claims resulted in more than $7 million in Medicare overpayments.[18]

Key recommendations to CMS include:

- CMS should change its regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care.

- Strengthen guidance to better explain Medicare rules for billing for elective surgeries that were canceled and instruct Medicare Administrative Contractors (MACs) to emphasize to hospitals the need for stronger utilization review controls for claims that include admissions for elective surgeries that did not occur.

- Direct Medicare contractors to review any claims with a procedure code indicating that a beneficiary had received at least 96 hours of mechanical ventilation when the beneficiary's length of stay was 4 days or fewer.

CMS Should Strengthen Oversight of Medicare Contractors

CMS relies on contractors to administer the various parts of the Medicare program. These contractors play a vital role in many facets of the Medicare program, including claims payment, overpayment identification, and overpayment recoupment. CMS contracts with MACs to process claims; Part C plans to provide managed care services; Part D plans to provide prescription drug coverage; and benefit integrity contractors to protect Medicare from waste, fraud, and abuse. In addition, CMS contracts with Recovery Auditors to identify and collect overpayments.

Regardless of the type of Medicare contractor, there are common issues that limit CMS's oversight. Chiefly, CMS has not leveraged contractor-reported data to improve oversight or addressed contractor performance issues in a timely manner.

[17] *Medicare Could Save Millions by Strengthening Billing Requirements for Canceled Elective Surgeries*, A-01-12-00509, August 5, 2013, available at http://oig.hhs.gov/oas/reports/region1/11200509.asp.

[18] *Medicare Inappropriately Paid Hospitals for Beneficiaries Who Had Not Received 96 or More Hours of Mechanical Ventilation*, A-09-12-02066, September 17, 2013, available at http://oig.hhs.gov/oas/reports/region9/91202066.asp.

CMS Should Better Leverage Contractor Data To Improve Oversight of Part C and Part D Plans

We have performed a number of reviews of both the data that Part C and Part D plans report to CMS, the Medicare Drug Integrity Contractor (MEDIC) and the data that the MEDIC reports to CMS. Among other things, we have found deficiencies with what data the plans report and CMS's use of the data that it receives. These are described below.

Require Reporting of Fraud and Abuse Data

CMS does not require Part C or Part D plans to report fraud and abuse data to CMS or the MEDIC.[19] CMS merely encourages plans to voluntarily report this data. We found that less than half of Part D plans reported fraud data, and reporting varied significantly from plan to plan.[20] Due to CMS's lack of follow up, we do not know whether Part C and Part D plans are reporting incorrect data, have ineffective programs to detect fraud and abuse, or lack a common understanding of what constitutes a potential fraud and abuse incident. Further, without detailed information on fraud and abuse incidents, CMS is missing the opportunity to discover and alert plans and law enforcement to emerging fraud and abuse schemes.

Make Better Use of Existing Data and Share as Appropriate With Stakeholders

CMS has made limited use of data to oversee Part C plans despite investments in contractor reviews of the data.[21] For example, CMS has not determined whether outlier data[22] reflect inaccurate reporting or atypical plan performance. CMS also has not used its contractor data reports and analysis to inform the selection of plans for audits or to issue compliance notices for performance concerns.

CMS is also not fully leveraging Part D data. CMS does not require Part D plans to report fraud and abuse data, but even when plans do report this data to CMS, CMS has not used it for monitoring or oversight purposes.

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[19] *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 9, 2013, available at http://oig.hhs.gov/oei/reports/oei-03-11-00310.asp.

[20] *Less Than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse*, OEI-03-13-00030, March 3, 2014, available at http://oig.hhs.gov/oei/reports/oei-03-13-00030.asp.

[21] *CMS Regularly Reviews Part C Reporting Requirements Data, But Its Followup and Use of the Data Are Limited*, OEI-03-11-00720, March 3, 2014, available at http://oig.hhs.gov/oei/reports/oei-03-11-00720.asp.

[22] An outlier data value is one that falls outside a specified range of reported values, or falls above or below a predetermined benchmark value.

Address Contractor Performance Issues in a Timely Manner

CMS conducts quality assurance reviews to ensure that MACs are providing the quality of services required in their contracts. We have found that while CMS's performance reviews of MACs were extensive, they were not always completed in a timely manner.[23] Even when CMS identified quality standards that were not met, CMS did not always ensure that MACs resolved the problem.

Further, two MACs consistently underperformed across various CMS reviews, but these MACs had their contract option years renewed. CMS told us that they considered not extending the option years, but the timeframe for renewal made the decision impractical based on the resources and risk involved in conducting an unforeseen procurement.

Key recommendations to CMS include:

- CMS should require mandatory reporting by Part C and Part D plans of potential fraud and abuse incidents.
- CMS should determine whether outlier data values submitted by Part C and Part D plans reflect inaccurate reporting or atypical performance.
- CMS should seek a legislative change to increase the time between MAC contract competitions to give CMS more flexibility in awarding new contracts when MACs are not meeting CMS requirements.

Conclusion

Effectively combating waste, fraud, and abuse requires a concerted effort by a number of key players, including CMS, CMS contractors, providers, beneficiaries, law enforcement, and Congress. While CMS has had some success in reducing Medicare waste, fraud, and abuse, our recent work demonstrates that further reductions are possible. A comprehensive list of OIG's priority recommendations can be found in our *Compendium of Priority Recommendations* on our Web site.[24]

While my testimony focuses on our work to help CMS improve program operations, I would like to make a request that would help OIG better meet our growing oversight responsibilities. We are responsible for oversight of about 25 cents of every Federal dollar, but our mission is challenged by declining resources, and our oversight responsibilities are increasing. By the end of this fiscal year, we expect to reduce Medicare and Medicaid oversight by about 20%. To

[23] *Medicare Administrative Contractors' Performance*, OEI-03-11-00740, January 8, 2014, available at http://oig.hhs.gov/oei/reports/oei-03-11-00740.asp.

[24] Available at http://oig.hhs.gov/reports-and-publications/compendium/index.asp.

ensure that we can continue to provide needed oversight as these programs expand, we ask for the Committee's support of our 2015 budget request.

We are committed to continuing our strong oversight of Medicare to reduce waste, fraud and abuse as comprehensively and effectively as possible with the tools and resources we have available. At stake are billions of dollars, the solvency of the program, and the health and well-being of beneficiaries.

Thank you for your interest and support and for the opportunity to discuss some of our work related to Medicare oversight. I am happy to answer any questions you may have.

Chairman BRADY. Thank you. Mrs. King.

STATEMENT OF KATHLEEN M. KING, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

Ms. KING. Mr. Chairman, Ranking Member McDermott and Members of the Subcommittee, thank you for inviting me here——

Chairman BRADY. Ms. King, is the microphone on there?

Ms. KING. I thought—I had a green—oh. Sorry.

Chairman BRADY. I know.

Ms. KING. Thank you for inviting me to talk about our work regarding Medicare fraud, waste and abuse.

CMS has made progress in implementing several recommendations we identified through our work to help protect Medicare from fraud and improper payments, but there are additional actions they should take. I want to focus my remarks today on three areas: provider enrollment, pre- and post-payment claims review, and addressing vulnerabilities to fraud.

With respect to provider enrollment, CMS has implemented provisions of the Patient Protection and Affordable Care Act to strengthen the enrollment process so that potentially fraudulent providers are prevented from enrolling in Medicare and higher-risk providers undergo more scrutiny before being permitted to enroll.

CMS has recently imposed moratoria on the enrollment of certain types of providers in fraud hotspots and has contracted for fingerprint-based criminal background checks for high-risk providers. These are all positive steps; however, CMS has not completed certain actions authorized by PPACA, which would also be helpful in fighting fraud. It has not yet published regulations to require additional disclosures of information regarding actions previously taken against providers, such as payment suspensions. And it has not published regulations establishing the core elements of compliance programs or requirements for surety bonds for certain types of high-risk providers, including home health agencies.

With respect to claims for payment, Medicare uses pre-payment review to deny payment for claims that should not be paid and post-payment claims review to recover improperly paid claims. Pre-payment reviews are typically automated edits in claims processing systems that can prevent payment of improper claims.

We found some weaknesses in the use of pre-payment edits and made a number of recommendations to CMS to promote implementation of effective edits regarding national policies and to encourage more widespread use of local pre-payment edits by Medicare administrative contractors, or MACs. CMS agreed with our recommendations and has taken steps to implement them.

With respect to post-payment review, we recently completed work that recommended greater consistency in the requirements under which four post-payment review contractors operate when it can be done without impeding the efficiency of efforts to reduce improper payments. CMS agreed with our recommendation and is taking steps to implement them.

We also recommended to CMS that they collect and evaluate how quickly one type of post-payment review contractor, the zone program integrity contractor, and takes action against suspect providers. CMS did not comment on this recommendation.

We also have further work underway on the post-payment review contractors to examine whether CMS has strategies in place to coordinate their work and whether these contractors comply with CMS's requirements regarding communications with providers.

With respect to vulnerabilities to fraud, we have made recommendations to CMS over the last several years, and CMS has implemented several of them, including establishing a single vulnerability tracking process and requiring MACs to report to them on how they have addressed vulnerabilities; however, CMS has not taken action to address our recommendations to remove Social Security numbers from Medicare cards, because display of these numbers increases beneficiaries' vulnerability to identity theft. We continue to believe that CMS should act on our recommendations, and we are currently studying the use of electronic card technologies for Medicare, including potential benefits on limitations and barriers to implementation.

Because Medicare is such a large and complex program, it is vulnerable to fraud and abuse. Constant vigilance is required to prevent, detect and deter fraud so that Medicare can continue to meet the health care needs of its beneficiaries.

This concludes my prepared remarks. Thank you, Mr. Chairman.

[The prepared statement of Ms. King follows:]

United States Government Accountability Office

Testimony

Before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

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MEDICARE FRAUD

Progress Made, but More Action Needed to Address Medicare Fraud, Waste, and Abuse

Statement of Kathleen M. King
Director, Health Care

GAO Highlights

Highlights of GAO-14-560T, a testimony before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

April 30, 2014

MEDICARE FRAUD

Progress Made, but More Action Needed to Address Medicare Fraud, Waste, and Abuse

Why GAO Did This Study

GAO has designated Medicare as a high-risk program, in part because the program's size and complexity make it vulnerable to fraud, waste, and abuse. In 2013, Medicare financed health care services for approximately 51 million individuals at a cost of about $604 billion. The deceptive nature of fraud makes its extent in the Medicare program difficult to measure in a reliable way, but it is clear that fraud contributes to Medicare's fiscal problems. More broadly, in fiscal year 2013, CMS estimated that improper payments—some of which may be fraudulent—were almost $50 billion.

This statement focuses on the progress made and important steps to be taken by CMS and its program integrity contractors to reduce fraud in Medicare. These contractors perform functions such as screening and enrolling providers, detecting and investigating potential fraud, and identifying improper payments and vulnerabilities that could lead to payment errors. This statement is based on relevant GAO products and recommendations issued from 2004 through 2014 using a variety of methodologies. In April 2014, GAO also received updated information from CMS on its actions related to the laws, regulations, and guidance discussed in this statement. Additionally, GAO updated information by examining public documents and relevant policies and procedures.

View GAO-14-560T. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

The Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) that oversees Medicare—has made progress in implementing several key strategies GAO identified in prior work as helpful in protecting Medicare from fraud; however, important actions that could help CMS and its program integrity contractors combat fraud remain incomplete.

Provider Enrollment: The Patient Protection and Affordable Care Act (PPACA) authorized, and CMS has implemented, actions to strengthen provider enrollment that address past weaknesses identified by GAO and HHS's Office of Inspector General. For example, CMS has hired contractors to determine whether providers and suppliers have valid licenses and are at legitimate locations. CMS also recently contracted for fingerprint-based criminal history checks for high-risk providers and suppliers. CMS could further strengthen provider enrollment by issuing a rule to require additional provider and supplier disclosures of information and establishing core elements for provider and supplier compliance programs, as authorized by PPACA.

Prepayment and Postpayment Claims Review: Medicare uses prepayment review to deny claims that should not be paid and postpayment review to recover improperly paid claims. GAO has found that increased use of prepayment edits could help prevent improper Medicare payments. For example, prior GAO work identified millions of dollars of payments inconsistent with selected coverage and payment policies and therefore improper. Postpayment reviews are also critical to identifying and recouping payments. GAO recommended better oversight of both the information systems analysts use to identify claims for postpayment review, in a 2011 report, and the contractors responsible for these reviews, in a 2013 report. CMS has addressed some of these recommendations.

Addressing Identified Vulnerabilities: Having mechanisms in place to resolve vulnerabilities that could lead to improper payments is critical to effective program management and could help address fraud. However, GAO work has shown weaknesses in CMS's processes to address such vulnerabilities, placing the Medicare program and its beneficiaries at risk. For example, GAO has made multiple recommendations to CMS to remove Social Security numbers from beneficiaries' Medicare cards to help prevent identity theft, and, while HHS agreed with these recommendations, the department also reported that CMS could not proceed with the changes for a variety of reasons, including funding limitations. Thus, to date, CMS has not taken action on these recommendations.

GAO has work underway addressing these key strategies, including assessing the potential use of electronic-card technologies to help reduce Medicare fraud. GAO is also examining the extent to which CMS's information system can prevent and detect the continued enrollment of ineligible or potentially fraudulent providers in Medicare. Additionally, GAO is studying CMS's oversight of program integrity efforts for prescription drugs and is examining CMS's oversight of some of the contractors that conduct reviews of claims after payment. These studies are focused on additional actions for CMS that could help the agency more systematically reduce potential fraud in the Medicare program.

Chairman Brady, Ranking Member McDermott, and Members of the Subcommittee:

I am pleased to be here today to discuss our work examining fraud in the Medicare program.[1] We have designated Medicare as a high-risk program since 1990, in part because we found the program's size and complexity make it vulnerable to fraud, waste, and abuse.[2] Although there have been convictions for multimillion-dollar schemes that defrauded the Medicare program, the extent of the problem is unknown.[3] There are no reliable estimates of the extent of fraud in the Medicare program or for the health care industry as a whole. By its very nature, fraud is difficult to detect, as those involved are engaged in intentional deception. For example, a provider submitting a fraudulent claim may include false documentation to substantiate a service not provided, and thus the claim may appear valid on its face. Fraud may also involve payments made to beneficiaries to obtain their Medicare number for fraudulent billing purposes. Although the full extent of the problem is unknown, it is clear that, as one of the largest programs in the federal government, the Medicare program is vulnerable to fraud, contributing to its fiscal problems.

In 2013, Medicare financed health care services for approximately 51 million individuals at a cost of about $604 billion, and reported some of the largest estimates of improper payments among federal programs—payments that either were made in an incorrect amount or should not

[1]Medicare is the federally financed health insurance program for persons age 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease.

[2]In 1990, we began to report on government operations that we identified as "high risk" for serious weaknesses in areas that involve substantial resources and provide critical services to the public. Medicare has been included among such programs since 1990. See GAO, *High-Risk Series: An Update*, GAO-13-283 (Washington, D.C.: February 2013).

[3]Fraud involves an intentional act or representation to deceive with the knowledge that the action or representation could result in gain.

have been made at all.[4] The Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that oversees Medicare, has estimated that improper payments in the Medicare program were almost $50 billion in fiscal year 2013, about $5 billion higher than in 2012.[5]

Since its inception, Medicare has been administered largely by contractors with federal oversight and these contractors have a responsibility to help ensure Medicare program integrity.[6] CMS must oversee their efforts to help ensure proper payments and address the program's many vulnerabilities, which include service- or system-specific weaknesses that can lead to payment errors, including those due to fraud.[7] If CMS suspects that providers or suppliers are billing fraudulently, it can take action through its contractors, including suspending claims

[4]Improper payments may be a result of fraud, waste, or abuse. They are any payments that should not have been made or that were made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements. This definition includes any payment to an ineligible recipient, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except where authorized by law), and any payment that does not account for credit for applicable discounts. Improper Payments Elimination and Recovery Act of 2010, Pub. L. No. 111-204, § 2(e), 124 Stat. 2224, 2227 (codified at 31 U.S.C. § 3321 note). Waste includes inaccurate payments for services, such as unintentional duplicate payments. Abuse represents actions inconsistent with acceptable business or medical practices.

[5]A list of abbreviations used in this statement is provided in appendix I.

[6]The Medicare program consists of four parts: A, B, C, and D. Medicare Parts A and B are known as Medicare fee-for-service (FFS). Medicare Part A covers hospital and other inpatient stays. Medicare Part B is optional, and covers hospital outpatient, physician, and other services. Medicare beneficiaries have the option of obtaining coverage for Medicare services from private health plans that participate in Medicare Advantage—Medicare's managed care program—also known as Part C. All Medicare beneficiaries may purchase coverage for outpatient prescription drugs under Part D, either as a stand-alone benefit or as part of a Medicare Advantage plan. Contractors are responsible for administering Medicare FFS claims and conducting activities to reduce improper payments.

[7]CMS defines vulnerabilities to the Medicare program as issues that can lead to fraud, waste, or abuse, which can either be specific, such as providers receiving multiple payments as a result of incorrect coding for a service, or general and programwide, such as weaknesses in online application processes. An example of a vulnerability that leads to improper payments is providers billing for more than one blood transfusion in a hospital outpatient setting for a Medicare beneficiary in a day, which Medicare policy does not allow.

payment, revoking billing privileges, or referring cases to law enforcement for investigation.[8]

My statement today focuses on the progress made and important steps to be taken by CMS to reduce fraud in Medicare. It is primarily based on our Medicare program integrity products issued and recommendations made from April 2004 through March 2014, as well as selected updates on CMS activities,[9] and will focus on progress related to three key strategies we have identified as important to reducing fraud, waste, and abuse, and ultimately improper payments:[10]

- strengthening provider enrollment standards and procedures,
- improving prepayment and postpayment review of claims, and
- addressing identified vulnerabilities.

We received updated information from CMS in April 2014 on its actions related to the laws, regulations, and guidance that we discuss in this statement. We also updated information by examining public documents and relevant policies and procedures. Our work for this statement and the products on which it was based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[8]In this testimony, the term *provider* includes entities such as hospitals or physicians, and *supplier* means an entity that supplies Medicare beneficiaries with durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) such as walkers and wheelchairs.

[9]The products listed at the end of this statement contain detailed information on the various methodologies used in our work.

[10]See GAO, *Program Integrity: Further Action Needed to Address Vulnerabilities in Medicaid and Medicare Programs*, GAO-12-803T (Washington, D.C.: June 7, 2012).

Background

Since 1996, Congress has taken important steps to increase Medicare program integrity funding and oversight, including the establishment of the Medicare Integrity Program. Table 1 summarizes several key congressional actions.

Table 1: Key Congressional Actions to Increase Medicare Program Integrity Funding and Oversight

Year	Congressional action	Statute
1996	Created the Medicare Integrity Program and established dedicated funding for activities to address fraud, waste, and abuse in federal health care programs, including Medicare[a]	Health Insurance Portability and Accountability Act of 1996[b]
2003	Directed CMS to conduct a 3-year demonstration project on the use of recovery audit contractors (RAC) for identifying Medicare underpayments and recouping overpayments	Medicare Prescription Drug, Improvement, and Modernization Act of 2003[c]
2006	Required CMS to implement a national RAC program by January 1, 2010.	Tax Relief and Health Care Act of 2006[d]
2010	Provided additional funding for program integrity activities and, among other things: • Established new provider enrollment requirements • Required CMS to extend the Medicare RACs to Parts C and D of the Medicare program • Required CMS to develop core elements for provider compliance programs • Authorized surety bond requirements for certain Medicare suppliers and providers[e]	Patient Protection and Affordable Care Act (PPACA)[f]
2010	Required Medicare fee-for-service to begin using predictive analytics to identify and prevent fraud[g]	Small Business Jobs Act of 2010[h]

Source: GAO analysis.

[a]The fund is known as the Health Care Fraud and Abuse Control account.

[b]Pub. L. No. 104-191, §§ 201(b)-202, 110 Stat. 1936, 1993-98 (codified at 42 U.S. C. §§ 1395i(k), 1395ddd).

[c]Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256-57.

[d]Pub. L. No. 109-432, div B., title III, § 302, 120 Stat. 2922, 2991-92 (codified at 42 U.S.C. § 1395 ddd(h)).

[e]A surety bond is a three-party agreement in which a company, known as a surety, agrees to compensate the bondholder if the bond purchaser fails to keep a specified promise.

[f]Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029

[g]Predictive analytics include the use of algorithms and models to analyze claims before payment is made in order to identify unusual or suspicious patterns or abnormalities in provider networks, claims billing patterns, and beneficiary utilization.

[h]Pub. L. No. 111-240, § 4241, 124 Stat. 2504, 2599.

CMS Has Taken Action to Improve Medicare Program Integrity, but More Can Be Done

CMS has made progress in strengthening provider enrollment provisions, but needs to do more to identify and prevent potentially fraudulent providers from participating in Medicare. Additional improvements to prepayment and postpayment claims review would help prevent and recover improper payments. Addressing payment vulnerabilities already identified could further help prevent or reduce fraud.

CMS Has Strengthened Provider Enrollment Provisions since PPACA, but Further Actions Needed to Help Ensure Potentially Fraudulent Providers Do Not Participate in Medicare

PPACA authorized and CMS has implemented new provider enrollment procedures that address past weaknesses identified by GAO and HHS's Office of Inspector General (OIG) that allowed entities intent on committing fraud to enroll in Medicare. CMS has also implemented other measures intended to improve existing procedures. Specifically, to strengthen the existing screening activities conducted by CMS contractors, the agency added screenings of categories of provider enrollment applications by risk level, contracted with new national enrollment screening and site visit contractors, and began imposing moratoria on new enrollment of certain types of providers.

- *Screening Provider Enrollment Applications by Risk Level*: CMS and OIG issued a final rule in February 2011 to implement many of the new screening procedures required by PPACA.[11] CMS designated three levels of risk—high, moderate, and limited—with different screening procedures for categories of Medicare providers at each level. Providers in the high-risk level are subject to the most rigorous screening.[12] Based in part on our work and that of OIG, CMS designated newly enrolling home health agencies and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) as high risk, and designated other providers as lower risk levels. Providers at all risk levels are screened to verify that they meet

[11] *Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers*, 76 Fed. Reg. 5862 (Feb. 2, 2011). In discussing the final rule, CMS noted that Medicare had already employed a number of the screening practices described in PPACA to determine whether a provider is in compliance with federal and state requirements to enroll or to maintain enrollment in the Medicare program.

[12] PPACA specified that the enhanced screening procedures apply to new providers and suppliers beginning 1 year after the date of enactment (March 23, 2010) and to currently enrolled providers and suppliers 2 years after that date.

specific requirements established by Medicare, such as having current licenses or accreditation and valid Social Security numbers.[13] High- and moderate-risk providers are also subject to unannounced site visits. Further, depending on the risks presented, PPACA authorizes CMS to require fingerprint-based criminal history checks. Last month, CMS awarded a contract that will enable the agency to access Federal Bureau of Investigation information to help conduct those checks of high-risk providers and suppliers. PPACA also authorizes the posting of surety bonds for certain providers.[14]

CMS has indicated that the agency will continue to review the criteria for its screening levels and will publish changes if the agency decides to update the assignment of screening levels for categories of Medicare providers. Doing so could become important because the Department of Justice (DOJ) and HHS reported multiple convictions, judgments, settlements, or exclusions against types of providers not currently at the high-risk level, including community mental health centers and ambulance providers.[15] CMS's implementation of accreditation for DMEPOS suppliers, and of a competitive bidding program, including in geographic areas thought to have high fraud rates, may be helping to reduce the risk of DMEPOS fraud.[16] While continued vigilance of DMEPOS suppliers is warranted, other types of providers may become more problematic in the future. Specifically, in September 2012, we found that a range of providers have been the

[13]Screening may include verification of the following: Social Security number; National Provider Identifier (NPI); National Practitioner Databank licensure; whether the provider has been excluded from federal health care programs by OIG; taxpayer identification number; and death of an individual practitioner, owner, authorized official, delegated official, or supervising physician.

[14]A surety bond is a three-party agreement in which a company, known as a surety, agrees to compensate the bondholder if the bond purchaser fails to keep a specified promise.

[15]Department of Health and Human Services and the Department of Justice, *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2013* (Washington, D.C.: February 2014).

[16]Competitive bidding is a process in which suppliers of medical equipment and supplies compete for the right to provide their products on the basis of established criteria, such as quality and price. See GAO, *Medicare: Second Year Update for CMS's Durable Medical Equipment Competitive Bidding Program Round 1 Rebid*, GAO-14-156 (Washington, D.C.: Mar. 7, 2014).

subjects of fraud investigations.[17] According to 2010 data from OIG and DOJ, over 10,000 providers that serve Medicare, Medicaid, and Children's Health Insurance Program beneficiaries were involved in fraud investigations, including not only home health agencies and DMEPOS suppliers, but also physicians, hospitals, and pharmacies.[18] In addition, the provider type constituting the largest percentage of subjects in criminal health care fraud investigations was medical facilities—including medical centers, clinics, or practices—which constituted almost a quarter of subjects in such investigations. DMEPOS suppliers make up a little over 16 percent of subjects.

- *National Enrollment Screening and Site Visit Contractors*: CMS contracted with two new types of entities at the end of 2011 to assume centralized responsibility for two functions that had been the responsibility of multiple contractors. One of the new contractors is conducting automated screenings to check that existing and newly enrolling providers and suppliers have valid licensure, accreditation, and a National Provider Identifier (NPI), and are not on the OIG list of providers and suppliers excluded from participating in federal health care programs. The second contractor conducts site visits of providers to determine whether sites are legitimate and the providers meet certain Medicare standards.[19] A CMS official reported that, since the implementation of the PPACA screening requirements, the agency had revoked over 17,000 suspect providers' ability to bill the Medicare program.[20]

[17]GAO, *Health Care Fraud: Types of Providers Involved in Medicare, Medicaid, and the Children's Health Insurance Program Cases*, GAO-12-820 (Washington, D.C.: Sept. 7, 2012).

[18]Medicaid is the federal-state program that covers acute health care, long-term care, and other services for certain low-income people. It is also one of the largest components of state budgets. Children's Health Insurance Program is the joint federal-state program that provides health coverage to children whose families have incomes that are low, but not low enough to qualify for Medicaid.

[19]Site visits for DMEPOS suppliers are to continue to be conducted by the contractor responsible for their enrollment. In addition, CMS at times exercises its authority to conduct a site visit or request its contractors to conduct a site visit for any Medicare provider or supplier.

[20]S. Agrawal, M.D., Deputy Administrator and Director, Center for Program Integrity, Centers for Medicare & Medicaid Services, *Preventing Medicare Fraud: How Can We Best Protect Seniors and Taxpayers?*, testimony before the Senate Special Aging Committee, Mar. 26, 2014.

- *Moratoria on Enrollment of New Providers and Suppliers in Certain Areas*: CMS suspended enrollment of new home health providers and ambulance suppliers in certain fraud "hot spots" and other geographic areas. In July 2013, CMS first exercised its authority granted by PPACA to establish temporary moratoria on enrolling new home health agencies in Chicago and Miami, and new ambulance suppliers in Houston.[21] In January 2014, CMS extended its first moratoria and added enrollment moratoria for new home health agency providers in Fort Lauderdale, Detroit, Dallas, and Houston, and new ground ambulance suppliers in Philadelphia. These moratoria are scheduled to be in effect until July 2014, unless CMS extends or lifts them. CMS officials cited areas of potential fraud risk, such as a disproportionate number of providers and suppliers relative to beneficiaries and extremely high utilization as rationales for suspending new enrollments of home health providers or ground ambulance suppliers in these areas.

We are currently examining the ability of CMS's provider enrollment system to prevent and detect the continued enrollment of ineligible or potentially fraudulent providers in Medicare. Specifically, we are assessing the process used to enroll and verify the eligibility of Medicare providers in Medicare's Provider Enrollment, Chain, and Ownership System (PECOS) and the extent to which CMS's controls are designed to prevent and detect the continued enrollment of ineligible or potentially fraudulent providers in PECOS.

Although CMS has taken many needed actions, we and OIG have found that CMS has not fully implemented other enrollment screening actions authorized by PPACA.[22] These actions could help further reduce the enrollment of providers and suppliers intent on defrauding the Medicare program. They include issuing a rule to implement surety bonds for certain providers, issuing a rule on provider and supplier disclosure requirements, and establishing the core elements for provider and supplier compliance programs.

[21]Under the moratoria, existing providers and suppliers can continue to deliver and bill for services, but no new provider and supplier applications will be approved in these areas. CMS re-evaluates the need for such moratoria every 6 months.

[22]GAO, *Medicare Program Integrity: CMS Continues Efforts to Strengthen the Screening of Providers and Suppliers,* GAO-12-351 (Washington, D.C.: Apr. 10, 2012).

- *Surety Bonds*: PPACA authorized CMS to require a surety bond for certain types of at-risk providers and suppliers. Surety bonds may serve as a source for recoupment of erroneous payments. DMEPOS suppliers are currently required to post a surety bond at the time of enrollment.[23] CMS reported in April 2014 that it had not scheduled for publication a proposed rule to implement the PPACA surety bond requirement for other types of at-risk providers and suppliers—such as home health agencies and independent diagnostic testing facilities. In light of the moratoria that CMS has placed on enrollment of home health agencies in fraud "hot spots," implementation of this rule could help the agency address potential concerns for these at-risk providers across the Medicare program.
- *Providers and Suppliers Disclosure*: CMS has not yet scheduled a proposed rule for publication for increased disclosures of prior actions taken against providers and suppliers enrolling or revalidating enrollment in Medicare, as authorized by PPACA, such as whether the provider or supplier has been subject to a payment suspension from a federal health care program.[24] Agency officials had indicated that developing the additional disclosure requirements has been complicated by provider and supplier concerns about what types of information will be collected, what CMS will do with it, and how the privacy and security of this information will be maintained.
- *Compliance Program*: CMS has not established the core elements of compliance programs for providers and suppliers, as required by PPACA. We previously reported that agency officials indicated that they had sought public comments on the core elements, which they were considering, and were also studying criteria found in OIG model

[23]42 U.S.C. § 1395m(a)(16)(B). A DMEPOS surety bond is a bond issued by an entity guaranteeing that a DMEPOS supplier will fulfill its obligation to Medicare. If the obligation is not met, the surety bond is paid to Medicare. Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), 74 Fed. Reg. 166 (Jan. 2, 2009).

[24]At the time of initial enrollment or revalidation of enrollment, PPACA requires providers and suppliers to disclose, in a form and manner and at such time as determined by the Secretary, any current or previous affiliation with another provider or supplier that has uncollected debt; has been or is subject to a payment suspension under a federal health care program; has been excluded from participation under Medicare, Medicaid, or State Children's Health Insurance Program; or has had its billing privileges denied or revoked. Pub. L. No. 111-148, § 6401(a), 124 Stat. 119, 750 (2010).

plans for possible inclusion.[25] As of April 2014, CMS reported that it had not yet scheduled a proposed rule for publication.

Additional Improvements to Prepayment and Postpayment Claims Review May Better Identify or Recover Improper Payments

Medicare uses prepayment review to deny claims that should not be paid and postpayment review to recover improperly paid claims. As claims go through Medicare's electronic claims payment systems, they are subjected to prepayment controls called "edits," most of which are fully automated; if a claim does not meet the criteria of the edit, it is automatically denied.[26] Other prepayment edits are manual; they flag a claim for individual review by trained staff who determine whether it should be paid. Due to the volume of claims, CMS has reported that less than 1 percent of Medicare claims are subject to manual medical record review by trained personnel.

Increased use of prepayment edits could help prevent improper Medicare payments. Our prior work found that, while use of prepayment edits saved Medicare at least $1.76 billion in fiscal year 2010, the savings could have been greater had prepayment edits been used more widely.[27] Based on an analysis of a limited number of national policies and local coverage determinations (LCD), we identified $14.7 million in payments in fiscal year 2010 that appeared to be inconsistent with four national policies and

[25]A compliance program is an internal set of policies, processes, and procedures that a provider organization implements to help it act ethically and lawfully. In this context, a compliance program is intended to help provider and supplier organizations prevent and detect violations of Medicare laws and regulations. OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

[26]Edits are instructions programmed in the systems to prevent payment of incomplete or incorrect claims. Some edits use provider enrollment information, while others use information on coverage or payment policies, to determine whether claims should be paid.

[27]See GAO, *Medicare Program Integrity: Greater Prepayment Control Efforts Could Increase Savings and Better Ensure Proper Payment*, GAO-13-102 (Washington, D.C.: Nov. 13, 2012).

therefore improper.[28] We also found more than $100 million in payments that were inconsistent with three selected LCDs that could have been identified using automated edits. Thus we concluded that more widespread implementation of effective automated edits developed by individual Medicare administrative contractors (MAC) in other MAC jurisdictions could also result in savings to Medicare. CMS has taken steps to improve the development of other types of prepayment edits that are implemented nationwide, as we recommended. For example, the agency has centralized the development and implementation of automated edits based on a type of national policy called national coverage determinations.[29] CMS has also modified its processes for identifying provider billing of services that are medically unlikely to prevent circumvention of automated edits designed to identify an unusually large quantity of services provided to the same patient.[30]

We also evaluated the implementation of CMS's Fraud Prevention System (FPS), which uses predictive analytic technologies as required by the Small Business Jobs Act of 2010 to analyze Medicare fee-for-service (FFS) claims on a prepayment basis. FPS identifies investigative leads for CMS's Zone Program Integrity Contractors (ZPIC), the contractors responsible for detecting and investigating potential fraud.[31] Implemented

[28]Each Medicare administrative contractor (MAC) has the authority to develop LCDs that delineate the circumstances under which services are considered reasonable and necessary and are therefore covered in the geographic area where that MAC processes claims. These local policies cannot conflict with national coverage and payment policies established by CMS or by law. MACs' authority to develop LCDs leads to differences in Medicare coverage policy in different areas of the country. MACs may create prepayment edits either to implement their LCDs or to implement national Medicare policies set by CMS, although not every LCD or national policy is structured in a way that makes edit development feasible. CMS has responsibility for providing information and oversight to MACs with respect to their use of prepayment edits to promote effective stewardship of Medicare funds.

[29]CMS typically develops national coverage determinations for services that have the potential to affect a large number of beneficiaries and that have the greatest effect on the Medicare program. Development of national coverage determinations is a lengthy process, which requires review of clinical evidence and allows for public comment.

[30]CMS refers to these as Medically Unlikely Edits. These edits are designed to deny payment for services where the number of units billed exceeds the maximum number a provider would bill under most circumstances for a beneficiary on a single date of service.

[31]GAO, *Medicare Fraud Prevention: CMS Has Implemented a Predictive Analytics System, but Needs to Define Measures to Determine Its Effectiveness*, GAO-13-104 (Washington, D.C.: Oct. 15, 2012).

in July 2011, FPS is intended to help facilitate the agency's shift from focusing on recovering potentially fraudulent payments after they have been made, to detecting aberrant billing patterns as quickly as possible, with the goal of preventing these payments from being made. However, in October 2012, we found that, while FPS generated leads for investigators, it was not integrated with Medicare's payment-processing system to allow the prevention of payments until suspect claims can be determined to be valid. As of April 2014, CMS reported that while the FPS functionality to deny claims before payment had been integrated with the Medicare payment processing system in October 2013, the system did not have the ability to suspend payment until suspect claims could be investigated. In addition, while CMS directed the ZPICs to prioritize alerts generated by the system, in our work examining the sources of new ZPIC investigations in 2012, we found that FPS accounted for about 5 percent of ZPIC investigations in that year.[32] A CMS official reported last month that ZPICs are now using FPS as a primary source of leads for fraud investigations, though the official did not provide details on how much of ZPICs' work is initiated through the system.[33]

Our prior work found that postpayment reviews are critical to identifying and recouping overpayments.[34] The use of national recovery audit contractors (RAC)[35] in the Medicare program is helping to identify underpayments and overpayments on a postpayment basis.[36] CMS

[32]GAO, *Medicare Program Integrity: Contractors Reported Generating Savings, but CMS Could Improve Its Oversight,* GAO-14-111 (Washington, D.C.: Oct. 25, 2013).

[33]S. Agrawal, *Preventing Medicare Fraud*, testimony before the Senate Special Aging Committee, Mar. 26, 2014. Additionally, CMS has not published a report detailing the results of the second year of implementation of the FPS system, as required by the Small Business Jobs Act of 2010. The report was due in 2013.

[34]See GAO, *Medicare Fraud, Waste, and Abuse: Challenges and Strategies for Preventing Improper Payments*, GAO-10-844T (Washington, D.C.: June 15, 2010).

[35]These contractors are also referred to as Recovery Auditors.

[36]Recovery auditing has been used in various industries, including health care, to identify and collect overpayments for about 40 years.

began the program in March 2009 for Medicare FFS.[37] CMS reported that, as of the end of 2013, RACs collected $816 million for fiscal year 2014.[38] PPACA required the expansion of Medicare RACs to Parts C and D. CMS has implemented a RAC for Part D, and CMS said it plans to award a contract for a Part C RAC by the end of 2014. Moreover, in February 2014, CMS announced a "pause" in the RAC program as the agency makes changes to the program and starts a new procurement process for the next round of recovery audit contracts for Medicare FFS claims. CMS said it anticipates awarding all five of these new Medicare FFS recovery audit contracts by the end of summer 2014.

Other contractors help CMS investigate potentially fraudulent FFS payments, but CMS could improve its oversight of their work. CMS contracts with ZPICs in specific geographic zones covering the nation. We recently found that the ZPICs reported that their actions, such as stopping payments on suspect claims, resulted in more than $250 million in savings to Medicare in calendar year 2012.[39] However, CMS lacks information on the timeliness of ZPICs' actions—such as the time it takes between identifying a suspect provider and taking actions to stop that provider from receiving potentially fraudulent Medicare payments—and would benefit from knowing whether ZPICs could save more money by acting more quickly. Thus, in October 2013, we recommended that CMS collect and evaluate information on the timeliness of ZPICs' investigative and administrative actions. CMS did not comment on our recommendation. We are currently examining the activities of the CMS contractors, including ZPICs, that conduct postpayment claims reviews. Our work is reviewing, among other things,

[37]The Medicare Prescription Drug, Improvement and Modernization Act of 2003 directed CMS to conduct a demonstration of the use of RACs in identifying underpayments and overpayments, and recouping overpayments in Medicare. Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256-57. Subsequently, the Tax Relief and Health Care Act of 2006 required CMS to implement a national RAC program by January 1, 2010. Pub. L. No. 109-432, div. B, title III, § 302, 120 Stat. 2922, 2991 (codified at 42 U.S.C. § 1395ddd(h)).

[38]See Centers for Medicare & Medicaid Services, *Medicare Fee for Service, National Recovery Audit Program, Quarterly Newsletter*, accessed Apr. 17, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-Recovery-Audit-Program-1st-qtr-2014.pdf.

[39]GAO-14-111.

whether CMS has a strategy for coordinating these contractors' postpayment claims review activities.

CMS has taken steps to improve use of two CMS information technology systems that could help analysts identify fraud after claims have been paid, but further action is needed. In 2011, we found that the Integrated Data Repository (IDR)—a central data store of Medicare and other data needed to help CMS program integrity staff and contractors detect improper payments of claims—did not include all the data that were planned to be incorporated by fiscal year 2010, because of technical obstacles and delays in funding.[40] As of March 2014, the agency had not addressed our recommendation to develop reliable schedules to incorporate all types of IDR data, which could lead to additional delays in making available all of the data that are needed to support enhanced program integrity efforts and achieve the expected financial benefits. However, One Program Integrity (One PI)—a web-based portal intended to provide CMS staff and contractors with a single source of access to data contained in IDR, as well as tools for analyzing those data—is operational and CMS has established plans and schedules for training all intended One PI users, as we also recommended in 2011. However, as of March 2014, CMS had not established deadlines for program integrity contractors to begin using One PI, as we recommended in 2011. Without these deadlines, program integrity contractors will not be required to use the system, and as a result, CMS may fall short in its efforts to ensure the widespread use and to measure the benefits of One PI for program integrity purposes.

[40]GAO, *Fraud Detection Systems: Centers for Medicare and Medicaid Services Needs to Ensure More Widespread Use*, GAO-11-475 (Washington, D.C.: June 30, 2011).

Addressing Identified Vulnerabilities Could Help Reduce Fraud

Having mechanisms in place to resolve vulnerabilities that could lead to improper payments, some of which are potentially fraudulent, is critical to effective program management, but our work has shown weaknesses in CMS's processes to address such vulnerabilities.[41] Both we and OIG have made recommendations to CMS to improve the tracking of vulnerabilities. In our March 2010 report on the RAC demonstration program, we found that CMS had not established an adequate process during the demonstration or in planning for the national program to ensure prompt resolution of vulnerabilities that could lead to improper payments in Medicare; further, the majority of the most significant vulnerabilities identified during the demonstration were not addressed.[42] In December 2011, OIG found that CMS had not resolved or taken significant action to resolve 48 of 62 vulnerabilities reported in 2009 by CMS contractors specifically charged with addressing fraud.[43] We and OIG recommended that CMS have written procedures and time frames to ensure that vulnerabilities were resolved. CMS has indicated that it is now tracking vulnerabilities identified from several types of contractors through a single vulnerability tracking process, and the agency has developed some written guidance on the process. We recently examined that process and found that, while CMS informs MACs about vulnerabilities that could be addressed through prepayment edits, the agency does not systematically compile and disseminate information about effective local edits to address such vulnerabilities.[44] Specifically, we recommended that CMS require

[41]Federal internal control standards state that an agency should have policies and procedures to ensure that (1) the findings of all audits and reviews are promptly evaluated, (2) decisions are made about the appropriate response to these findings, and (3) actions are taken to correct or resolve the issues promptly. See GAO, *Standards for Internal Control in the Federal Government*, AIMD-00-21-3.1 (Washington, D.C.: November 1999). These are all aspects of internal control, which is the component of an organization's management that provides reasonable assurance that the organization achieves effective and efficient operations, reliable financial reporting, and compliance with applicable laws and regulations. Internal control standards provide a framework for identifying and addressing major performance challenges and areas at greatest risk for mismanagement. See GAO, *Internal Control Standards: Internal Control Management and Evaluation Tool*, GAO-01-1008G (Washington, D.C.: August 2001).

[42]GAO, *Medicare Recovery Audit Contracting: Weaknesses Remain in Addressing Vulnerabilities to Improper Payments, Although Improvements Made to Contractor Oversight*, GAO-10-143 (Washington, D.C.: Mar. 31, 2010).

[43]Department of Health and Human Services, Office of Inspector General, *Addressing Vulnerabilities Reported by Medicare Benefit Integrity Contractors*, OEI-03-10-00500 (December 2011).

[44]GAO-13-102.

MACs to share information about the underlying policies and savings related to their most effective edits, and CMS generally agreed to do so. In addition, in 2011, CMS began requiring MACs to report on how they had addressed certain vulnerabilities to improper payment, some of which could be addressed through edits.

We also recently made recommendations to CMS to address the millions of Medicare cards that display beneficiaries' Social Security numbers, which increases beneficiaries' vulnerability to identity theft.[45] In August 2012, we recommended that CMS (1) select an approach for removing Social Security numbers from Medicare cards that best protects beneficiaries from identity theft and minimizes burdens for providers, beneficiaries, and CMS and (2) develop an accurate, well-documented cost estimate for such an option. In September 2013, we further recommended that CMS (1) initiate an information technology project for identifying, developing, and implementing changes for the removal of Social Security numbers and (2) incorporate such a project into other information technology initiatives. HHS concurred with our recommendations and agreed that removing the numbers from Medicare cards is an appropriate step toward reducing the risk of identity theft. However, the department also said that CMS could not proceed with changes without agreement from other agencies, such as the Social Security Administration, and that funding was also a consideration. Thus, CMS has not yet taken action to address these recommendations. We are currently examining other options for updating and securing Medicare cards, including the potential use of electronic-card technologies.

In addition, we and others have identified concerns with CMS oversight of fraud, waste, and abuse in Medicare's prescription drug program, Part D, including the contractors tasked with this work. To help address potential vulnerabilities in that program, we are examining practices for promoting prescription drug program integrity, and the extent to which CMS's oversight of Medicare Part D reflects those practices.

[45]GAO, *Medicare Information Technology: Centers for Medicare and Medicaid Services Needs to Pursue a Solution for Removing Social Security Numbers from Cards,* GAO-13-761 (Washington, D.C.: Sept. 10, 2013) and GAO, *CMS Needs an Approach and a Reliable Cost Estimate for Removing Social Security Numbers from Medicare Cards*, GAO-12-831 (Washington, D.C.: Aug. 1, 2012).

Concluding Observations

Although CMS has taken some important steps to identify and prevent fraud, the agency must continue to improve its efforts to reduce fraud, waste, and abuse in the Medicare program. Identifying the nature, extent, and underlying causes of improper payments, and developing adequate corrective action processes to address vulnerabilities, are essential prerequisites to reducing them. As CMS continues its implementation of PPACA and Small Business Jobs Act provisions, additional evaluation and oversight will help determine whether implementation of these provisions has been effective in reducing improper payments. We are investing resources in a body of work that assesses CMS's efforts to refine and improve its fraud detection and prevention abilities. Notably, we are currently assessing the potential use of electronic-card technologies, which can help reduce Medicare fraud. We are also examining the extent to which CMS's information system can help prevent and detect the continued enrollment of ineligible or potentially fraudulent providers in Medicare. Additionally, we have a study underway examining CMS's oversight of fraud, waste, and abuse in Medicare Part D to determine whether the agency has adopted certain practices for ensuring the integrity of that program. We are also examining CMS's oversight of some of the contractors that conduct reviews of claims after payment. These studies are focused on additional actions for CMS that could help the agency more systematically reduce potential fraud in the Medicare program.

Chairman Brady, Ranking Member McDermott, and Members of the Subcommittee, this concludes my prepared remarks. I would be pleased to respond to any questions you may have at this time.

GAO Contact and Staff Acknowledgments

For further information about this statement, please contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Karen Doran, Assistant Director; Stephen Robblee; Lisa Rogers; Eden Savino; and Jennifer Whitworth were key contributors to this statement.

Appendix I: Abbreviations

CMS	Centers for Medicare & Medicaid Services
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DOJ	Department of Justice
FFS	fee-for-service
FPS	Fraud Prevention System
HHS	Department of Health and Human Services
IDR	Integrated Data Repository
LCD	local coverage determinations
MAC	Medicare administrative contractor
NPI	National Provider Identifier
OIG	Office of Inspector General
One PI	One Program Integrity
PECOS	Provider Enrollment, Chain, and Ownership System
PPACA	Patient Protection and Affordable Care Act
RAC	recovery audit contractor
ZPIC	Zone Program Integrity Contractor

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Chairman BRADY. Thank you, Ms. King. Dr. Agrawal.

STATEMENT OF SHANTANU AGRAWAL, M.D., DEPUTY ADMINISTRATOR AND DIRECTOR, CENTER FOR PROGRAM INTEGRITY, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. AGRAWAL. Thank you. Chairman Brady, Ranking Member McDermott and Members of the Committee, thank you for the invitation to discuss the Centers for Medicare and Medicaid Services Program Integrity efforts.

Enhancing program integrity is a top priority for the administration and an agency-wide effort at CMS, and we have made important strides in reducing waste, abuse and fraud with the strong support of this Committee and Congress. I know that this also is an area of particular interest to the Members of this Committee, and I look forward to hearing your input and working with you on strengthening program integrity in the Medicare program.

Before proceeding, I would like to take a moment to introduce myself. I am a board certified emergency medicine physician. For the past several years and concurrently with other positions I have held, I continue to work as an emergency medicine doctor, both in large academic centers and in area community hospitals.

Shortly after completing my medical training, I joined a management-consulting firm, where I had the opportunity to help hospitals, health systems and biotech and pharma companies improve the quality and efficiency of health care delivery.

In 2011, I joined CMS to serve as the chief medical officer of the Center for Program Integrity, where I had the chance to apply both my medical knowledge and private sector health experience to helping CMS fight fraud and ensure quality care for the millions of patients insured through Medicare and Medicaid. I view program integrity through the lens of these experiences and as a physician who fundamentally cares about the health of patients.

Our health care system should offer the highest quality and most appropriate care possible to ensure the well-being of individuals and populations. CMS is committed to protecting taxpayer dollars by preventing or recovering payments for wasteful, abusive or fraudulent services, helping to extend the life of the trust fund, but the importance of program integrity efforts extend beyond dollars and health care costs alone. It is fundamentally about protecting our beneficiaries, our patients, and ensuring we have the resources to provide for their care.

Numerous experts have cited the waste endemic to our system caused by multiple factors, from inefficiencies in care delivery to outright fraud. Underlying the issues and numbers are real patients. We are all too familiar with the stories of a patient getting inappropriate care or services due to the malfeasance of others to defraud our system. When providers and suppliers are influenced by their own financial interests or incentives, this can lead to upcoding or other gaming of Medicare and Medicaid.

Fraud is not merely deception for dollars through falsified billing. It threatens beneficiary health through blatantly unnecessary services, substandard or non-existent care, dangerous prescribing through pill mills, and a host of other schemes.

Examples of such waste and abuse are driving our agency and my team to rethink the way it approaches program integrity. Due to new authorities and resources provided by Congress over the past few years, CMS is changing the program integrity paradigm to one of focus on prevention and collaboration to identify and combat waste, abuse and fraud in our system, and in partnership with other stakeholders.

As deputy administrator, I will continue to lead CMS on this course with three main areas of intention: coordination across the agency and the broader health care system, excellence in program integrity operations, and a clear view towards improving the costs and appropriateness of care.

First, coordination. The Center for Program Integrity is responsible for leading and coordinating agency efforts to reduce waste, abuse and fraud. Collaboration with stakeholders external to the agency is vital to—as well for the identification of vulnerabilities and increasing our impact. Led by the interagency HHS–DOJ partnership, HEAT, the Federal Government made its highest recovery of funds this past year, $4.3 billion in fiscal year 2013. This resulted in the highest return on investment in the HCFAC program, $8.10 for every $1 invested. We are continuing to build on existing partnerships with private sector pairs, health care organizations and providers through our public-private partnership. Results from the initial data exchanges under the partnership have helped identify fraudulent schemes and specific providers impacting private and public payers, and led to CMS administrative actions such as revocations, as well as law enforcement referrals.

Second, operational excellence. CMS's robust measures of the return on program integrity appropriations, the result of audit and investigation activities, and the impact of advanced data analytic systems, all of which shows strongly positive returns on investment. I intend to build on this foundation by managing performance and strategic decision making based on the areas of greatest risk and return. In particular, CPI's work on provider enrollment and screening has enhanced program integrity while lowering burden for providers.

Finally, the cost and appropriateness of care. CMS has a comprehensive Program Integrity strategy that includes multiple tools and interventions that are used individually and in tandem to tackle specific vulnerabilities. By applying these tools across Medicare and Medicaid in a coordinated way, CMS can impact the overall cost of care. We can and should aim to do even more.

As just one example, CMS has been piloting the use of a fraud prevention system, which is applying predictive analytics technology to all streaming Medicare fee-for-service claims to identify not only potentially fraudulent providers for investigation, but all providers who are billing inappropriately and may require education or medical review.

Thank you for your time and opportunity. I appreciate your support in achieving these goals. I look forward to hearing your ideas on how we can work together as we continue to focus on beneficiaries and strive every day to protect their health and well-being.

[The prepared statement of Dr. Agrawal follows:]

STATEMENT OF

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DEPUTY ADMINISTRATOR AND DIRECTOR,
CENTER FOR PROGRAM INTEGRITY
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

"IDEAS TO IMPROVE MEDICARE OVERSIGHT TO REDUCE WASTE, FRAUD AND ABUSE"

BEFORE THE
UNITED STATES HOUSE WAYS & MEANS COMMITTEE
SUBCOMMITTEE ON HEALTH

APRIL 30, 2014

U.S. House Ways & Means Committee
Subcommittee on Health
Hearing on
"Ideas to Improve Medicare Oversight to Reduce Waste, Fraud and Abuse"
April 30, 2014

Chairman Brady, Ranking Member McDermott, and members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) program integrity efforts. Enhancing program integrity is a top priority for the administration and an agency-wide effort at CMS. We have made important strides in reducing fraud, waste, and abuse across our programs and I appreciate the opportunity to discuss the priorities of CMS' Center for Program Integrity.

Thanks in part to the authorities and resources provided by the Affordable Care Act and the Small Business Jobs Act of 2010, CMS has powerful tools to improve our efforts to detect and prevent fraud, waste, and abuse in Medicare. The fundamental change in the Administration's approach to fraud-fighting is a stronger focus on prevention. Historically, CMS and our law enforcement partners have been forced to use "pay and chase" by paying claims and then working to identify and recoup fraudulent payments. Now, CMS is using a variety of tools to keep fraudsters out of our programs, and to uncover fraudulent schemes quickly, before they drain valuable resources from our Trust Funds. Our efforts in Medicare and Medicaid strike an important balance: protecting beneficiary access to necessary health care services and reducing the administrative burden on legitimate providers and suppliers, while ensuring that taxpayer dollars are not lost to fraud, waste, and abuse.

Earlier this year, the government announced that in fiscal year (FY) 2013, its fraud, waste, and abuse prevention and enforcement efforts in the Health Care Fraud and Abuse Control (HCFAC) program resulted in the record-breaking recovery of $4.3 billion in taxpayer dollars from individuals trying to defraud Federal health care programs serving seniors and taxpayers.[1] Over the last five years, the administration's enforcement efforts have recovered $19.2 billion, up from $9.4 billion over the prior five-year period. Over the last three years, the average return on

[1] http://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf

investment of the HCFAC program is $8.10 for every dollar spent, which is an increase of $2.70 over the average ROI for the life of the HCFAC program since 1997.

In 2014, as program integrity efforts mature, CMS is applying three key operational principles to guide all of our initiatives. First, we aim to achieve operational excellence in addressing the full spectrum of program integrity causes, in taking swift administrative actions, and in the performance of audits, investigations and payment oversight. Second, CMS will provide leadership and coordination in program integrity efforts across the health care system. Finally, we will focus on impacting the cost and appropriateness of care across health care programs. Fraud can inflict real harm to Medicare patients. When fraudulent providers steal a beneficiary's identity and bill for services or goods never received, the beneficiary may later have difficulty accessing needed and legitimate care. Medicare beneficiaries are at risk when fraudulent providers perform medically unnecessary tests, treatments, procedures, or surgeries, or prescribe dangerous drugs without thorough examinations or medical necessity. Our efforts are focused on ensuring that beneficiaries receive appropriate health care services, protecting both beneficiaries and taxpayers from unnecessary costs.

Operational Excellence

CMS is working to achieve operational excellence in addressing the full spectrum of program integrity causes, in taking swift administrative actions, and in the performance of audits, investigations and payment oversight. To support these efforts, CMS is launching an improved contracting approach, the Unified Program Integrity Contractors (UPIC) to integrate the program integrity functions for audits and investigations across Medicare and Medicaid from work currently performed by several existing contractors.

Strengthening Provider Enrollment

The Affordable Care Act required CMS to implement categorical risk-based screening of providers and suppliers who want to participate in the Medicare and Medicaid programs, and CMS put these additional requirements in place for newly enrolling and revalidating Medicare providers and suppliers in March 2011. This enhanced screening requires certain categories of providers and suppliers that have historically posed a higher risk of fraud to undergo greater

scrutiny prior to their enrollment or revalidation in Medicare. Categories of providers and suppliers designated as limited risk undergo verification of licensure and a wide range of database checks to ensure compliance with any provider or supplier-specific requirements. Categories of providers and suppliers designated as moderate or high categorical risk are subject to all the requirements in the limited screening level, plus additional screening including unannounced site visits. In April 2014, CMS announced that upon notification, providers assigned to the high screening level will begin fingerprint-based background checks.

The Affordable Care Act also required CMS to screen all existing 1.5 million Medicare suppliers and providers under the new screening requirements. CMS embarked on an ambitious project to revalidate the enrollment information of all existing providers and suppliers, and these efforts will ensure that only qualified and legitimate providers and suppliers can provide health care items and services to Medicare beneficiaries. Since March 25, 2011, more than 770,000 providers and suppliers have been subject to the new screening requirements and over 260,000 provider and supplier practice locations had their billing privileges deactivated for non-response as a result of these screening efforts.[2] Since implementation of these requirements, CMS has also revoked 17,534 providers' and suppliers' ability to bill the Medicare program. These providers and suppliers were removed from the program because they had felony convictions, were not operational at the address CMS had on file, or were not in compliance with CMS rules, such as licensure requirements.

CMS is collaborating with our State partners to ensure that those caught defrauding Medicare will not be able to defraud Medicaid, and those identified as fraudsters in one State will not be able to replicate their scams in another State's Medicaid program. Specifically, the Affordable Care Act and CMS's implementing regulations require States to terminate from Medicaid and the State Children's Health Insurance Program (CHIP) those providers whose Medicare billing privileges have been revoked for cause or that another State's Medicaid or CHIP agency has terminated for cause. Similarly, under current authority, the Medicare program may also revoke

[2] Deactivated providers could reactivate over time with updated practice information or after showing evidence of proper licensing.

the billing privileges of its providers or suppliers that were terminated by State Medicaid or CHIP agencies.

Enrollment Moratoria

The Affordable Care Act provides the Secretary the authority to impose a temporary moratorium on the enrollment of new Medicare, Medicaid, or Children's Health Insurance Program (CHIP) providers and suppliers, including categories of providers and suppliers, if the Secretary determines the moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. States affected are required to determine whether the imposition of a moratorium would adversely affect Medicaid beneficiaries' access to medical assistance and may refuse the moratorium if there would be an adverse effect. When a moratorium is imposed, existing providers and suppliers may continue to deliver and bill for services, but no new applications will be approved for the designated provider or supplier-types in the designated areas. The moratoria enable CMS to pause provider entry or re-entry into markets that CMS has determined have a significant potential for fraud, waste or abuse while working with law enforcement to use other tools and authorities to remove bad actors from the program. CMS is required to re-evaluate the need for such moratoria every six months.

In the last year, CMS has used this authority to fight fraud, waste, and abuse, and to safeguard taxpayer dollars while ensuring patient access to care is not interrupted. In July 2013, CMS announced temporary moratoria on the enrollment of new home health agencies (HHAs) and ambulance companies in Medicare, Medicaid, and CHIP in three "fraud hot spot" metropolitan areas of the country: HHAs in and around Miami and Chicago, and ground-based ambulances in and around Houston.[3] In January 2014, CMS announced new temporary moratoria on the enrollment of HHAs in four metropolitan areas: Fort Lauderdale, Detroit, Dallas, and Houston, and on ground ambulances in the metropolitan Philadelphia area.[4]

CMS also extended for six months the existing moratoria for HHAs in and around Chicago and Miami, and ground ambulance suppliers in the Houston area. In each moratoria area, CMS is

[3] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-07-26.html

[4] http://cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-01-30-2.html

taking administrative actions such as payment suspensions and revocations of home health agencies and ambulance companies, as well as working with law enforcement to support investigations and prosecutions. During the first six-month period of the moratorium, for example, CMS has revoked or deactivated billing privileges of 21 Miami HHAs in the first 60 days of the moratorium. Additionally, law enforcement made arrests in a $48 million home health scheme, and secured guilty pleas against three home health recruiters in that scheme as well as guilty pleas from the owners of a clinic involved in an $8 million fraud scheme.

Before taking these actions, CMS consulted with HHS OIG, the Department of Justice (DOJ), and the relevant State Medicaid Agencies, and found that fraud trends warranted moratoria on certain types of providers in these geographic areas. CMS also reviewed key factors of potential fraud risk including a disproportionately high number of providers and suppliers relative to the number beneficiaries, and extremely high utilization. All the geographic areas included in the moratoria ranked as high-risk in these fraud risk factors.

CMS carefully examined Medicare beneficiary access to services in all of these areas, and concluded that the moratoria will not affect access to care. The Agency also worked closely with each of the affected states to evaluate patient access to care, and these states reported that Medicaid and CHIP beneficiaries will continue to have access to services. During the moratoria period, CMS and the affected states will continue to monitor access to care to ensure that Medicare, Medicaid, and CHIP beneficiaries are receiving the services they need.

Fraud Prevention System

Under the Small Business Jobs Act of 2010, CMS is required to use predictive modeling and other analytic technologies to identify and prevent fraud, waste, and abuse in our fee-for-service Medicare program. Since June 2011, CMS has been using the Fraud Prevention System (FPS) to apply advanced analytics on all Medicare fee-for-service claims on a streaming, national basis. CMS designed the FPS to accommodate different analytic model types to address a variety of fraud schemes. The most important indicator of success is that the models in the FPS have led to administrative action – we have used our revocation authority to remove bad actors from the Medicare program, which is the surest way to protect Trust Fund dollars and

beneficiaries, suspended potentially fraudulent payments from going out the door, and referred leads and cases to law enforcement.

When FPS models identify egregious, suspect, or aberrant activity, the system automatically generates and prioritizes leads for review and investigation by CMS's Zone Program Integrity Contractors (ZPICs). When suspect behavior or billing activity is identified, the ZPICs identify administrative actions that can be implemented swiftly, such as revocation, payment suspension, or prepayment review, as appropriate. The FPS is also an important management tool, as it prioritizes leads for ZPICs to review and investigate Medicare fraud in their designated region, making our program integrity strategy more data-driven. The FPS also gives CMS a provider-level view of ZPIC activities and administrative actions.

Early results from the FPS show significant promise and CMS expects increased returns as the system matures over time. As reported in the FPS FY 2012 Report to Congress,[5] in its first year of implementation, the FPS stopped, prevented or identified an estimated $115.4 million in improper payments. These savings are the outcome of activities such as revocations of provider billing privileges, the implementation of payment edits, the suspension of payments, and changes in behavior that result from CMS actions. The FPS achieved a positive return on investment, saving an estimated three dollars for every one dollar spent in the first year; CMS anticipates that the ability of FPS to identify bad actors and focus investigative resources on most egregious schemes will continue to expand.

National Correct Coding Initiative

CMS has developed the National Correct Coding Initiative (NCCI), which consists of edits designed to reduce improper payments in Medicare Part B and Medicaid. This program was originally implemented with procedure-to-procedure edits to ensure accurate coding and reporting of services by physicians.[6] In addition to procedure-to-procedure edits, CMS established the Medically Unlikely Edit (MUE) program to reduce the paid claims error rate for

[5] http://www.stopmedicarefraud.gov/fraud-rtc12142012.pdf

[6] Procedure-to-procedure edits stop payment for claims billing for two procedures that could not be performed at the same patient encounter because the two procedures were mutually exclusive based on anatomic, temporal or gender considerations.

Medicare Part B claims as part of the NCCI program.[7] NCCI edits are updated quarterly and, prior to implementation, edits are reviewed by national health care organizations and their recommendations are taken into consideration before implementation. Since October 2008, all procedure-to-procedure edits and the majority of MUEs have been made public and posted on the CMS website.[8] The use of the NCCI procedure-to-procedure edits saved the Medicare program $483 million in FY 2012, and the NCCI methodology procedure-to-procedure edits applied to practitioner and outpatient hospital services have prevented the improper payment by Medicare of over $5 billion since 1996 based on savings reports from claims-processing contractors.

Leadership and coordination across the health care system

CMS is coordinating a variety of efforts with Federal and state partners, as well as the private sector to better share information to combat fraud. CMS enhanced its data analysis and improved coordination with law enforcement to get a more comprehensive view of activities in Medicare Advantage and Part D. CMS issued new compliance program guidelines to assist Medicare Advantage plans and prescription drug plans design and implement a comprehensive plan to detect, correct and prevent fraud, waste and abuse.

CMS also contracts with the Medicare Drug Integrity Contractor (MEDIC) to perform analysis to identify fraud, waste and abuse as well as identifies vulnerabilities in MA and Part D. In September 2013, CMS directed the MEDIC to increase its focus on proactive data analysis in Part D. As a result, the MEDIC identified vulnerabilities and then performed analysis that resulted in notification to plan sponsors to remove records associated with inaccurate data leading to improper payments made in FYs 2011 and 2012. This increased focus on proactive analysis resulted in savings of $4.8 million from decreased provider payments, $21 million for unallowable charges for medications during a hospice stay, and $80 million for Transmucosal Immediate Release Fentanyl drugs without a medically-acceptable indication. To increase the impact of the proactive analysis, CMS issued a proposed rule that would provide CMS, the

[7] MUEs stop payment for claims that are beyond the maximum units of service that a provider would report under most circumstances for a single beneficiary on a single data of service.
[8] Certain edits are not published because of CMS concerns that they may be used or manipulated by fraudulent individuals and entities.

MEDIC, OIG and GAO the ability to request and collect information directly from pharmacy benefit managers, pharmacies and other downstream entities of Part D Plans.

The rule also proposes to require prescribers of Part D drugs to enroll in Medicare or have a valid opt-out affidavit on file in order to ensure that only qualified individuals are prescribing for Medicare beneficiaries. This proposed enrollment requirement would work in conjunction with another proposed requirement that would allow CMS to revoke a Part D prescriber's enrollment based on abusive prescribing practices and patterns. This proposal would provide CMS the authority to revoke a physician's or eligible professional's Medicare enrollment if CMS determines that he or she has a pattern or practice of prescribing Part D drugs that is abusive and represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. Additionally, prescribing authority could be revoked if a prescriber's Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked or the applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs.

Healthcare Fraud Prevention Partnership

In July 2012, the Secretary of HHS and the Attorney General announced a historic partnership with the private sector to fight fraud, waste, and abuse across the health care system. The ultimate goal of the Healthcare Fraud Prevention Partnership (HFPP) is to exchange facts and information to identify trends and patterns that will uncover fraud, waste and abuse that could not otherwise be identified. The HFPP currently has 35 partner organizations from the public and private sectors, law enforcement, and other organizations combatting fraud, waste, and abuse. In 2013, the HFPP completed early proof-of-concept studies that have enabled partners, including CMS, to take substantive actions to stop payments from going out the door.

Health Care Fraud Prevention & Enforcement Action Team

In addition to CMS's commitment to collaboration, the sustained success of Health Care Fraud Prevention & Enforcement Action Team (HEAT) demonstrates the effectiveness of the Cabinet-level commitment between HHS and DOJ to prevent and prosecute health care fraud. Since its

creation in May 2009, HEAT has played a critical role in identifying new enforcement initiatives and expanding data sharing to a cross-government health care fraud, waste, and abuse data intelligence sharing workgroup. A key component of HEAT is the presence of Medicare Strike Force Teams, interagency teams of analysts, investigators, and prosecutors, who target emerging or migrating fraud schemes such as criminals masquerading as providers or suppliers.

In the six and a half years since its inception,[9] Strike Force prosecutors have filed more than 788 cases charging more than 1,727 defendants who collectively billed the Medicare program more than $5.5 billion; 1,137 defendants pleaded guilty and 148 others were convicted in jury trials; 1087 defendants were sentenced to imprisonment for an average term of about 47 months.

Educating Beneficiaries: A Key Tool in Preventing Fraud

Beneficiary involvement is a key component of all of CMS's anti-fraud efforts. Alert and vigilant beneficiaries, family members, and caregivers are some of our most valuable partners in stopping fraudulent activity. Information from beneficiaries and other parties helps us to quickly identify potentially fraudulent practices, stop payment to suspect providers and suppliers for inappropriate services or items, and prevent further abuses in the program. In June 2013, CMS began sending redesigned Medicare Summary Notices (MSNs),[10] the explanation of benefits for people with Medicare fee-for-service, to make it easier for beneficiaries to spot fraud or errors. The new MSNs include clearer language, descriptions and definitions, and have a dedicated section that tells beneficiaries how to spot potential fraud, waste, and abuse. Beneficiaries are encouraged to report fraud, waste, and abuse to 1-800-MEDICARE, and this is promoted in the re-designed MSN. CMS has an incentive reward program that currently offers a reward of 10 percent of the amount recovered up to $1,000 paid to Medicare beneficiaries and other individuals whose tips about suspected fraud lead to the successful recovery of funds. Last year, CMS released a proposed rule that if finalized, would increase these rewards to 15 percent of the amount recovered up to $10 million.[11]

[9] Specifically, the period from May 7, 2007, through September 30, 2013.
[10] http://blog.medicare.gov/2013/06/06/redesigned-with-you-in-mind-your-medicare-summary-notice/
[11] http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-04-24.html

CMS has also been partnering with the Administration for Community Living (ACL) to lend support to the Senior Medicare Patrol (SMP) program, a volunteer-based national program that educates Medicare beneficiaries, their families, and caregivers to prevent, detect, and report Medicare fraud, waste and abuse. The SMP program empowers Medicare beneficiaries through increased awareness and understanding of health care programs and educates them on how to recognize and report fraud. During 2012, SMP program grantees' staff and more than 5000 volunteers reached nearly 1.5 million people with group education sessions and one-on-one counseling.[12] SMP projects also work to resolve beneficiary complaints of potential fraud in partnership with State and national fraud control and consumer protection entities, including Medicare contractors, State Medicaid fraud control units, State attorneys general, HHS OIG, and the Federal Trade Commission.

Impact on Cost and Appropriateness of Care

CMS is implementing program integrity activities that will prevent improper payments while ensuring that only appropriate care is provided. Such efforts targeting target waste, fraud and abuse have already helped extend the life of the Medicare Trust Fund, and it is critical in doing more to protect Medicare for years to come. Fraud can also inflict real harm on Medicare beneficiaries. By preventing fraud, we ensure that beneficiaries are less exposed to risks and harm from fraudulent providers, and providing them reliable access to quality health care from legitimate providers while preserving Trust Fund dollars.

Proposals to Improve the Prevention of Waste, Fraud, and Abuse

The FY 2015 President's Budget reflects the Administration's commitment to strong program integrity initiatives. For FY 2015, the Budget invests a total of $428 million in new HCFAC funds and the Medicaid Integrity Program. Together with program integrity investments in the Budget will yield $13.5 billion in gross savings for Medicare and Medicaid over 10 years. The Budget also includes 17 legislative proposals that provide additional tools to further enhance program integrity efforts in the Medicare and Medicaid programs, as well as authority to retain recoveries from certain program integrity activities to help correct vulnerabilities and administer

[12] http://oig.hhs.gov/oei/reports/oei-02-13-00170.pdf.

the programs. The Budget includes additional investments and flexibility for the Medicaid Integrity Program.

The Budget proposes new authorities to prevent improper payments from ever being made. One proposal builds on the success of the Power Mobility Device (PMD) Prior Authorization Demonstration by giving CMS the authority to require prior authorization for all Medicare fee-for-service items, particularly those items at the highest risk for improper payment. Based on claims submitted as of September 30, 2013, spending for PMDs has decreased by $117 million (assuming that the month expenditures for PMDs would have remained constant).[13] By allowing prior authorization on additional items, CMS can ensure in advance that the correct payment goes to the right provider for the appropriate service, and preventing potential improper payments before they are made.

The Budget also aims to improve payment accuracy by allowing the Secretary to create a Medicare claims ordering system requiring electronic submission of orders prior to payment for certain high risk products and services, like durable medical equipment and home health, to validate that a physician or other eligible practitioner ordered the service. Many existing systems do not automatically validate the elements of an order prior to payment of a claim. This new system would ensure that the supplier billing for the service or equipment has received all necessary components from the ordering physician or the eligible practitioner prior to payment.

New data transparency initiatives

CMS recently released new, privacy-protected data on services and procedures provided to Medicare beneficiaries by physicians and other health care professionals. Release of physician-identifiable payment information will serve a significant public interest by increasing transparency of Medicare payments to physicians, which are governed by statutory requirements, and shed light on Medicare fraud, waste, and abuse. The new data also show payment and submitted charges, or bills, for those services and procedures by provider. The new data set has

[13] http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-CompliancePrograms/CERT/Downloads/PMD_Demo_1yrUpdate_12182013_508Clean.pdf

information for over 880,000 distinct health care providers who collectively received $77 billion in Medicare payments in 2012, under the Medicare Part B fee-for-service program. With this data, it will be possible to conduct a wide range of analyses that compare 6,000 different types of services and procedures provided, as well as payments received by individual health care providers.

Later this year, CMS will release additional data to help consumers make informed choices under the Open Payments program. As required by the Affordable Care Act, the data will provide information about payments to physicians made by certain manufacturers of covered drugs and devices. This program is a national resource for beneficiaries, consumers, and providers to better understand relationships between physicians, teaching hospitals, and industry. Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices. However, while some collaboration is beneficial, payments from manufacturers to physicians and teaching hospitals can also introduce conflicts of interests.

Moving Forward

Medicare fraud, waste, and abuse affect every American by draining critical resources from our health care system. Our health care system should offer the highest quality and most appropriate care possible to ensure the well-being of individuals and populations. CMS is committed to protecting taxpayer dollars by preventing or recovering payments for wasteful, abusive, or fraudulent services. But the importance of program integrity efforts extends beyond dollars and health care cost alone. It is fundamentally about protecting our beneficiaries – our patients – and ensuring we have the resources to provide for their care. Although we have made significant progress in stopping fraud and improper payments, more work remains to be done.

Going forward, we must continue our efforts to move beyond "pay and chase" to prevent fraud before it happens, provide leadership and coordination to address these issues across the health care system, and ensure that we take administrative action as swiftly as possible to stop suspected instances of waste, fraud, and abuse. We appreciate committee members' high level of interest in program integrity, many of whom have introduced or sponsored legislation in this

area. I look forward to working with you and the Congress on your ideas to continue making improvements in protecting the integrity of our health care programs and safeguarding taxpayer resources.

Chairman BRADY. Thank you, Doctor.

Thank you to all the panelists.

Dr. Agrawal, you have highlighted a number of actions CMS has taken to reduce waste, fraud and abuse, and we appreciate them. While your fellow panelists acknowledge that your agency has made progress, the inspector general, General Accountability Office identify a number of areas for improvement. I am particularly troubled by the inspector general's revelation that Medicare pays $23 million for services to those who have died, according to the testimony, $117 million lost to those unlawfully present, and $33 million paid to those in prison. And there is more fraud within the fee-for-service area: overprescribing by physicians, the hospital transfer of payment issue, which is more than half a billion dollars lost to Medicare. These are problems that hurt seniors and erode public confidence in the Medicare program, and to my mind, reading the testimony, are preventable. I truly believe that preventing fraud is a bipartisan issue and has been a long-standing challenge, and my hope is that we can work collaboratively with CMS.

And since this is your first time before the House and before the Committee, can I get a commitment from you that your agency will work with me and our Committee to stop the nearly $50 billion in improper payments each year?

Dr. AGRAWAL. Thank you for the question. Focus on improper payments is absolutely very important for the agency. We appreciate the work of the OIG and the GAO in identifying further vulnerabilities that we can work on. I think we can all agree, and it has been stated, that these are areas that we have made important progress in. That is not to say that we should stop being aggressive on these issues.

I think there are numerous factors in our more recent kind of programs that have provided important progress. So work that we have done on enrollment and screening standards on advanced analytics have, I think, really started to and made significant strides in addressing improper payments as well as the other access—improper payment issues that OIG and GAO have identified. We will continue to work on those and look forward to working with this Committee in doing so.

Chairman BRADY. It will go easier if you just start with yes. Just so you know.

Dr. AGRAWAL. Yes, sir.

Chairman BRADY. Doctor, I want to thank you for your willingness to work. As a followup on the fundamental challenges that you have and will face is moving CMS from a pay-and-chase fraud-fighting model. I am glad you mentioned it in your written statement, but I am concerned your efforts focus mostly on recouping money that has already gone out the door. Many Members on this panel, again, bipartisan, believe we should be copying what private payers are doing already to prevent, detect and deter fraud, stopping payments before they go out the door. And so what actions is CMS taking to move in that direction, and how do we as a Committee measure that movement and those results?

Dr. AGRAWAL. I think that is a very important question. We have taken a lot of steps to both emulate the private sector where appropriate and work with the private sector in our common pro-

gram integrity challenges. As one example, we have recently completed a demonstration on the use of prior authorization to mitigate improper payments as well as other fraud, waste and abuse issues, and there is language in the President's budget that would allow us to expand that program.

Another example, I think a notable one, is the health care flawed prevention partnership, which specifically brings up private payers together with CMS in order to jointly and in a coordinated manner, detect and prevent fraud. Under that partnership, we have already engaged in numerous data exchanges and also sort of qualitative exchanges around best practices. It has led to some real actions for us.

The way that I think you could measure them is similar to how we measure them. We look at identified savings from HFPP activities as well as other activities and specific outcomes, like revocations and law enforcement referrals.

Chairman BRADY. Ms. Jarmon, in her testimony, laid out a number of recommendations, but more importantly what seems to be a fairly simple sharing of data that would have prevented improper payments in a number of areas. Why aren't those being done?

Dr. AGRAWAL. Well, sir, I think there are multiple examples of where we are sharing data. We are sharing data with State Medicaid agencies, with the private sector, with law enforcement and that—and all of those examples are really by directional sharing of data, so we are getting data from them and learning from all of these entities as well as providing our data to these other parties.

There is certainly more that we can do, and we continue to expand our data-sharing activities. I am happy to continue to work on those, but I think there are really notable examples in numerous programs where data exchange is central to those programs.

Chairman BRADY. Thank you.

Ms. King, I understand GAO generally directs CMS to make or recommend changes with which the agency has administrative authority, and that General Accountability Office recommendations that require legislation are directed to us in Congress. Can you give us—so that we can track these and so we can measure the progress and know where we need to focus; can you give us a rough percentage of the GAO unimplemented recommendations that CMS has authority to implement, and your sense of why it has not yet acted?

Ms. KING. We do track all of our recommendations over time, and we keep them open for a considerable period of time, and I don't have the exact numbers at my fingertips, but our track record is pretty good on whether they have been implemented, and we have supplied to your staff a list of the open recommendations.

Chairman BRADY. But approximately how many are there? I am not trying to pin it down. I am just trying to figure out——

Ms. KING. Oh, jeez. Off the top of my head, 20 to 30.

Chairman BRADY. To put it in perspective, these 20 to 30 recommendations, what potential impact do they have? How important are these recommendations not yet implemented for either stopping improper payments or recouping them once done?

Ms. KING. Well, I don't think we make a recommendation unless we think that it is going to have a real effect. We identify a problem and we identify a way that it can be fixed. And some of those recommendations are actually not on the improper payment side, they are for all of Medicare, and some of them go to changes in payment policy and some of them go to changes in management, and others do go to improper payments.

And I think on the improper payment side, I think a good many of those recommendations have been implemented or are in the process of being implemented. And we don't close a recommendation until we are satisfied fully that it has been implemented.

Chairman BRADY. Can you share that information with us?

Ms. KING. Yes, sir.

Chairman BRADY. Great. And we will make sure the Committee has it.

Ms. Jarmon, I have introduced legislation with my colleague, Dr. McDermott, to expand your authority to exclude individuals and companies from participation in Medicare and other Federal programs.

Our intent is to prevent individuals who are responsible for fraud from jumping to another company before sanctions are handed down and prevent a company from creating a shell company that could further commit fraud and shield a parent company from liability. That is the intent of the legislation.

I think these situations—we can all agree need to be prevented. Several types of providers have understandably expressed concern that this expansion could leave companies that serve seniors at serious legal risk, even if they have no role in fraudulent activity exposed to the OIG overreach.

So how do you respond to these concerns?

Ms. JARMON. Well, we—well, I would like to note that OIG—we don't have the resources to actually go—even go after all of the people who maybe should be excluded. So the chance of us even going broader is very limited.

We do—we are very careful about how we use the authorities that we have. We have guidance on our website as far as reasonable factors to consider when determining—when deciding to do an exclusion, which includes the seriousness of the misconduct or the alleged fraud and whether it hurt—harms beneficiaries or the health plan.

And this exclusion authority is very important to us because we do need the authority to be able to exclude people who actually leave the organization before the citation who have been accused of fraud.

So that was a loophole in the prior legislation that is very important that we fixed so that the wrongdoers would be able to be excluded. So we are very careful——

Chairman BRADY. Thank you.

Dr. McDermott and I are very serious about closing this loophole and——

Ms. JARMON. Thank you.

Chairman BRADY [continuing]. And stopping this jumping from company to company, and it—continues to be a problem.

So now I recognize the Ranking Member, Dr. McDermott, for 5 minutes for his questions.

Mr. MCDERMOTT. Thank you, Mr. Chairman.

Ms. Jarmon, I appreciate your testimony and recognize that you are with the Office of Audit Services component of OIG.

And I have questions that are more appropriately perhaps addressed to the Office of Counsel within OIG; therefore, I want to make a statement and I will submit several questions for the record. I will look forward to the responses from the OIG.

I remain concerned about the application of our current fraud and abuse laws, given our movement to new payment methods. My concern exists on several levels.

First, I believe that Federal regulators have sufficient experience with some models such that these arrangements should not be afforded protection under broad waiver authority, which is unclear exactly how the False Claims Act applies and where whistleblowers can be reticent—may be reticent to bring qui tam cases.

Instead, regulators should put forth, I believe, an appropriate exception under the self-referral law and make modifications to other laws, including the gain sharing civil monetary penalty laws necessary to provide parameters for such conduct.

As an example, I am aware that OIG has issued no fewer than 15 advisory opinions—I have read some of them, not all of them—on various incentive compensation programs between hospitals and patients—and physicians.

And, Mr. Chairman, I would like to enter into the record these advisory opinions that OIG has issued since 2001 in the area of incentive arrangements between hospitals and physicians.

Chairman BRADY. Without objection.

Mr. MCDERMOTT. Rather than issue a case-by-case advisory opinion, it seems to me that more structure should be put in place around such arrangements.

This would allow regulators to better monitor these arrangements and would afford participants some level of certainty that participation in such arrangements would not be problematic under the fraud laws.

My bill, H.R. 1487, called the Improved Care of Lower Cost Act of 2013, seeks to require regulators to provide more structure around certain arrangements that regulators have been approving for over a decade on a case-by-case basis to allow broad participation by providers, but also ensure an adequate scrutiny by regulators.

This case-by-case thing—as we spread the Accountable Care Act over the country, they are going to have endless case-by-case things, and I think it ought to be done systematically.

Second, I remain concerned that there are new fraud, waste and abuse schemes that we may not be fully aware of, given the different incentives under emerging payment models. So everyone agrees and usually mentions that we need to be concerned about stinting on care for Medicare beneficiaries.

One of the ways you can save money is don't give care. But what about monitoring whether a few unscrupulous providers would game the system by manipulating quality measures since these

measures have taken on an increased importance in this new era of health care?

All a patient would have to say is, "I like the doctor and they have got good quality," but that doesn't mean they have gotten the care they needed.

This conduct seems to me to be much harder to identify than a false storefront, for example. This type of fraud is just as detrimental to our beneficiaries as to the solvency of the Medicare trust fund.

And I will submit these questions in writing to the counsel.

I am also a co-sponsor of a bill, H.R. 2914, the Promoting Integrity in Medicare Act, which would retain, but narrow, the in-office ancillary services exception under the Physician's Self-Referral Act so that the law and implemented regulations would more closely approximate what Congress intended.

CBO has suggested that the change reflected in this legislation would save the Federal Government $3.4 billion over the next 10 years.

Ms. King, can you provide the GAO's key findings related to the in-office ancillary services exception and the existing policy in this area?

Ms. KING. Yes. We have done a few reports on that, and what we have found is that, in instances where there is an ownership interest, that the utilization is higher.

And, in our view, the self-referral component of it is one of the primary driving forces behind the higher utilization.

And we have made a recommendation to CMS that they more closely track when services are provided in a self-referral situation, but they did not agree with us on that. And we wish they had and we wish they would.

Mr. MCDERMOTT. Could you give us their reasoning that they gave you when they didn't agree with you?

Ms. KING. They said that they thought it would be really complicated to track.

Mr. MCDERMOTT. It would be complicated to track.

Ms. KING. Yes, sir.

Mr. MCDERMOTT. And since it is complicated in this day of computers and programming and all the rest, they couldn't figure out how to do it? Is that what you are telling me?

Ms. KING. Well, sir, I can't speak for them, but that is, you know, what they responded to us.

Mr. MCDERMOTT. Dr. Agrawal, does that make sense to you?

Dr. AGRAWAL. Sir, I appreciate the question, and I appreciate the issue that you are raising.

I would say that Stark and self-disclosure laws don't actually fall within the activities of the Center for Program Integrity. I am happy to take your comments back and connect you with the right expert at CMS.

Mr. MCDERMOTT. All right. If you would, I appreciate it.

Because I think that, when there is this much money on the table as there is in health care today, it is bound to attract some folks who don't have the best interests of the patients or the government or the taxpayers at heart.

And it is going to be difficult for us—certainly with Medicare, we have got problems already. We are going to have more problems with the Accountable Care Act.

And I think it is important that these fraud laws be updated to move from fee-for-service application, which is what we have had in the past, to now these more complicated other payment arrangements for physicians.

Physicians are hired by hospitals or get into relationships with hospitals. That whole of the fraud thing changes—or at least it seems to me it changes.

And I want us to look carefully at that and make the kinds of changes we need to so that we don't come here 5 years from now and say, "Here is $100 billion that has been wasted" or 50 billion or whatever. I want us to try and stop it before it starts.

I yield back the balance of my time.

Chairman BRADY. Thank you, Mr. McDermott.

Mr. Johnson is recognized.

Mr. JOHNSON. Thank you.

Mr. McDermott, I agree with you. They refuse to do anything.

Dr. Agrawal, I understand you are now in charge of the CMS Program Integrity mission. Is that true? True or false?

Dr. AGRAWAL. Sir, I am in charge of the Center for Program Integrity. Yes.

Mr. JOHNSON. Okay. You may not know, but in recent years, the House has twice overwhelmingly passed bills to take the Social Security number off the Medicare card.

My colleague, Lloyd Doggett, and I have been trying to get this done for years. And it seems to us that CMS, who tells seniors they must carry their Medicare card with their Social Security number in their wallet, refuses to protect seniors from becoming victims of identify theft. And, you know, you talk big about doing things over there, but you guys haven't done anything.

Do you care about protecting seniors from identity theft?

Dr. AGRAWAL. Unequivocally, yes, sir, we care about protecting seniors from identity theft.

Mr. JOHNSON. Well, when are you going to do that?

Dr. AGRAWAL. We have taken a number of actions to do so. We have, for example, beneficiary education activities, campaigns, in order to make them more aware of identity theft issues, given them real tactical solutions and ideas for how to not be victimized by identify theft.

Beyond that, sir, when it looks like somebody has become a victim of identify theft, we have a way of tracking their existing numbers and incorporating that through our compromised numbers database into other analytical work that we have underway.

So we are able to use that information in our activities to help prevent fraudulent billing under their HCCN.

Mr. JOHNSON. Yeah. But how are you going to stop them from stealing their Social Security number off of your Medicare card?

Dr. AGRAWAL. Well, I appreciate the issue and I realize its importance to this Committee.

I also know that you are very aware of the dialogue that the agency has had with the Committee and the operational kind of re-

quirements in order to be able to remove the Social Security number from the card.

I think, given the right resources to be able to do it, we would be very open to further discussion on—on——

Mr. JOHNSON. Well, you could at least just put the last four digits on there instead of the whole number.

Does CMS support our bipartisan bill, H.R. 781, the Medicare Identify Theft Prevention Act of 2013? Yes or no?

Dr. AGRAWAL. Sir, I would have to review the specifics of that bill to give you a——

Mr. JOHNSON. How long have you been there?

Dr. AGRAWAL. Pardon me?

Mr. JOHNSON. How long have you been there?

Dr. AGRAWAL. 2 months.

Mr. JOHNSON. Well, you ought to know it by now.

When are you going to do something about it? I would like to know what your plan is and when CMS will try to do the right thing.

Ms. King, GAO told us that CMS has efforts underway to modernize their IT system and that these efforts could be used to remove Social Security numbers off Medicare cards, yet CMS has not included removing Social Security numbers. And you just talked about it.

Is it still true that you agree with that?

Ms. KING. Yes, sir, it is. I mean, I think—CMS' position on that, at least at the time that we did our work, is that they knew that it was really complicated and they had revised their cost estimates, but they believed that they needed additional funding to do it.

Mr. JOHNSON. Well, I am not sure about that. But I want you to know that both Lloyd Doggett, who is a Democrat, by the way, and I agree that something needs to be done. We have been working on this for what seems like 8 years, and you guys haven't moved off that center.

Thank you, Mr. Chairman. Yield back.

Chairman BRADY. Thank you.

Just as a note, the money saved from not paying felons, those who are dead and those who are here undocumented would pay for the implementation of removal of those Social Security numbers.

Mr. Blumenauer.

Mr. BLUMENAUER. Thank you, Mr. Chairman.

And I do appreciate what you and our Ranking Member have done in terms of moving forward with this and setting the stage for it, and I share both the sense of the urgency and the potential of doing something.

You may have noticed occasionally we are cranky around here and we don't always see eye to eye, but what has been outlined today and what you are going to hear is an area, I think, of tremendous consensus.

And beyond the consensus, I think there is a commitment and a passion to get something done. It doesn't make any difference about how you feel about the Affordable Care Act or global warming. These are incontrovertible facts. And we are looking at $50, $60 billion, whatever the number is.

Now, the individual areas in the vast payment scheme are maybe understandable, but the target number needs to be addressed aggressively.

And you are going to hear from some of my colleagues. I am not going to steal their thunder. Just because of the luck of the draw, a couple of my colleagues come after me, and I will let them elaborate on their bills.

But I am happy to have been a co-sponsor of the Prime Act. I think my friend Mr. Roskam and a number of people have zeroed in—there is about 60 bipartisan co-sponsors with provisions that would probably welcome some refinement, but the essentials there are solid and need to be pursued.

I have been working for several years with Mr. Gerlach on a universal access card. And I think if anything, it started a little timid. It has been—you know, it has been very careful and calculated to try and move this forward, and I think he is going to weigh forth.

And I couldn't agree more with Congressman Johnson about getting the flipping numbers off the Social Security card. We understand that it takes resources and takes time and you have had a lot going on, but we are into a phase now of implementation of the Affordable Care Act and you have had time.

And I think that there is—this is something that is not rocket science, and I think people would be open to what needs to happen in terms of some modification of a budget going forward.

But it is going—these things collectively are going to save far more than they are going to cost, and it speaks to the integrity of the system and the protection of the people that we represent.

Now, Mr. Chairman, I would hope that we could continue with a little deeper dive on some of these proposals. I would hope that these would be at sort of a level.

I have talked with some of my colleagues about what would happen if we took some of—and we have had this conversation—we take some of the things that are second- or third-tier issues that don't have to, you know, stop the planet, they—the leadership doesn't much care in either party, to break some of this stuff loose, be with it on the floor.

Maybe that would be a going-away present—Mr. Roskam and I talked about this last week—to Members of Congress, that this would be kind of a wrap-up session that we would have on the Thursday or Friday when we leave, to have one of these specifics on the floor that could bring people together, that would make a difference, that would be a signal to the people out there who are cheating and, more important, to the people that we are representing.

So I will get off my high horse. I won't go any further because you need to hear from the people who are the principal authors and who have put huge amounts of work into it.

But I would respectfully request, Mr. Chairman, that our witness friends could be able to give a little deeper analysis on each of these items that they are going to hear from about how—about what we need to do to do that.

And the last thing I would recommend is that we think about working with CBO on some scoring mechanisms, because things that actually save money we ought to be able to apply present-

value accounting, particularly if we can hold agencies accountable for the savings, that this isn't a pipe dream, but this is something that is beyond theoretical, and that we have the hammer to go back and make sure that they deliver. Then maybe we can cut some slack in terms of CBO scoring.

I appreciate your courtesy, Mr. Chairman. If there is something that my colleagues don't get to, I will submit it to our witnesses in writing. But at this point I will yield back.

Chairman BRADY. Thank you, Mr. Blumenauer.

Two comments, if I may.

One, this is a bipartisan concern. This is the first hearing of what we hope will be deeper dives, as you have laid out, and the goal is to begin moving legislation in these areas.

Second, I agree with you completely on the scoring challenge. Often very good ideas that we know will work and improve and save money elsewhere are not given the score we think they deserve.

We are eager to work with you and CBO on those issues. So thank you.

Mr. BLUMENAUER. Thank you.

Chairman BRADY. Mr. Roskam is recognized.

Mr. ROSKAM. Thank you, Mr. Chairman, for your leadership and convening this hearing, and for Mr. Blumenauer and his thoughtful setting of this discussion.

I think most Americans when they hear these numbers are actually scandalized by them. It is very difficult to absorb.

We are in this very clinical, antiseptic setting, but this is a situation that is bad. It has been bad and it is actually getting worse. This is not getting better. And these are the numbers—these are objective numbers.

So CMS's own numbers in 2010 said that this number, in terms of fraud and abuse and waste and so forth, was $48 billion. A year later, it jumped up, according to GAO, to $64 billion. The latest estimate from the FBI is $75 billion plus and climbing.

So, Doctor, with due respect, in my view, you don't get to use words like "top priority," "robust," and "strongly positive." They should be out of your lexicon. This is a scandal. This is an embarrassment.

And there is an irony in that Ms. Jarmon in her opening statement makes an inquiry of this Committee, "Would you please support our request for a budget, an appropriation?" And the irony is you have got all the money already.

So can you imagine the level of confidence that would be buoyant in our country if we were able to come together? And you have brought us together in ways that we have never been brought together before.

As Mr. Blumenauer alluded, we can hardly agree what time it is between the two of our parties. We cannot agree on what day of the week it is. Yet, we are nearly unanimously scandalized by just these big, big numbers.

I have got three inquiries of you. And I recognize you are the new person on the job. You have been there 2 months. So I am measured by that, but here are three legitimate issues that are upon us that have broken through.

One is the Medi-Medi data sharing. This is this whole notion of Medicaid and Medicare being in communication, if there is fraud in one area, communicating that in another area. Right now only 10 States are participating. In my view, that is ridiculous.

What is your remedy to that?

Dr. AGRAWAL. Thank you.

I think the Medi-Medi program is very important for our activities. It does, as you pointed out, allow us to exchange data with the States so that we can, again, find those providers and schemes that are crossing the line between Medicare and Medicaid and kind of committing schemes against us all.

Expansion is an important element of that, and we have been working to expand the numbers of States that participate in Medi-Medi. This is, I would just point out, a voluntary program, and there are a number of other data exchange activities that the States are engaged in.

We have heard consistently from them that, while they would in some cases value participation, they have to weigh that against other priorities and data exchanges that they have.

So we are very open to more expansion, have actually added more States since that figure of 10. And I could get you a more updated number.

Mr. ROSKAM. So the next time we meet in a hearing setting so that you can claim those superlatives that I admonished you from using before, what is your plan in terms of the Medi-Medi goal?

Let's say you are back in a hearing in 6 months. There are currently 10 states that are participating. What is reasonable for us to assume. I am not asking pipe dreams.

What is a reasonable number for you to coax, cajole, urge States to participate if only 20 percent of the Nation is participating now?

Dr. AGRAWAL. I am not sure that I could give you a specific number——

Mr. ROSKAM. Sure you can.

Dr. AGRAWAL [continuing]. That would—you know, to kind of—for a followup hearing.

I think what is important to note is that Medi-Medi is just one of the many activities that we perform with the States.

We also collaborate with them in the Medicaid Integrity Institute, which is all about best practice and knowledge-sharing.

We work with them on specific cases that might fall out of the Medi-Medi context, but are active investigations either that we have initiated or that they have.

So I am not sure that participation alone in Medi-Medi is the best measure of how well that——

Mr. ROSKAM. Yeah. But it would help. I mean, my Home State of Illinois just paid out $12 million to people who are dead.

Dr. AGRAWAL. Yes, sir. I—I also am aware of that.

Do you—I think I go back to the answer that I had about Medi-Medi. If you are asking specifically about Illinois, I could certainly look into what activities we have with them.

Mr. ROSKAM. So here is my question: If only 10 States are participating and we are losing $75 billion a year, according to the FBI, doesn't it follow that, if we had every State participating, that

this gets better? And don't you play a key role in whether every State participates or not? Am I over-characterizing this?

Dr. AGRAWAL. I think it is fair to say we, too, want more States to participate. I think——

Mr. ROSKAM. What is your plan to have that happen? That is my question.

Dr. AGRAWAL. So we have lots of outreach activities with the States to let them know about the existence of the program, to indicate the sort of portion of the Medi-Medi budget that we are willing and able to handle versus what they would need to undertake, and we engage, you know, with States in numerous different venues in order to be able to do that.

Again, I believe States are under a lot of pressure to also produce data for CMS, including the T–MSIS program. So there will be exchange of data. And I am not sure, again, that Medi-Medi is the singular kind of measure of that collaboration——

Mr. ROSKAM. But you are not satisfied——

Dr. AGRAWAL [continuing]. Of examples.

Mr. ROSKAM. You are not satisfied with 10 states, are you?

Dr. AGRAWAL. Oh, we always want more states to collaborate.

Mr. ROSKAM. How many more? Next time we meet, how many more is a reasonable number?

Dr. AGRAWAL. Sir, I am not sure I could give you a particular number.

Mr. ROSKAM. Okay. Let's switch gears.

Provider legitimacy, this notion of a provider being illegitimate, losing a licensing, being a hustler and so forth, being thrown out of a system and, yet, that doesn't sync up with other systems. There was a ProPublica piece not long ago, I am sure you are familiar with it.

Could you speak to that?

Dr. AGRAWAL. Sure. And I think that is a great example of data exchange outside of the Medi-Medi program.

So, for example, as a result of the ACA, Medicaid programs are now required to share their termination data with CMS, and we are then able to take relevant action in Medicare, if that provider is indeed enrolled in Medicare, as well as take a reciprocal action in other State Medicaid programs.

I think there are very good examples. We have had compliance in sharing that kind of data increase dramatically since the beginning of the program. We get a lot more information from the States in terminations that they are able to perform.

Now, I would point out licensure decisions are very different from enrollment in Medicare or Medicaid. Those are conducted by non-CMS-affiliated bodies. Those are State licensure boards. They operate very independently of us.

We certainly can take an action if a license is revoked, but we, as such, have no more authority in that process than anybody outside the licensure board.

Mr. ROSKAM. Okay. We would love to help you.

I yield back.

Chairman BRADY. Thank you.

Mr. Kind is recognized.

Mr. KIND. Thank you, Mr. Chairman.

I commend you for holding this important hearing. And it is one that really should be non-partisan and, hopefully, we will have an opportunity to work in a bipartisan way.

You are never going to find any Member of Congress defending fraud, waste and abuse, whether it is Medicare or any other Federal program. But I think we need to approach this in the proper context.

It is not just Medicare fraud that we are talking about here. We are talking about system-wide health care fraud, and Medicare is a subset of that.

I would assume that, if we are detecting fraudulent practices, fraudulent billing, in Medicare, it is much larger than that and it involves private payers and those involved in the health care system.

Is that right, Dr. Agrawal?

Dr. AGRAWAL. Yes. I think that is a very important point.

Part of the reason for the creation of the health care fraud prevention partnership is this very notion that fraud crosses the public-private divide, and the fact that private payers have joined the partnership really does indicate that they face these challenges, too.

Mr. KIND. And that—the private partnership program right now, how successful do you think that has been working, the collaboration with the private sector and the private payers? And what more do you think could be added to it in order to enhance its success?

Dr. AGRAWAL. Thank you. I appreciate the question.

It has—the collaboration has been extensive. For example, next week a number of private payers are going to be coming to the command center at CPI as part of partnership activities.

We have over 30 partners at this point between private payers, national health care agencies, and law enforcement bodies.

We have conducted numerous data exchanges within the confines of the partnership, specific data exchanges, not just qualitative data around best practices, though we have done that as well.

And each of us has then used that data—each participant has used that data to go and take action wherever appropriate in our own systems, and CMS has been able to do that. So I think the partnership has really continued to mature.

Mr. KIND. Mr. Roskam did point out some startling numbers as far as trend lines, from $48 billion to $75 billion or so. But I also sense there is a little bit of the dial being moved in the right direction as well.

I mean, because of the existing tools now in the Affordable Care Act and some pre-existing authorities, we have got the HEAT strike force that has been out there.

I think, since passage of ACA, over $20 billion has been recouped or recaptured of Medicare fraud, 1,400 individuals have been charged up and criminal charges are pending against.

So there are some instances that we can point to showing some progress is made, but, obviously, there is no reason for a victory lap or satisfaction from any of us here.

My question for you, Doctor, coming from the profession yourself, we just had a huge CMS physician reimbursement data dump recently.

Where do you think this is going to lead as far as looking at overutilization practices and possible fraudulent detection?

Dr. AGRAWAL. Thank you.

I think that data release was a very important element of the administration's overall approach to transparency and health care data. Since then, we have heard from a lot of external stakeholders about their use of the data, how they would like to leverage it.

I think that kind of innovation, you know, among stakeholders is very important. It also fits into an overall kind of set of programs that we have at the Center for Program Integrity.

Another example that we are implementing now is the Sunshine Act that will allow more transparency into the financial interactions between industry and physicians. I think, you know, all of these programs are designed to give beneficiaries and other stakeholders a view into data.

And one group that we have heard from pretty extensively is the physician community, especially, for example, in emergency medicine where physicians have written back to CMS saying, "Thank you. This is data I did not have before." And it would facilitate their own practice.

Mr. KIND. I think, to be fair to them that was only a small piece of the information out there. What is lacking in that is quality measurements, protocols of care, things of that nature, and the overall success rate and how doctors are practicing medicine.

But, finally, let me ask with the remaining time, from you, Doctor—and I would also like to hear Ms. Jarmon and Ms. King's opinion—we are trying to move the system—the payment system away from fee-for-service and volume-based—outcome and value-based. And, obviously, we are seeing a lot of effort in bundled payments as well.

What are the implications of that new payment model when it comes to the detection of fraud and how successful? Because, obviously, under the fee-for-service model, there is a lot of reporting and a lot of steps that people are being reimbursed for.

Is this going to make it easier or harder for us to detect fraud, moving to a more bundled form of payment system or a value-based system, ultimately?

Dr. AGRAWAL. Yeah. Thank you for that question as well.

I think the movement, obviously, towards value is extremely important. It is a central tenet of the ACA. And that movement is important for health care overall.

I think, while I will sort of leave the specifics of new payment models to the experts at CMS who handle the new payment models, what I would just want to clarify is that none of the payment models that are new and innovative preclude us from performing the activities that we already have in place for fee-for-service.

We are still able to conduct the medical review that we conduct. We can still open up investigations and take appropriate actions whether a provider is participating in just traditional fee-for-service or one of the newer models.

So we still have and continue to have the same level of oversight and have the same level of authority. So I think, as the new systems mature, certainly it will be an opportunity for all of us to learn more, but the oversight and the controls are still very much there.

Mr. KIND. Okay. Thank you.

Chairman BRADY. Dr. Price.

Mr. PRICE. Thank you, Mr. Chairman.

And I want to thank the panelists as well. Having practiced medicine for over 20 years before I got here, I think, as I mentioned, often we lose sight of the patients in all of this.

We all want to save money. None of us want to have fraud exist out there, pay for folks that are scamming the system.

But sometimes that money that is taken is taken from folks who are actually trying to provide care and potentially destroying the quality health care for seniors.

And so it is important that we have a feedback mechanism to be able to tell whether or not we are actually doing the right thing.

Ms. King, there was a GAO report that was released earlier this month on the competitive bidding program for durable medical equipment, DME, including home oxygen supply and the like.

These are services that affect real lives, whether or not individuals can actually live a comfortable life or whether or not they live at all. And, again, we all want to hold contractors accountable.

We are into round 2. Nearly 2 years into round 2, the OIG found that there were problems and concerns that they had with round 1 and, yet, CMS went ahead with round 2. GAO said that was a good idea.

Recently your report said that there was decreased utilization of durable medical equipment, there was decrease in suppliers, and no adverse effect to the beneficiaries.

So, you read the top line of that and you jump up and down and you say, "Hallelujah. That is a wonderful thing."

Are you aware of any of the concerns that have been voiced about this by the COPD—the Chronic Obstructive Pulmonary Disease Foundation?

Ms. KING. Not specifically the COPD Foundation, but we have done a considerable amount of work on the implementation of competitive bidding for DME and——

Mr. PRICE. Did you interview them for your report?

Ms. KING. I don't know, but I can get back to you on that.

Mr. PRICE. How did you decide who you interviewed for your report?

Ms. KING. We laid out the methodology in our report—and we have a very transparent methodology—and we contacted a number of people in the industry and met with them several times. But I don't recall whether they included the COPD folks.

Mr. PRICE. I don't think you did. I would encourage you to talk to them. They disagree strenuously with the conclusions that you have made and the recommendations that you provided.

Did you use data that you had or did you use CMS data in your evaluation?

Ms. KING. We got claims data from them and did our own analysis.

Mr. PRICE. Claims data?

Ms. KING. Yes, we did.

Mr. PRICE. No clinical data?

Ms. KING. No. They had clinical data and they set up areas——

Mr. PRICE. They have claims data. They have claims data. Right?

Ms. KING. Yeah. And they——

Mr. PRICE. That is what we are looking at, looking at claims. We are looking at money, which is wise. We need to do that. But oftentimes we don't look at patients.

Did you ask or did you find out or did your data tell you whether or not a patient that fell off, wasn't utilizing the service anymore—whether they needed the service anymore? Could you tell that?

Ms. KING. CMS did their own beneficiary satisfaction work and we evaluated that, and in their work they did not find significant access problems. And we——

Mr. PRICE. That wasn't what I asked.

I asked: Did you ask whether or not patients fall off? Do they go to self-pay? Do they pay for the service themselves, or have they been transferred to a nursing home? Is there any way to know whether they have been transferred into a nursing home in the data that you used?

Ms. KING. Not that I am aware of.

Mr. PRICE. That is correct.

These are chronic diseases. These are chronic diseases. And CMS says it only tracks data for 120 days. If you don't have a current claim within 120 days, they don't care.

You could have gotten the pennies together in your sofa and paid for the oxygen to keep you alive or you could pull it out of our pocket or you could go to a nursing home. CMS doesn't know.

So I would suggest that we have got a long way to go toward getting the right data when you are talking about quality.

When the Federal Government is defining quality, then anybody that doesn't do what the Federal Government wants to do is fraudulent. I would suggest that is not the right place to define quality.

Let me just touch on—I have got a few more seconds here.

Ms. Jarmon, you mentioned about the in-office ancillary self-referral increase utilization. You are aware that there are studies in individuals that have been done that demonstrate that that is not the case, that there is no increase in utilization in use of in-office ancillaries.

Are you aware of that?

Ms. JARMON. No. I was not aware of that.

Mr. PRICE. All right. Well, we will get that for you, and we will be happy to see the change in the next report.

Ms. Jarmon, talking about the number of counties that have the kind of high incidents of home health outliers, 3,143 counties in the country, 25 counties have the highest incidents.

Wouldn't we do a whole lot better job if we would just concentrate on those 25 counties?

Ms. JARMON. When we are doing our work, we do try to focus on the areas where there is higher risk. So we do try to focus on those areas in our analysis.

Mr. PRICE. The work wouldn't demonstrate that, though, because we continue to have that same statistic, that same statistic, year after year after year. So I would encourage you to focus where the real problems are.

Thank you, Mr. Chairman.

Chairman BRADY. Thank you.

Mr. Pascrell.

Mr. PASCRELL. Thank you, Mr. Chairman.

I am encouraged that we get some bipartisan support. One area that has been of particular interest to me is the hip and knee replacements.

I first became involved in this issue in 2007 when five of the Nation's biggest makers of artificial hips and knees agreed to pay $311 million in penalties to settle Federal accusations that they used so-called consulting agreements, better known as bribes, and other tactics to get surgeons to use their products, regardless of the effect of the product.

So this may be the cost of doing business, but it is serious, because in the next 10 years, if we are going to spend $65 billion on knee and hip replacements, Medicare and Medicaid will pick up most of the cost.

So if we are not concerned in this particular issue in avoiding the debacle that happened just 10 years ago, what are we?

Strong action needed to be taken, and instead of anyone going to jail, no one went to jail. Five companies got deferred prosecution agreements where they simply paid a fine and agreed to be monitored by private firms.

That is not the subject of what I am going to get into today, but let me tell you, your hair would stand up. Go back and read those cases.

I introduced two bills that I believe get at the root of the issues here.

First is the Accountability and Deferred Prosecution Agreements Act, which will require the Department of Justice to establish guidelines for the use of deferred prosecution agreements. I plan to introduce this bill later this week.

And second is the National Knee and Hip Replacement Registry Act, which would establish a registry to help identify failing implants into identified—we are talking about senior citizens that got shafted over and over again, had to be re-surged because of what we did not do. Make no mistake. Problems with faulty joint implants are no means behind us.

Just last year one of the largest medical device companies agreed to pay $2.5 billion to settle lawsuits filed by thousands of patients who had to undergo—we are talking mostly seniors. That is what we are talking about. And in the next 10 years, again, we are going to spend $65 billion.

By the way, do you agree that we should have a registry in this country so we know who is stealing from other people?

Dr. AGRAWAL. Sir, on the hip and knee registry, you know, I think we would be open to reviewing the proposal and offering you any guidance that would be helpful.

I do think that we are aligned in certain other ways already. I alluded earlier to the Physician Payment Sunshine Act.

We will be able to see through that program as just one example of financial interactions between medical device companies and physicians, and I think that will be a level of data transparency that is important——

Mr. PASCRELL. Do you believe, Doctor, that collecting patient data in a registry on knee and hip replacements could help us to identify ineffective knee and hip devices so that we can cut down on unnecessary surgery? Do you agree with that or you don't agree with it? It is a pretty simple question.

Dr. AGRAWAL. I think that we are happy to review any proposal that comes from this Committee and help you in the evolution of that proposal.

Mr. PASCRELL. Well, it would seem to me, if you know the history—and I was trying to give it to you in capsule form, unfortunately.

Back in 2007—much of it occurred before 2007. And you folks have not—even though you just came on the job, you folks have not done anything about this, encouraging anything. This is a major part of your budget. This is a major part of the fraud.

It would seem to me that we should be interested in these kinds of things. Correct?

Dr. AGRAWAL. Yes, sir. I think we are interested. As I have alluded to a couple of times now, I think the Sunshine Act will get at this issue as well.

Mr. PASCRELL. Mr. Chairman, I think that, when we speak of trying to make the system better and when we speak about trying to save money—because there is tremendous amount of fraud and the many people who committed the fraud never went to jail. Okay?

Talk about our system of justice about, when you have a buck in your pocket, you stay out of jail; when you don't have a buck, you sure the hell will go to jail.

And one way to stop this is to look at this registry, which I am talking about here so that one hand knows what the other is doing. And I think it would reduce health care costs, period, not only in this area, but also in other areas.

And I yield back. And I thank you.

Chairman BRADY. Thank you, Mr. Pascrell.

Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

And thank you to our witnesses here today for sharing your insight. It is a tough job out there that I think you are trying to do.

And it is frustrating from our standpoint. I get especially frustrated when I hear from providers wanting to do the right thing and, yet, it is so cumbersome, it is so complex, that even doing the right thing has become so difficult. And I am afraid that that is just getting worse.

And we know that Medicare is on an unsustainable path. At least that is my opinion. And we need to make some changes.

We did hear about the embarrassing situations of improper payments, Ms. Jarmon.

Any of you, how do these improper payments happen?

What can you tell us is being done to fix this, Dr. Agrawal?

Dr. AGRAWAL. Sure. One thing I would just want to clarify is certainly the improper payment rate is a huge focus for the agency and we are focused on reducing the improper payment rate. I just want to differentiate that rate from a measure of fraud.

The improper payment rate is not a true measure of fraud. It is really more a measure of perhaps waste and abuse. A lot of the major drivers of the improper payment rate are insufficient documentation, which is often caused by providers sometimes not understanding regulatory requirements. But if we got the documentation that was required, chances are those claims would have been just fine.

Mr. SMITH. So services for a dead person, how does that happen?

Dr. AGRAWAL. Yeah. So there are—you know, we utilize——

Mr. SMITH. Would that be fraud or would that be improper payment?

Dr. AGRAWAL. It could be either. I think, obviously, you know, establishing fraud depends on establishing intent, and that really is a law enforcement determination. What we do is we look at drivers of improper payment and try to go after the biggest drivers.

With respect to dead beneficiaries or dead providers in specific, we work very closely with the Social Security Administration to get information on their Death Master File to be able to link that information to our own data so that we can stop claims from being paid for those beneficiaries or to those providers.

Mr. SMITH. So would you say that current measures are sufficient? More measures are needed? Lack of enforcement? How would you sum up what the current situation is or needs to be?

Dr. AGRAWAL. Well, I think, if you were to look at the improper payment overall, certainly, you know, there is more that we can do and we are working on various initiatives to decrease the improper payment rate.

Again, because documentation issues drive a huge portion of that rate, we are working with providers to educate them on real documentation requirements.

Some of the other things that drive the rate are medically necessary services, but being provided in the wrong place. So, again, that does come down to education and working with providers.

Mr. SMITH. The wrong place, could you elaborate?

Dr. AGRAWAL. Sure. So there might be a service like a stress test, for example, that is provided in an inpatient setting that could be provided in an office or outpatient setting.

That inpatient claim could potentially lead to an improper payment, you know, depending on how it was documented and all that.

But, you know, nobody is contending necessarily that the service should not have been provided. It should just have been provided in a more medically reasonable location.

So a lot of that, again, does come down to working with providers. I take your point very seriously about provider burden and agree, as a physician myself, that we should do whatever we can to lower burden as feasible while still meeting our obligations to protect trust fund dollars and educating providers as best we can on the front end so mistakes are not made.

Mr. SMITH. Well, I would also add, as I have in previous hearings in working on health care issues, especially in rural America, there are arbitrary regulations that I think might be intended for greater efficiencies and, yet, the result is the exact opposite.

And I am afraid patients actually suffer as a result of the Federal bureaucracy supposedly in the name of striving for efficiency, but services are worse. I think it is arbitrary and I would hope that we could have your cooperation as we do move forward on trying to find some efficiency there.

We know that hardworking taxpayers need protection, so to speak, and that we have, I think, many options ahead of us, hopefully, we will pursue that will have the Federal Government step back instead of step forward and into the lives of so many patients because I think it is counterproductive.

Thank you. I yield back.

Chairman BRADY. Thank you.

Mr. Gerlach.

Mr. GERLACH. Thank you, Mr. Chairman.

Thank you all for coming and testifying today.

The amount of fraud and abuse in the program is staggering. We all know that. And I relate it back to just where I am from, Pennsylvania. The Commonwealth of Pennsylvania State budget is about $32 billion a year.

So, really, what we are talking about here is fraud and abuse in one program of the Federal Government that has doubled the size of the Commonwealth of Pennsylvania's budget each year. That is staggering.

And I am really concerned that, in the years that I have been on this Committee and we have had these kinds of hearings, very little progress has been made to deal with it from the witness side of things, where the same questions have been asked by Mr. Johnson year after year after year, why there are still Social Security numbers on these cards. Still don't have a solid answer as to what you are doing about it.

And, frankly, not to take it personally, you ought to be embarrassed. You ought to be embarrassed for the agency you work for and for the American people. Now, that doesn't mean you are personally responsible for that. So please don't take that as a personal slight to any of you.

But it ought to just remind you, as you sit here today, how important these issues are and how important it is to make progress on these issues. And I hope a year from now you are not back testifying and you are giving the same answers to the same questions and no progress has been made.

A number of us on this Committee—my lead cosponsor, Mr. Blumenauer, and other Members of this Subcommittee—have cosponsored H.R. 3024, which will create a smart card program within the Medicare program to deal with this issue, having both a provider and the beneficiary have a card without a Social Security number on it that would be swiped at the time of the medical transaction to try to reduce fraud and abuse and, in particular, deal with fraudulent billing, phantom billing, duplicate billing, dealing with unlawfully present beneficiaries, dealing with deceased beneficiaries, dealing with identity theft.

We think this kind of technology, which is already being used in the Department of Defense to prevent people from getting access to certain buildings of the department or into computer systems, being used by perhaps yourselves—I understand all Federal employees have a Homeland Security technology card that they use.

Other health care delivery systems around the world are using smart card technology to deal with waste, fraud and abuse. Yet, here in the United States we don't have that as part of our program and we also include the Social Security numbers on our cards.

So a number of us not only here in the House, but, also, on a bipartisan, bicameral basis, have sponsored this kind of legislation to bring smart card technology into the program. And we have asked GAO—Ms. King, I know you are well aware—we have asked GAO to do some preliminary background evaluation of the idea.

Ms. King, can you give us an update as to—the work you are doing in GAO with this particular idea, where you might be in that process and when do—what you think there would be a completion to that so that we can move forward with evaluating that information from you and then move forward legislatively?

Ms. KING. Yes. Thank you for that question.

At your request and the request of several other Members of Congress, we are looking at the use of electronic cards in Medicare, and we are looking at several aspects of that.

We want to try and find out what—the potential benefits and any limitations, if there are any, with the use of them, what issues might be involved in the implementation of smart cards, and we also want to evaluate where they are in use in other settings. And we hope to finish up that work about the end of the year.

Mr. GERLACH. Okay. And then will you come back to us with a report and recommendations relative to the idea?

Ms. KING. We will.

Mr. GERLACH. Okay. Doctor, on that same idea, are you currently out of your shop looking at the use of digital technology solutions to more accurately authenticate providers and beneficiaries at the time of the medical transaction rather than continuing this pay-and-chase process we have today, having more front-end verification methods in place, could include smart card technology, could include other types of technology, to, again, address this issue?

Dr. AGRAWAL. Yes. Obviously, we do look forward to seeing GAO's findings. That will certainly help the agency as well.

We did conduct a little while ago a swipe card pilot with DME ordering. That basically required or allowed providers to swipe an electronic card at the time of the order being placed in the office and then a beneficiary taking that card essentially to a DME supplier to be able to connect the order in the office to the supply that was actually given.

And I think the outcomes of that program have highlighted, you know, some of the challenges that might emerge in this report as well.

Number one; there are obviously some operational constraints that we should be aware of on the part of the provider.

I think we have to be very careful in instituting any kind of alternative technology approach, that we not place too much of a burden on providers, whether it is a resource burden or other kind of technology acquisition burden.

Second, I would just highlight or emphasize that, in any new technology implementation, we not get in the way of the physician-patient relationship.

This was actually some specific feedback that we got to our pilot, that certain physicians saw that as an intrusion, having to swipe a card when they were seeing a patient.

Obviously, beyond that, there are other operational constraints of implementation, but I would just ask the Committee to keep these things in mind.

Mr. GERLACH. We will look forward to your information. Thank you.

Mr. BLUMENAUER. Mr. Chairman, just a point of clarification, please.

Chairman BRADY. Yes.

Mr. BLUMENAUER. I would note that this particular project of Mr. Gerlach—he has unfortunately decided that he is not going to be with us next year. And I am pained with the notion that we are not going to get a report for 6 months.

Is it possible to get some sort of interim report in the next few months that could feed back into the work we are doing here, that we might be able to wrap this up? He has invested years in this very positive idea. Is there some way that we could get a little something sooner?

Ms. KING. We are not at the point right now of being able to tell you what our preliminary findings are, but I think we will be before the end of the year.

Mr. BLUMENAUER. Yes.

And I am just saying respectfully, because we have a different timetable here——

Ms. KING. I understand.

Mr. BLUMENAUER [continuing]. If there is some way—even not a final preliminary, but something that would give guidance sooner, late in the summer or early in the fall, would make a big difference.

Chairman BRADY. And, Ms. King, I imagine every one of us would add our support for that request as well.

All right. Thank you.

Mrs. Black.

Mrs. BLACK. Thank you, Mr. Chairman. And I do sincerely appreciate the opportunity to participate in this hearing. And I thank you for your leadership on this issue. This is a very important issue in understanding the fraud, waste and abuse in the Medicare program.

Myself and all my colleagues that have spoken here do have serious concerns about the future of Medicare, the program, and appreciate viewing some of the recommendations that have been made by the GAO that has been published in order for CMS to address some of these fundamental structural changes that are facing our growing system.

I think it was our colleague, Mr. Roskam, that made mention of $75 billion. When I think about billions of dollars that potentially cannot be accounted for, it is a tremendous, tremendous amount of money. I certainly appreciate the good work that is done by both the GAOs and the Inspector General as well.

Just recently I sent a letter to Ms. Tavenner on this very topic to understand why CMS has not adopted two recommendations made by GAO to reduce improper payments issued by CMS. One of them goes back pretty far, and we still don't see that there has been a resolution on this.

It goes back to a 2007 GAO recommendation that was a requirement for contractors to develop thresholds for unexplained increases in billing in order to implement the controls under an automated payment system.

And prior to issuing these payments under a fee-for-service, thresholds have not been developed to explain unexpected increases in billing.

And that seems to me to be one that just ought to jump out and ought to be one that takes priority to say, "Why is that happening?" and, "Let's put thresholds there so we can at least catch that," as has already been said by the previous questioner.

Dr. Agrawal, would you be able to help me understand why this still has not been put into place?

Dr. AGRAWAL. Sure. So we have the fraud prevention system, which is a predictive analytics system that allows us to look at claims in real-time.

One of the models in that system does look at the type of spike billing that you are talking about, essentially, significant changes in billing behavior in a relatively brief period of time.

We also have other models that look at just the absolute dollars that are going out. So, you know, some that look at the change and others that just look at high-dollar amounts.

We could perhaps work with the GAO to close that recommendation, but I do believe we have addressed it.

Mrs. BLACK. Well, if you have, I think it would be a great idea to work with GAO because it continues to show up, the recommendations.

Dr. AGRAWAL. Yes, ma'am.

Mrs. BLACK. And if we go all the way back to 2007 and we see this continue to be a recommendation that hasn't been closed, then there is a question about why that is.

A lot of money is spent with the GAO in trying to get these recommendations to you all. Understanding that you are very busy on administering the program, I think when the recommendations are given, they need to be taken seriously and we don't need to see them being open year after year.

I want to go to just one other one. And I am interested in the recommendation that was made by GAO regarding the home health agencies with known high rates of improper billing. The GAO recommended that the CMS conduct post-payment reviews, and that also seems to have not been done yet.

Can you speak to that?

Dr. AGRAWAL. Yes, ma'am. So we receive regular reports from our zone program integrity contractors that conduct investigations against various providers that have, you know, risen in priority.

Each one of our zone program integrity contractors does conduct post-pay reviews of home health agencies in their zones. Again, this perhaps may be a recommendation that we could close.

In specific, you know, the Committee is aware of the moratorium that we have implemented in home health services in a number of different geographies as a result of those activities and other activities.

As just one example, we have revoked over 100 home health agencies in just Miami alone in the last year, half of them after the moratorium was put in place. So home health care is something that we are closely looking at.

We, in fact, do conduct post-pay audits and payment suspensions and pre-pay reviews just in alignment with our other authorities. So I would be happy to work with them to perhaps close that recommendation.

Mrs. BLACK. Just an observation that—you did talk about several of these recommendations that you all are trying to address.

I think that, since you are fairly new with the organization, the agency, that it might be a good change in culture to go back and look at these and be able to report back to this Committee in particular, but to Congress in general, to let them know that you are taking these recommendations seriously.

Because, as I say, there is a lot of money that goes into researching these recommendations and giving them to CMS, and I would hope that we would have you close those out.

If you are really doing these, let us know. And let us know, also, how much has been saved. If you can help us to know that, that is very helpful.

Thank you, Mr. Chairman.

Chairman BRADY. Thank you, Mrs. Black.

And to the witnesses, thank you for being here.

The bipartisan frustration you hear expressed is not because fraud in Medicare is new. It is not. It is growing as the program is growing. It, at times, seems super human and immortal, and it is not. Much of the fraud and abuse we have seen is preventable.

And so, one, this won't be the last time you are before the Subcommittee. We are dead serious about both aggressive oversight to ensure that the recommendations by the Inspector General and GAO are implemented in a timely way by the agency. I appreciate your support and commitment to work with us to do that.

Second, the Subcommittee hopes to develop and advance a package of legislative bills related to fraud. So if you have views on the legislation that you heard from the Members today, I would encourage you to get with them immediately because we intend to move on the area of fraud.

With that, I would like to thank all of the witnesses for their testimony today. Appreciate the continued assistance getting answers to the questions that are asked by our Committee and Members.

As a reminder, any Member wishing to submit a question for the record will have 14 days to do so. Any questions that are submitted, I ask the witnesses to respond in a timely manner.

With that, the Subcommittee is adjourned.
[Whereupon, at 3:35 p.m., the Subcommittee was adjourned.]
[Submissions for the Record follow:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 31, 2012

Posted: January 7, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-22

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an arrangement in which a hospital pays a cardiology group compensation that includes a performance bonus based on implementing certain patient service, quality, and cost savings measures associated with procedures performed at the hospital's cardiac catheterization laboratories (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions arising under: (i) sections 1128A(b)(1)–(2) of the Social Security Act (the "Act"), the civil monetary penalty for a hospital's payment to a physician to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care; or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1) – (2) of the Act, the Office of Inspector General ("OIG") will not impose sanctions on [name redacted] in connection with the Arrangement; and (ii) although the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] ("Requestor") is a large, rural acute care hospital located in a medically underserved area in [town, state redacted] ("the Town"). Requestor operates four cardiac catheterization laboratories (the "Labs"), all of which are located in Requestor's main building on its campus. Requestor operates the only cardiac catheterization laboratories within a fifty-mile radius of its campus. Requestor bills for and collects all non-professional fees generated for services provided in the Labs. Requestor provides space, certain non-physician staff, equipment and supplies for the Labs. Requestor certified that the Labs are operated as a provider-based department of Requestor's hospital, in accordance with 42 C.F.R. § 413.65.

Requestor entered into a cardiac catheterization co-management agreement (the "Management Agreement"), with [name redacted] (the "Group") for a term of three years. The Group consists of approximately eighteen full-time physicians, including general cardiologists, interventional cardiologists, and electrophysiologists. Six interventional cardiologists who are members of the Group perform procedures in the Labs. The Group bills Medicare Part B and other payors for cardiology services rendered by its physicians. The Group is the only cardiology group on Requestor's medical staff and the only physician group in the Town that provides cardiac catheterization services.[1]

[1] The Arrangement is not exclusive. If additional cardiologists were to join Requestor's medical staff, Requestor would consider including those individuals within the Arrangement.

The Group does not provide cardiac catheterization services at any location other than the Labs. The Group refers patients to Requestor for inpatient and outpatient procedures, in addition to the cardiac catheterization procedures.

Under the Management Agreement, the Group provides management and medical direction services for Requestor's Labs in exchange for a co-management fee comprised of two components: (1) a guaranteed, fixed payment equal to [amount redacted] per year (the "Fixed Fee"), and (2) a potential annual performance-based payment equal to a maximum of [amount equal to Fixed Fee redacted] per year (the "Performance Fee"). Requestor pays an installment of the Fixed Fee and an estimated installment of the Performance Fee to the Group quarterly. Every year, Requestor reconciles the quarterly installment payments of the Performance Fee under the Arrangement.[2]

Payment under the Arrangement is made by Requestor to the Group. Requestor certified that the Group has agreed that, to the extent revenue derived from the Arrangement results in dividends payable to the Group's shareholders, the Group distributes such dividends based on each shareholder's *pro rata* share of ownership, and that distributions have no relation to an individual physician's participation in the Arrangement.

In exchange for the Fixed Fee and Performance Fee, the Group performs the following duties under the Management Agreement: overseeing Lab operations; providing strategic planning and medical direction services; developing Requestor's cardiology program; serving on medical staff committees; providing staff development and training; providing credentialing for Lab personnel; recommending Lab equipment, medical devices, and supplies; consulting with Requestor regarding information systems; providing assistance with financial and payor issues; and providing public relations services.

The Performance Fee consists of the following components: Requestor's employee satisfaction ("Employee Satisfaction Component"), 5%; patient satisfaction with Requestor's Labs ("Patient Satisfaction Component"), 5%; improved quality of care within the Labs ("Quality Component"), 30%; and implementation of certain measures to reduce costs attributable to Lab procedures ("Cost Savings Component"), 60%. Requestor selected performance measures within these components based on its financial, purchasing, employee satisfaction, patient satisfaction, and quality measurement data systems, as well as certain national cardiology quality measures.

Most measures within the Performance Fee components incorporate three possible achievement levels that trigger payment. If the Group fails to achieve the lowest, baseline achievement level for a measure within a component, it receives no payment for

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[2] In the event that the annual reconciliation shows that the Group received a Performance Fee that exceeds the amount it earned, the Group will refund any excess to Requestor.

that measure. The baseline achievement level for any measure reflects improvement over Requestor's *status quo* performance for that measure prior to the effective date of the Agreement. If the Group meets the baseline achievement level for a measure within a Performance Fee component, it receives 50% of the total compensation available for that measure; if it meets the middle benchmark, it receives 75%; and if it achieves the highest benchmark, it receives 100%.

To obtain the portion of the Performance Fee allocable under the Employee Satisfaction Component, the Group must receive a rank between 94.5th–96th percentile as compared to other hospitals surveyed nationally following a bi-annual employee opinion survey of Requestor's employees, performed by Requestor.

To obtain the portion of the Performance Fee allocable under the Patient Satisfaction Component, the Group must meet the following measures on behalf of the Labs:

- Labs must be ranked at the 96th percentile in an annual independent patient satisfaction survey.[3]
- Group physicians must start the first Lab surgical case each day by 8:15 a.m., at least 85% of the days the Lab operates.
- The Group must reduce the time a physician spends between surgical cases in Labs to 25 minutes or less in at least 50% of cases.

To obtain the portion of the Performance Fee allocable under the Quality Component, the Labs must improve their performance as measured by standards promulgated by the Joint Commission, the Centers for Medicare and Medicaid Services ("CMS"), the American College of Cardiology (the "ACC"), and the National Cardiovascular Data CathPCI® Registry (the "NCDR")[4], each of which develops national cardiology quality measures for hospitals. Requestor's performance is measured against hospitals' performance nationally and given a percentile ranking.[5] These standards are subject to revision and update to reflect the appropriate standard of care and currently consist of the following:

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[3] The ranking is based on an independent survey analysis that compares Requestor's patient satisfaction survey data with survey data from a proprietary database of hospitals nationwide.

[4] The NCDR is a cardiovascular data repository developed by the ACC.

[5] Requestor used standards published in the Specifications Manual for National Hospital Quality Measures, Version 4.1 (the "Manual") to establish certain measures within the Quality Component. The Manual is published by the Joint Commission (formerly the Joint Commission on Accreditation of Health Care Organizations) and represents the joint efforts of CMS and the Joint Commission to publish a uniform set of national hospital quality measures. See http://www.jointcommission.org/specifications_manual_

- Reduce "door to balloon time" so that at least 85% of Lab patients' "door to balloon" time is below 90 minutes.[6]
- Prescribe a Beta blocker at discharge[7] to rank between the 70th and 90th percentile of hospitals measured.
- Prescribe an ACE-1 or ARB for left ventricular systolic dysfunction at discharge[8] to rank between the 70th and 90th percentile of all hospitals measured.
- Prescribe an Aldosterone blocking agent at discharge[9] to rank between the 70th and 90th percentile of hospitals measured.
- Document LDL-c level in hospital record[10] to rank between the 70th and 90th percentile of hospitals measured.
- Reduce occurrence of Percutaneous Coronary Intervention complications[11] to a level between 1.4% and 1.7% of patients.
- Reduce the incidence of bleeding in Lab patients within 72 hours of surgery[12] to a level between 0.9% and 1.1% of patients.
- Reduce Percutaneous Intervention Risk Adjustment Complications Index[13] to between 1.25% and 0.96% of patients.

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for_national_hospital_inpatient_quality_measures.aspx.

[6] For this measure, Requestor selected a published guideline set forth in the Manual and adopted by the ACC for measuring the time between a patient's entry to the Emergency Department, when experiencing a heart attack, and the time the physician opens the blocked vessel.

[7] For this measure, Requestor selected a published guideline set forth in the Manual and the ACTION Registry®-GWTG™, which is part of the NCDR. According to Requestor, a Beta blocker is a medication prescribed at discharge that reduces heart rate and blood pressure by dilating blood vessels.

[8] For this measure, Requestor selected a published guideline set forth in the Manual and the ACTION Registry®-GWTG™.

[9] For this measure, Requestor selected a published guideline set forth in the ACTION Registry®-GWTG™.

[10] For this measure, Requestor selected a published guideline set forth in the ACTION Registry®-GWTG™.

[11] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

[12] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

To obtain the portion of Performance Fee allocable under the Cost Savings Component, the Group must reduce the cardiac catheterization costs per case from [amount redacted] to an amount ranging from [amount redacted] to [amount redacted] per case; and average contrast costs per case from [amount redacted] to an amount ranging from [amount redacted] to [amount redacted] per case. Similar to the other components of the Performance Fee, if the Group meets the baseline achievement level for the cost savings measure, it receives 50% of the total compensation available for that measure; if it meets the middle benchmark, it receives 75%; and if it achieves the highest benchmark, it receives 100%.

Requestor certified the following information. It bases purchasing decisions on the best interests of patient care and utilizes products that are clinically safe and effective. An Interventional Cardiology Committee consisting of all interventional cardiologists who utilize the Labs generates initial product recommendations. It selects products and supplies following a review of evidence-based medicine, empirical trial data, and proven effectiveness. Performance standards drive selection of supplies and equipment in the Labs.

Requestor further certified as follows. It collaborated with the Group's physicians to reduce cardiac catheterization costs by contracting with a single vendor for drug-eluting and bare metal stents, from whom they obtained a highly competitive price. Cost savings also are achieved through better management of the usage of coronary stents and product standardization. Unique-sized stents or other types of drug-eluting stents remain available upon request by an interventional cardiologist, and no physician is ever prohibited from requesting a particular device or supply required to address a patient's unique health needs. Unless otherwise clinically indicated, the Group's physicians adhere to clinical guidelines developed by the ACC regarding the use of bare metal rather than drug-eluting stents. The parties also reduce costs by implementing better management practices with other devices, items, and supplies. For example, Requestor purchases frequently used supplies directly from manufacturers to obtain a better price, and adjusts supply stock levels to reduce shipping costs. The parties also reduce wasted supplies by evaluating necessary items and supplies used during cardiac catheterization procedures and restricting certain items for use only "as needed" during a procedure.

Additionally, Requestor certified that the Group receives [amount redacted] as part of the annual Performance Fee, subject to the aggregate Performance Fee cap, if Requestor

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[13] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

achieves a designation as one of Thomson Reuters Top 50 Cardiovascular Hospitals for that year.[14]

Requestor certified that it and the Group's physicians protect against inappropriate reductions in services in the following ways. A team of Requestor's medical staff, including members of the Group, the nurse manager, and administrative leadership, developed the cost savings measures based on evidence and clinical outcomes. The team based product standardization decisions on clinical outcomes ascertained through reviews of clinical studies and documented clinical outcomes.[15] Requestor obtained an independent, third-party valuation regarding the Fixed Fee and Performance Fee paid under the Arrangement. According to Requestor, both the Fixed Fee and the potential Performance Fee are consistent with fair market value and are commercially reasonable. We rely on Requestor's fair market value certification in issuing this opinion.

Requestor uses an independent, third-party utilization review firm to annually review data related to the components of the Performance Fee as well as the clinical appropriateness of the cardiac catheterization procedures performed at the Labs. This firm also annually reviews the Group's performance under the Arrangement to confirm that the Arrangement does not adversely impact patient care. Requestor certified that implementation of the Arrangement has not adversely affected patient care.

Under the Arrangement, all commercially available stents and balloons are available as needed. A Group physician may use the device or supply he or she determines to be most clinically appropriate for each patient. Moreover, receipt of any part of the Performance Fee under the Arrangement is conditioned upon the Group's physicians not taking any of the following actions: 1) stinting on care provided to Requestor's patients; 2) increasing referrals to Requestor; 3) cherry-picking healthy patients or those with desirable insurance for treatment in the Labs; or 4) accelerating patient discharges.

To monitor the Group's performance under the Arrangement, Requestor uses several approaches. First, Requestor's internal audit department reviews all supporting data and

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[14] See Thomson Reuters Top 50 Cardiovascular Hospitals *available at* http://100tophospitals.com/top-cardio-hospitals/. Requestor has not received this designation for a number of years. If the Group achieves the top achievement level for all performance measures, it earns the maximum annual Performance Fee and receives no additional compensation for this top hospital designation.

[15] Members of both Requestor's and the Group's leadership jointly evaluate supply, equipment, and purchasing decisions. The Group participates in evaluation and selection of medical supplies and equipment used in the Labs and evaluates, advises, and assists Requestor in the vendor negotiation process.

documentation related to the Quality and Cost Savings Components. An independent accounting firm then reviews the internal audit department's findings. The firm reports its independent findings to Requestor's compliance officer, who reports to Requestor's Board of Directors. Requestor's Board of Directors' Compliance and Audit Committee reviews the independent accounting firm's findings and approves payment of any amount under the Performance Fee.

Requestor also uses multiple hospital committees to monitor performance of the Group under the Arrangement. The Performance Monitoring Committee, consisting of key hospital management and Lab staff, provides direct oversight to ensure that stinting on patient care, patient cherry-picking, and other improper practices do not occur. Requestor's Credentials and Peer Review Committee monitors and reports on the quality of care provided by the Group and performs peer case review. This committee reports its results to the Medical Executive Committee of the Medical Staff and the Board of Directors' Quality Standards Committee.[16] Also, Requestor's Best Practices Utilization Review Committee, led by physicians on Requestor's medical staff, reviews quality assurance and utilization of the Labs.[17]

Patients and their families are notified in writing of the existence of the Arrangement and their physician's participation in the Arrangement prior to performance of a Lab procedure and concurrent with obtaining the patient's consent to the procedure.

II. LEGAL ANALYSIS

Incentive compensation arrangements like the Arrangement are designed to align incentives by offering physicians compensation in exchange for implementing strategies to meet quality, service, and cost savings targets. However, like any payment arrangement between a hospital and physicians who refer business to the hospital, payments purportedly intended to encourage quality improvements and cost savings might be misused by unscrupulous parties to induce limitations or reductions in care or to disguise kickbacks for Federal health care program referrals. Therefore, such arrangements must be evaluated in light of applicable Federal statutes and the potential for abuse.

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[16] The Board of Directors' Quality Standards Committee monitors the overall quality of care provided by Requestor.

[17] No opinion is expressed or implied in this advisory opinion regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or conduct directly or indirectly related to the Arrangement.

Properly structured, arrangements that compensate physicians for achieving hospital cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care, (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements, (iii) payments to induce patient referrals, and (iv) unfair competition among hospitals offering incentive compensation programs to foster physician loyalty and to attract more referrals.

Hospital cost-savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of services provided to Medicare and Medicaid beneficiaries, sections 1128A(b)(1)–(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[18] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We therefore express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)–(2) of the Act (the "CMP") establish a civil monetary penalty against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit services[19] provided with respect to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for civil monetary penalties of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of services provided to Medicare and Medicaid fee-for-

[18] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[19] We have interpreted services under the CMP to include items used or provided as part of a service.

service beneficiaries.[20] The CMP prohibits payments by hospitals to physicians as an inducement to a physician to reduce or limit services furnished to Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces the Group's physicians to reduce or limit services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

Having reviewed the Performance Fee components, we conclude that the Cost Savings Component implicates the CMP. With respect to the measures under the Arrangement regarding standardization of devices and supplies and limiting use of specific stents, contrast agents, and medical devices, the Arrangement might induce physicians to alter their current medical practice to reduce or limit services.[21] However, based on Requestor's certifications, we conclude that the Fixed Fee, Employee Satisfaction, Patient Satisfaction, and Quality Components contained in the Arrangement do not involve an inducement to reduce or limit services and, therefore, do not implicate the CMP. Notwithstanding that the CMP applies to the Cost Savings Component, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against Requestor for the Arrangement under sections 1128A(b)(1)–(2) of the Act.

First, Requestor certified that the Arrangement has not adversely affected patient care.[22] Requestor also certified that it monitors both the performance of the Group under the

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[20] Physician incentive arrangements related to Medicare and Medicaid risk-based managed care contracts and Medicare Advantage plans are subject to regulation by the Secretary, pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)–(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

[21] We recognize that the physicians' medical practice may have involved care that exceeded the requirements of medical necessity and thus would be reduced without posing a risk of harm to patients. However, liability under the CMP does not require that the payments be tied to a reduction in medically necessary care.

[22] An independent medical expert reviewed the Arrangement on behalf of OIG. The medical expert concluded that the quality and cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on Requestor's certifications, and nothing in this opinion should be construed as an

Arrangement and its implementation of the Cost Savings Component throughout the term of the Management Agreement to protect against inappropriate reductions or limitations in patient care or services. Requestor's Board of Directors, internal auditing staff, and certain hospital staff committees also monitor the Group's performance under the Arrangement. Additionally, Requestor uses an independent, external third-party utilization review firm to annually review data related to the components of the Performance Fee and the clinical appropriateness of the cardiac catheterization procedures performed at the Labs.

Second, the risk that the Arrangement will lead the Group's physicians to apply a specific cost savings measure, such as the use of a standardized or bare metal stent, in medically inappropriate circumstances is low. The parties structured the benchmarks within the Cost Savings Component of the Performance Fee to allow the Group's physicians flexibility to use the most cost-effective clinically appropriate items and supplies. Requestor certified that unique-sized stents or other types of drug-eluting stents remain available upon request by an interventional cardiologist, and that no physician is ever prohibited from requesting a particular device or supply required to address a patient's unique health needs. Thus, each of the Group's physicians has access to the device or supply he or she determines to be most clinically appropriate for each patient. The Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. The three-tiered benchmarks within the Cost Savings Component allow the Group to receive a portion of the Performance Fee based on the aggregated performance by the Group and not based on meeting a specific standard in the case of a particular patient if the standard is contraindicated with regard to that patient.

Third, the financial incentive tied to the Cost Savings Component is reasonably limited in duration and amount. The Performance Fee is subject to a maximum annual cap and the term of the Arrangement is limited to three years.

Fourth, receipt of any part of the Performance Fee under the Arrangement is conditioned upon the Group's physicians not taking any of the following actions: 1) stinting on care provided to Requestor's patients; 2) increasing referrals to Requestor; 3) cherry-picking healthy patients or those with desirable insurance for treatment in the Labs; or 4) accelerating patient discharges. While we believe such a contract provision alone would not sufficiently reduce the risk of harm to patients or Federal health care programs, in combination with other features of the Arrangement, it provides an additional safeguard on which we rely.

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endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

For all of these reasons, in an exercise of our discretion, we choose not to impose sanctions under the CMP as a result of the Arrangement.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), potentially applies to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement does not fit in the safe harbor because the aggregate payment to the Group is not set in advance. However, the absence

of safe harbor protection is not fatal. Instead, we evaluate the facts and circumstances specific to the Arrangement.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from Requestor to reward or induce referrals by the Group. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to Requestor, because the physicians receive not only their Medicare Part B professional fee, but also may receive the Fixed Fee and the Performance Fee. While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, for the following reasons we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, Requestor certified that the compensation paid to the Group under the Management Agreement, which includes both the Fixed Fee and the Performance Fee, is fair market value for the services provided.[23] These services include overseeing Lab operations; providing strategic planning and medical direction services; developing Requestor's cardiology program; serving on medical staff committees; providing staff development and training; providing credentialing for Lab personnel; recommending Lab equipment, medical devices, and supplies; consulting with Requestor regarding information systems; providing assistance with financial and payor issues; and providing public relations services. The fact that the Group provides substantial services under the Management Agreement reduces the risk that compensation paid by Requestor is a payment for referrals, rather than for actual services rendered.

Second, the compensation paid to the Group does not vary with the number of patients treated. Thus, an increase in patient referrals to Requestor does not result in an increase in compensation paid to the Group under the Arrangement.[24]

Third, because Requestor operates the only cardiac catheterization laboratories within a fifty-mile radius, and because the Group does not provide cardiac catheterization services

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[23] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See Section 1128D(b)(3)(A) of the Act. If the fees are not fair market value, this opinion is without force and effect.

[24] We note that the Group distributes dividends *pro rata,* based on percentage ownership in the Group. We have no facts indicating that the Group allocates ownership interests or other compensation based on an individual physician owner's participation or performance under the Arrangement. We might have reached a different conclusion had this been the case.

at any location other than Requestor's Labs, it is unlikely that Requestor offered compensation to the Group under the Arrangement as an incentive for the Group's physicians to refer business to the Labs instead of to a competing cardiac catheterization lab.

Fourth, the specificity of the measures within the Arrangement helps ensure that its purpose is to improve quality, rather than reward referrals. The Arrangement specifically defines the Quality Component and bases the included measures on nationally recognized standards. The Arrangement sets out particular actions that generate the quality improvements on which the payments are based. The measures contained in the Quality and Cost Savings Components represent specific changes in cardiac catheterization laboratory procedures, which the Group's physicians are responsible for implementing. Additionally, the lowest, baseline achievement level for any measure reflects improvement over Requestor's *status quo* performance for that measure prior to the effective date of the Agreement.

Fifth, the Management Agreement is a written agreement with a three-year term, and thus is limited in duration.[25]

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.[26]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1) –(2) of the Act, the OIG will not impose sanctions on [name redacted] in connection with the Arrangement; and (ii) although the Arrangement could potentially

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[25] We note that the Arrangement contains an automatic renewal provision, unless terminated; however, this advisory opinion applies only to the current three-year term. We express no opinion with respect to future extensions of the Arrangement. We would expect that quality improvement and cost saving measures under the Arrangement would be subject to adjustment over time, to avoid payment for improvements achieved in prior years and to provide incentives for additional improvements in the future. Continuing compensation for conduct that has come to represent the accepted standard of care could, depending on the circumstances, implicate the anti-kickback statute.

[26] We express no opinion with regard to any future changes in the Arrangement (particularly changes to the Quality or the Cost Savings Components) that diverge from those to which Requestor certified.

generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

- The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [name redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requester.*]

Date Issued: January 11, 2001

Date Posted: January 18, 2001

[Names and Addresses Redacted]

Re: OIG Advisory Opinion No. 01-1

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies and medications during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, section 1128A(b)(1)-(2) of the Social Security Act (the "Act"), or (ii) the anti-kickback statute, section 1128B(b) of the Act.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request letter and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to section 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") will not impose sanctions on the requestors of this advisory opinion,

[names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that the OIG will not subject the Requestors to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital"), is an acute care, not-for-profit hospital in [City X], [State Y], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgeon Group. [Name redacted] (the "Surgeon Group"), is a professional association composed exclusively of cardiac surgeons who are licensed in [State Y] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgeon Group is the dominant group of cardiac surgeons that practices at the Hospital.[1] Surgeons in the Surgeon Group also practice at several other hospitals in the [City X] area.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement. The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arms-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied to cost savings or the Surgeon Group's compensation under the Proposed Arrangement.

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[1]Surgeons in the Surgeon Group perform 85% of the Hospital's cardiac surgery. Several cardiac surgeons who are not members of the Surgeon Group have active medical staff privileges at the Hospital. These cardiac surgeons will not participate in the Proposed Arrangement; however, the Hospital expects to include them in future cost savings sharing arrangements on terms and conditions substantially comparable to those under which it offers cost savings sharing to the Surgeon Group.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgeon Group a share of the first year cost savings directly attributable to specific changes in the Surgeon Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified nineteen specific cost-savings opportunities. The results of the Program Administrator's study of the Surgeon Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report".[2] The Hospital and the Surgeon Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgeon Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The nineteen specific recommendations can be roughly grouped into three categories. The first category consists of fourteen recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies. These items will be readily available, albeit unopened, in the operating room. One "open as needed" recommendation involves not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. The Requestors have certified that the resulting delay in cell saver readiness should not exceed two to five minutes and will not adversely affect patient care. The second category, involving four recommendations, consists of the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons. The final category consists of a recommendation to limit use of Aprotinin – a medication currently given to many surgical patients pre-operatively to prevent hemorrhaging – to patients that are at higher risk of perioperative hemorrhage as indicated by objective clinical standards.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the cell saver and the substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" below which no savings would accrue to the Surgeon Group. For example, the cell saver is currently used in approximately [A]% of the cardiac procedures specified under the Proposed Arrangement. Accordingly, the Surgeon Group will receive no share of any savings resulting from any reductions in cell saver use

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[2]The Practice Patterns Report for the Surgeon Group, dated April 4, 2000, is attached to this advisory opinion as Appendix A.

for cases below the [A]% floor. Similarly, for each of the proposed substitution recommendations, the Program Administrator has identified historic patterns of use at the Hospital or at hospitals with comparable practices and patient populations and has established thresholds below which no cost savings will be credited. For example, the Practice Patterns Report indicates that certain less expensive forms of sutures could be used in [B]% of the cases without having an adverse impact on patient care.[3] Accordingly, any savings from using less expensive sutures in more than [B]% of the cases will not be credited to the Surgeon Group.

With respect to Aprotinin, the Proposed Arrangement uses specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Hospital and its patient population to determine medical appropriateness.[4] Currently, approximately [C]% of patients to whom Aprotinin is administered by the Surgeon Group at the Hospital meet these objective clinical indicators. Under the Proposed Arrangement, savings from reduced use of Aprotinin will not be credited to the Surgeon Group if the savings result from utilization of Aprotinin in less than [C]% of cases or if the savings result from failure to use Aprotinin in a case that meets the clinical indicators. All surgical cases – including cases in which Aprotinin is not administered – will be reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether Aprotinin was used appropriately.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the nineteen recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care. Seventy-five percent of the potential cost savings would come from the proposed reduction in routine use of Aprotinin and another ten percent from the proposed delay in setting up the cell saver.

The Hospital will pay the Surgeon Group 50% of the cost savings achieved by implementing the nineteen recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the nineteen recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization below the set targets will not be credited to the Surgeon

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[3]We note that the Practice Patterns Report identifies with specificity the kinds of sutures at issue.

[4]The objective clinical indicators used in the Proposed Arrangement to determine when Aprotinin is administered appropriately are cited in medical literature. Lemmer et al., ATS 62: 1659-68 (1996).

Group. This payment will constitute the entire compensation paid to the Surgeon Group for services performed under the contract memorializing the Proposed Arrangement between the Surgeon Group and the Hospital. The payment to the Surgeon Group will be calculated by subtracting the actual costs incurred for the items specified in the nineteen recommendations when used by surgeons in the Surgeon Group during the specified surgical procedures (the "current year costs"[5]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[6]). The current year costs will be adjusted to account for any inappropriate reductions in use of items below the targets set in the Practice Patterns Report. The Surgeon Group will be paid 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgeon Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgeon Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Surgeon Group will not exceed 50% of the

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[5]The current year will be the twelve month term of the contract for which the Surgeon Group will be compensated under the Proposed Arrangement.

[6]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

projected cost savings identified in the Practice Patterns Report.

The Requestors have certified that this payment methodology will generate payments to the Surgeon Group that will be consistent with fair market value for services rendered to the Hospital in arms-length transactions.

The Hospital and the Surgeon Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the U.S. Department of Health and Human Services (the "Department"), upon request. In addition, the Hospital and the Surgeon Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgeon Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments based on cost savings to physicians may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, cost sharing arrangements can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost sharing programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three legal authorities: (i) the civil monetary penalty for reductions

or limitations of direct patient care services provided to Federal health care program beneficiaries, section 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[7] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 to the Proposed Arrangement.

A. The Civil Monetary Penalty, Section 1128A(b)(1)-(2) of the Act

Section 1128A(b)(1)-(2) of the Act establishes a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments (section 1128A(b)(1) & (2) of the Act). There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[8]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their

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[7]In addition, non-profit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113.

[8]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare + Choice plans are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1) and (2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/frdalrt/gsletter.htm; see also 42 C.F.R. § 417.479(i); 61 Fed. Reg. 13430, 13439 (Mar. 27, 1996); 42 C.F.R. § 434.70 (comparable regulations for physician incentive plans associated with Medicaid managed care organizations).

potential impact on patient care.

Having reviewed the nineteen individual recommendations, we conclude that, except for the unopened surgical tray items (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the disposable cell saver components, Aprotinin, and the substitution of less costly items, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. However, this conclusion does not apply to the disposable cell saver components. Because the components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's availability beyond merely opening the disposable components. Therefore, there is a greater potential for harm. Accordingly, we conclude that the cell saver incentive is subject to the statutory proscription of the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving the cell saver components, Aprotinin, and the various substitutions. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under section 1128A(b)(1) and (2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on non-clinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations, including the reduction in routine use of Aprotinin, will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed to confirm that the Proposed Arrangement is not having an adverse

impact on clinical care.[9]

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds below which no savings accrue to the Surgeon Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the Hospital and the Surgeon Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[10]

Sixth, the financial incentives under the Proposed Arrangement are reasonably limited in

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[9]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert. Both have concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

[10]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in operating rooms, we believe that patient satisfaction surveys would not be effective.

duration and amount.

Seventh, because the Surgeon Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).
- The individual actions that would give rise to the savings are not identified with specificity.
- There are insufficient safeguards against the risk that the other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."
- The quality of care indicators are of questionable validity and statistical significance.
- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. Specifically, the statute provides that:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

Id. Thus, where remuneration is paid purposefully to induce referrals of items or services for which payment may be made by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. The OIG may also initiate administrative proceedings to exclude persons from Federal and State health care programs or to impose

civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.[11]

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The regulatory safe harbor potentially applicable to the Proposed Arrangement is the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d). In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in an arms-length transactions, 42 C.F.R. § 1001.952(d)(5). The Proposed Arrangement would not fit in the safe harbor because the Surgeon Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgeon Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here. First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the

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[11]Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.

medical staff, thus limiting the Proposed Arrangement's effectiveness in attracting other surgeons. Only surgeons in the Surgeon Group will participate; however, based on the Requestors' certifications, we expect that if the Proposed Arrangement is renewed or continued beyond the one year term, the Hospital and the Program Administrator will offer a substantially comparable cost savings program to other cardiac surgeons on the medical staff. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payer. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgeon Group or its surgeons. The Surgeon Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgeon Group or share in its profit distributions. Within the Surgeon Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, the preparation of the cell saver and the administration of Aprotinin both carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). While we are precluded from opining on whether a payment is fair market value,[12] the payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the nineteen recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgeon Group. We caution

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A).

that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to section 1128A(b)(1)-(2) of the Act, but that the OIG will not impose sanctions under section 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts present in the Proposed Arrangement as described and certified in the request letter and supplemental submissions, the OIG will not subject the Requestors to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above in the first paragraph of this opinion. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed

against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General

[Appendix A redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: January 28, 2005

Posted: February 4, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-01**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgeon Group. [Name redacted] (the "Surgeon Group") is a professional association composed exclusively of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgeon Group is the only group of cardiac surgeons that practices at the Hospital.[1]

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgeon Group's compensation under the Proposed Arrangement.

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[1]Surgeons in the Surgeon Group also practice at two other hospitals in the region.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgeon Group a share of the first year cost savings directly attributable to specific changes in the Surgeon Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-four specific cost-savings opportunities. The results of the Program Administrator's study of the Surgeon Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Surgeon Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgeon Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The Practice Patterns Report identifies twenty-four specific recommendations that can be roughly grouped into the following four categories.

The first category consists of eleven recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies. These items will be readily available, albeit unopened, in the operating room. One "open as needed" recommendation involves not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. The Requestors have certified that the resulting delay in cell saver readiness should not exceed two to five minutes and will not adversely affect patient care.

The second category is similar and involves performing blood cross-matching only as needed. The Requestors have certified that all patients would be typed and screened prior to the procedure, with a cross-match being performed only when a patient requires a transfusion. The Hospital does not outsource its blood supply. The Requestors have certified that the resulting delay in blood readiness should be minimal when a cross match is necessary and that the delay will not adversely affect patient care.

The third category, involving seven recommendations, consists of the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons.

The final category, involving five recommendations, consists of product standardization of certain cardiac devices where medically appropriate. For this category, the Surgeon Group would be required to work in conjunction with the Hospital to evaluate and

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[3]The Practice Patterns Report for the Surgeon Group, dated October 2004, is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors set for each recommendation) set forth in the Practice Patterns Report as appropriate for the Requestors. Similar cost savings recommendations involving different facts could produce a different result.

clinically review vendors and products.[4] The Surgeon Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the cell saver, blood cross-matching, and the substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Surgeon Group. For example, the cell saver is currently set-up for 100% of the cases, but is only utilized in approximately 30% of the cardiac procedures specified under the Proposed Arrangement. Accordingly, the Surgeon Group will receive no share of any savings resulting from any reductions in cell saver use for cases beyond the 30% floor. Similarly, blood cross-matching is currently performed for 100% of the cases, with less than 30% of the cases actually resulting in a transfusion. Thus, the Surgeon Group will receive no share of any savings resulting from the reduction of blood cross-matching beyond the 30% floor. For each of the proposed substitution recommendations, the Program Administrator has identified historic patterns of use at the Hospital or at hospitals with comparable practices and patient populations and has established thresholds beyond which no cost savings will be credited. For example, the Practice Patterns Report indicates that certain less expensive catheters could be used in 90% of the cases without having an adverse impact on patient care.[5] Accordingly, any savings from using less expensive catheters in more than 90% of the cases will not be credited to the Surgeon Group.

Importantly, with respect to the product standardization recommendations, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate cardiac device and the availability of the full range of cardiac devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-four recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will pay the Surgeon Group 50% of the cost savings achieved by

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]We note that the Practice Patterns Report identifies with specificity the catheters at issue.

implementing the twenty-four recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-four recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgeon Group. This payment will constitute the entire compensation paid to the Surgeon Group for services performed under the contract memorializing the Proposed Arrangement between the Surgeon Group and the Hospital. For purposes of calculating the payment to the Surgeon Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-four recommendations when used by surgeons in the Surgeon Group during the specified surgical procedures (the "current year costs"[6]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[7]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgeon Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgeon Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgeon Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Surgeon Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

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[6]The current year will be the twelve-month term of the contract for which the Surgeon Group will be compensated under the Proposed Arrangement.

[7]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

The Hospital and the Surgeon Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgeon Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgeon Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Section 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-four individual recommendations, we conclude that, except for the unopened surgical tray items (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the disposable cell saver components, the blood cross-matching, the substitution of less costly items, and the standardization of devices, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at

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[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. However, this conclusion does not apply to the disposable cell saver components. Because the cell saver components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's availability beyond merely opening the disposable components. Accordingly, we conclude that the cell saver incentive is subject to the statutory proscription of the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving the cell saver components, the blood cross-matching, the substitutions of less costly items, and the standardization of devices. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[10]

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal

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[10]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert. Both have concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgeon Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of cardiac devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgeon Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgeon Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in operating rooms, we believe that patient satisfaction surveys would not be effective.

Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).
- The individual actions that would give rise to the savings are not identified with specificity.
- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."
- The quality of care indicators are of questionable validity and statistical significance.
- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgeon Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgeon Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would

receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgeon Group or its surgeons. The Surgeon Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgeon Group or share in its profit distributions. Within the Surgeon Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, the preparation of the cell saver, blood cross-matching, and product standardization each carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-four recommended actions, the specificity of the

payment formula, and the cap on total remuneration to the Surgeon Group.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

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[12] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the

modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 10, 2005

Posted: February 17, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-02**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with five cardiology groups a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain cardiac catheterization laboratory procedures (the "Proposed Arrangement"). The cost savings will be measured based on the cardiologists' use of specific supplies during designated cardiology procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the

Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital"), is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Names redacted], (collectively, the "Cardiology Groups," individually, where applicable, the "Cardiology Group") are professional corporations that separately employ physicians duly licensed in [state redacted] who have active medical staff privileges at the Hospital.[1] The Cardiology Groups refer patients to the Hospital for inpatient and outpatient hospital services. Each Cardiology Group will enter into a separate contract with the Hospital that will set forth the projected savings opportunities applicable to the individual Cardiology Group.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Cardiology Groups' compensation under the Proposed Arrangement.

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[1]The Cardiology Groups have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in the Cardiology Groups.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay each Cardiology Group a share of the first year cost savings directly attributable to specific changes in each Cardiology Group's cardiac catheterization laboratory practices. The majority of the changes involve product standardization. The Program Administrator conducted a study of the historic practices at the Hospital's cardiology department and identified eighteen specific cost-savings opportunities. The results of the Program Administrator's study of each Cardiology Group and the specific cost-savings opportunities for each Group are summarized in a "Practice Patterns Report."[3] The Hospital and each Cardiology Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to curb inappropriate use or waste of medical supplies. The eighteen recommendations can be grouped into two categories.

The first category, involving sixteen recommendations, consists of product standardization where medically appropriate. The Practice Patterns Report recommends that each Cardiology Group standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) used by the Cardiology Group.[4] Each Cardiology Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. Each Cardiology Group would agree to use the selected products, where medically appropriate, which may require additional training or changes in clinical practice.

The second category, involving two recommendations, consists of limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. The Requestors have certified that the vascular closure devices will be readily available, albeit unopened, in the procedure room. The Requestors have certified that the reduction in use of vascular closure devices will not adversely affect patient care.

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[3]The Practice Patterns Report for the Cardiology Groups, dated October 2004, is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors set for each recommendation) set forth in the Practice Patterns Report as appropriate for the Requestors. Similar cost savings recommendations involving different facts could produce a different result.

[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, with respect to the product standardization, the Requestors have certified that the individual cardiologists will make a patient-by-patient determination of the most appropriate device and the availability of the full range of devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

With respect to the limitation on use of vascular closure devices, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Cardiology Groups. For example, according to the Requestors, vascular closure devices for coronary interventional patients are currently utilized at the Hospital on 30% of the cases specified under the Proposed Arrangement. The Program Administrator has determined through analysis of national data that it is reasonable to reduce the use of vascular closure devices to 10% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Groups will receive no share of any savings resulting from the reduction of use of vascular closure devices beyond the 10% floor.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the eighteen recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will enter into a separate contract with each Cardiology Group that will specify the historic costs, base year costs, and projected cost-savings opportunities applicable to each individual group. Under each contract, the Hospital will pay the contracting Cardiology Group 50% of the cost savings achieved by implementing the eighteen recommendations in the Practice Patterns Report, applicable to the contracting Cardiology Group, for a period of one year. At the end of the year, cost savings will be calculated separately for each of the eighteen recommendations for each Group; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to each Cardiology Group. This payment will constitute the entire compensation paid to each Cardiology Group for services performed under the individual contracts memorializing the Proposed Arrangement. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the eighteen recommendations when used by cardiologists in the Cardiology Group during the specified procedures (the "current year

costs"[5]) will be subtracted from the historic costs for the same items when used during comparable procedures in the base year (the "base year costs"[6]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to each Cardiology Group will be 50% of the difference between their adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to each Cardiology Group, all of which distribute profits to their members on a per capita basis. Payments to each Cardiology Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the cardiologist at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to each Cardiology Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Cardiology Groups will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups will disclose the Proposed Arrangement to the patient, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure

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[5]The current year will be the twelve-month term of the contract for which each of the Cardiology Groups will be compensated under the Proposed Arrangement.

[6]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the procedure. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[7] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

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[7]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[8]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the eighteen recommendations, we conclude that the recommendations implicate the CMP. Simply put, the recommendations, under the Proposed Arrangement, regarding standardization of devices and limitations on the use of vascular closure devices constitute an inducement to reduce or limit the current medical practice at the Hospital. Thus, we find that the CMP would apply to the Proposed Arrangement. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately

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[8]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[9]

Third, the payments under the Proposed Arrangement are based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in catheterization laboratory practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Cardiology Groups will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings

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[9]We have had the Proposed Arrangement reviewed by a government medical expert, who concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[10]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because each Cardiology Group's profits are distributed to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

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[10]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in catheterization laboratory procedures, we believe that patient satisfaction surveys would not be effective.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such

practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Cardiology Groups will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Proposed Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to cardiologists already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward surgeons or other physicians who refer patients to the

Cardiology Groups or their cardiologists. The Cardiology Groups are the sole participants in the Proposed Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in its profit distributions. Within the Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. The recommendations in the Practice Patterns Report represent a change in cardiac catheterization laboratory procedure, for which the cardiologist is responsible and will have liability exposure. Both the product standardization and the limitation on vascular closure devices carry some increased liability risk for the physicians. It is not unreasonable for the cardiologist to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the eighteen recommended actions, the specificity of the payment formula, and the cap on total remuneration to each of the Cardiology Groups.[11] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered

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[11]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 10, 2005

Posted: February 17, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-03**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this

advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgical Group. [Name redacted], (the "Surgical Group") is a professional association composed exclusively of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgical Group is the only group of cardiac surgeons that practices at the Hospital and performs 100% of the Hospital's cardiac surgery.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[1] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgical Group's compensation under the Proposed Arrangement.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgical Group a share of the first year cost savings directly attributable to specific changes in the Surgical Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-nine specific

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[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

cost-savings opportunities. The results of the Program Administrator's study of the Surgical Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[2] The Hospital and the Surgical Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgical Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The Practice Patterns Report identifies twenty-nine specific recommendations that can be roughly grouped into the following four categories.

The first category consists of thirteen recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies. These items will be readily available, albeit unopened, in the operating room. One "open as needed" recommendation involves not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. The Requestors have certified that the resulting delay in cell saver readiness should not exceed two to five minutes and will not adversely affect patient care.

The second category is similar and involves performing blood cross-matching only as needed. The Requestors have certified that all patients would be typed and screened prior to the procedure, with a cross-match being performed only when a patient requires a transfusion. The Hospital does not outsource its blood supply. The Requestors have certified that the resulting delay in blood readiness should be minimal when a cross match is necessary and that the delay will not adversely affect patient care.

The third category, involving fourteen recommendations, consists of the substitution, in whole or in part, of less costly items for items currently being used by the surgeons (hereafter, the "product substitution" recommendations). The identified substitutions[3] have no appreciable clinical significance (e.g. slush drape, wrist splints, armboards, aortic punches, or suture boots). For example, wrist splints or armboards are used for support and protection after insertion of a radial artery line. Under one recommendation, surgeons would be asked to utilize a less expensive wrist splint or armboard that has similar characteristics to the surgeons' historic preference.

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[2]The Practice Patterns Report for the Surgical Group, dated October 2004, is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors set for each recommendation) set forth in the Practice Patterns Report as appropriate for the Requestors. Similar cost savings recommendations involving different facts could produce a different result.

[3]The Practice Patterns Report clearly identifies with specificity the items and products at issue for each proposed product substitution recommendation.

The final category involves product standardization of certain cardiac heart valves where medically appropriate. For this category, the Surgical Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products.[4] The Surgical Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the cell saver and blood cross-matching recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and in some cases, national averages to establish a "floor" beyond which no savings would accrue to the Surgical Group.

For example, the cell saver is currently set-up for 100% of the cases, but is utilized in approximately 5% of the cardiac procedures specified under the Proposed Arrangement. Accordingly, the Surgical Group will receive no share of any savings resulting from any reductions in cell saver use for cases beyond the established 10% floor set by the Program Administrator based upon national averages. Similarly, blood cross-matching is currently performed for 100% of the cases, with less than 50% of the cases actually resulting in a transfusion. Thus, the Surgical Group will receive no share of any savings resulting from the reduction of blood cross-matching beyond the 50% floor. With respect to the product substitution recommendations in the Proposed Arrangement, the Practice Patterns Report clearly identifies with specificity each substitution recommendation under this category. No floors will be set, because the identified substitutions will have no appreciable clinical significance.[5]

Importantly, with respect to the product standardization recommendations for cardiac devices, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate device and the availability of the full range of cardiac devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-nine recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]We note that for product substitution recommendations that have clinical significance, we would require additional safeguards, including, for example, the establishment of appropriate quality thresholds beyond which no cost savings would be credited.

quality of patient care.

The Hospital will pay the Surgical Group 50% of the cost savings achieved by implementing the twenty-nine recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-nine recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgical Group. This payment will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Proposed Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-nine recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "current year costs"[6]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[7]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgical Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgical Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

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[6]The current year will be the twelve-month term of the contract for which the Surgical Group will be compensated under the Proposed Arrangement.

[7]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

- The aggregate payment to the Surgical Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Surgical Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgical Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgical Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following:
(i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-nine individual recommendations, we conclude that, except for the unopened surgical tray items and the product substitutions (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the disposable cell saver components, the blood cross-matching, and the standardization of devices, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of

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[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items and product substitutions, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. However, this conclusion does not apply to the disposable cell saver components. Because the cell saver components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's availability beyond merely opening the disposable components. Accordingly, we conclude that the cell saver incentive is subject to the statutory proscription of the CMP. With respect to the specific product substitution recommendations, the identified substitutions will have no appreciable clinical significance; therefore, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items and the specific product substitutions do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving the cell saver components, blood cross-matching, and the standardization of devices. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[10]

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[10]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert. Both have concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgical Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgical Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgical Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin").

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).
- The individual actions that would give rise to the savings are not identified with specificity.
- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."
- The quality of care indicators are of questionable validity and statistical significance.
- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible

"kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgical Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgical Group or its surgeons. The Surgical Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgical Group or share in its profit distributions. Within the Surgical Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, the preparation of the cell saver, blood cross-matching, and product standardization each carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-nine recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation,

ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 10, 2005

Posted: February 17, 2005

[names and addresses redacted]

Re: OIG Advisory Opinion No. 05-04

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with each of eight cardiology groups a percentage of the hospital's cost savings arising from the cardiology group's implementation of a number of cost reduction measures in certain cardiac catheterization laboratory procedures (the "Proposed Arrangement"). The cost savings will be measured based on the cardiologists' use of specific supplies during designated cardiology procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction

or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Names redacted] (collectively, the "Cardiology Groups," and individually, where applicable, the "Cardiology Group") are four professional associations and one professional corporation that separately employ cardiologists duly licensed in [state redacted] who have active medical staff privileges at the Hospital.[1] The Cardiology Groups refer patients to the Hospital for inpatient and outpatient hospital services. Each Cardiology Group will enter into a separate contract with the Hospital that will set forth the projected savings opportunities applicable to the individual cardiology group.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to

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[1]The Cardiology Groups have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in the Cardiology Groups.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

cost savings or the Cardiology Groups' compensation under the Proposed Arrangement.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay each Cardiology Group a share of the first year cost savings directly attributable to specific changes in each Cardiology Group's cardiac catheterization laboratory practices. The majority of the changes involve product standardization for cardiology devices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac catheterization laboratory and identified seventeen specific cost-savings opportunities. The results of the Program Administrator's study of each Cardiology Group and the specific cost-savings opportunities for each Group are summarized in a "Practice Patterns Report."[3] The Hospital and each Cardiology Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to curb inappropriate use or waste of medical supplies. The seventeen recommendations can be grouped into three categories.

The first category, involving twelve recommendations, consists of product standardization of certain cardiology devices where medically appropriate. The Practice Patterns Report recommends that each Cardiology Group standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure, diagnostic devices, pacemakers, and defibrillators) used by the Cardiology Group.[4] Each Cardiology Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. Each Cardiology Group would agree to use the selected products, where medically appropriate, which may require additional training or changes in clinical practice.

The second category, involving three recommendations, consists of limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. The Requestors have certified that the vascular closure devices will be readily available, albeit unopened, in the procedure room. The Requestors have certified that the reduction in use of vascular closure devices will not adversely affect patient care.

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[3]The Practice Patterns Report for the Cardiology Groups, dated October 2004, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

The final category, involving contrast agents, consists of two recommendations to substitute, in whole or in part, less costly items for the items currently being used by the physicians (hereafter, the "products substitution" recommendations).

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the "as needed" use of vascular closure devices and the products substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital and in some cases national averages to establish a "floor" beyond which no savings would accrue to any Cardiology Group.

For example, according to the Requestors, the national average for utilization of vascular closure devices for stent patients is 15.5%. Vascular closure devices are currently utilized at the Hospital on 30% of the cases specified under the Proposed Arrangement. Based upon this information, the Program Administrator has set the floor for this recommendation at 20% of stent patients. Cardiology Groups will receive no share of any savings resulting from the reduction of use of vascular closure devices beyond the 20% floor.

For the proposed product substitution recommendations, the Program Administrator has identified national averages and historic patterns of use at the Hospital or at hospitals with comparable practices and patient populations and has established quality thresholds beyond which no cost savings will be credited. For example, the Practice Patterns Report indicates that certain less expensive contrast agents could be used in 95% of the cases without an adverse impact on patient care.[5] Accordingly, any savings from using a less expensive contrast agent in more than 95% of the cases will not be credited to the Cardiology Groups.

Importantly, with respect to the product standardization of cardiology devices, the Requestors have certified that the individual cardiologists will make a patient-by-patient determination of the most appropriate device and the availability of the full range of devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the seventeen recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

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[5]We note that the Practice Patterns Report identifies with specificity the product subsitutions at issue.

The Hospital will enter into a separate contract with each Cardiology Group that will specify the historic costs, base year costs, and projected cost-savings opportunities applicable to the group resulting from implementation of the seventeen recommendations in the Practice Patterns Report. Under each contract, the Hospital will pay the contracting Cardiology Group 50% of the cost savings for a period of one year. At the end of the year, cost savings will be calculated separately for each of the seventeen recommendations for each Group; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to each Cardiology Group. This payment will constitute the entire compensation paid to each Cardiology Group for services performed under the individual contracts memorializing the Proposed Arrangement. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the seventeen recommendations when used by cardiologists in the Cardiology Group during the specified procedures (the "current year costs"[6]) will be subtracted from the historic costs for the same items when used during comparable procedures in the base year (the "base year costs"[7]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to each Cardiology Group will be 50% of the difference between its adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to each Cardiology Group, all of which distribute profits to their members on a per capita basis. Payments to each Cardiology Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical

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[6]The current year will be the twelve-month term of the contract for which each of the Cardiology Groups will be compensated under the Proposed Arrangement.

[7]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

measures, the cardiologist at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to each Cardiology Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Cardiology Groups will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups will disclose the Proposed Arrangement to the patient, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the procedure. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the seventeen recommendations, we conclude that all of the recommendations implicate the CMP. Simply put, the recommendations under the Proposed Arrangement regarding standardization of devices, limitations on the use of vascular closure devices, and products substitution constitute an inducement to reduce or limit the current medical practice at the Hospital. Thus, we find that the CMP would

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[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

apply to the Proposed Arrangement. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[10]

Third, the payments under the Proposed Arrangement are based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in catheterization laboratory practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects

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[10]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert, who both concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Cardiology Groups will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because each Cardiology Group's profits are distributed to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of any savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include,

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items used in the catheterization laboratory, we believe that patient satisfaction surveys would not be effective.

but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).
- The individual actions that would give rise to the savings are not identified with specificity.
- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."
- The quality of care indicators are of questionable validity and statistical significance.
- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose

civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Cardiology Groups will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Proposed Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to cardiologists already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will

be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward surgeons or other physicians who refer patients to the Cardiology Groups or their cardiologists. The Cardiology Groups are the sole participants in the Proposed Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in its profit distributions. Within the Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. The recommendations in the Practice Patterns Report represent a change in cardiac catheterization laboratory procedure, for which the cardiologists are responsible and will have liability exposure. The products standardization, limitation on vascular closure devices, and product substitutions carry some increased liability risk for the physicians. It is not unreasonable for the cardiologists to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the seventeen recommended actions, the specificity of the payment formula, and the cap on total remuneration to each of the Cardiology Groups.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the

False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 18, 2005

Posted: February 25, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-05**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain procedures (the "Proposed Arrangement"). The cost savings will be measured based on the cardiologists' use of specific supplies during designated cardiac catheterization laboratory procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the

Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Group. [Name redacted] (the "Cardiology Group") is a professional association that employs physicians who are duly licensed in [state redacted] and have active medical staff privileges at the Hospital.[1] The Cardiology Group refers patients to the Hospital for inpatient and outpatient hospital services.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Cardiology Group's compensation under the Proposed Arrangement.

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[1]The Cardiology Group has members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in the Cardiology Group.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Cardiology Group a share of the first year cost savings directly attributable to specific changes in the Cardiology Group's cardiac catheterization laboratory practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac catheterization laboratory and identified twelve specific cost-savings opportunities. The results of the Program Administrator's study of the Cardiology Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Cardiology Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Cardiology Group change current cardiac catheterization laboratory practices to curb inappropriate use or waste of medical supplies. The twelve recommendations can be grouped into two categories.

The first category, involving ten recommendations, consists of product standardization where medically appropriate. The Practice Patterns Report recommends that the Cardiology Group standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) used by the Cardiology Group.[4] The Cardiology Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Cardiology Group would agree to use the selected products, where medically appropriate, which may require additional training or changes in clinical practice.

The second category, involving two recommendations, consists of limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. The Requestors have certified that the vascular closure devices will be readily available, albeit unopened, in the procedure room. The Requestors have certified that the reduction in use of vascular closure devices will not adversely affect patient care.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, with respect to the product standardization recommendation, the Requestors have certified that the individual

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[3]The Practice Patterns Report for the Cardiology Group, dated October 2004, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

cardiologists will make a patient-by-patient determination of the most appropriate device and the availability of the full range of devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

With respect to the limitation on use of vascular closure devices, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Cardiology Group. For example, according to the Requestors, vascular closure devices for femoral access cases are currently utilized at the Hospital on 26.1% of the cases specified under the Proposed Arrangement. The Program Administrator has determined through analysis of national data that it is reasonable to reduce the use of vascular closure devices on these cases to 15% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Group will receive no share of any savings resulting from the reduction of use of vascular closure devices beyond the 15% floor.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twelve recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will pay the Cardiology Group 50% of the cost savings achieved by implementing the twelve recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twelve recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Cardiology Group. This payment will constitute the entire compensation paid to the Cardiology Group for services performed under the contract memorializing the Proposed Arrangement between the Cardiology Group and the Hospital. For purposes of calculating the payment to the Cardiology Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twelve recommendations when used by cardiologists in the Cardiology Group during the specified procedures (the "current year costs"[5]) from the historic costs for the same items

[5]The current year will be the twelve-month term of the contract for which the Cardiology Group will be compensated under the Proposed Arrangement.

when used during comparable procedures in the base year (the "base year costs"[6]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Cardiology Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Cardiology Group, which distributes its profits to each of its members on a per capita basis. Payments to the Cardiology Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the cardiologist at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Cardiology Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Cardiology Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Group will disclose the Proposed Arrangement to the patient, including the fact that the Cardiology Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the procedure. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost

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[6]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[7] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See

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[7]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[8]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twelve recommendations, we conclude that the recommendations implicate the CMP. Simply put, the recommendations under the Proposed Arrangement regarding standardization of devices and limitations on the use of vascular closure devices constitute an inducement to reduce or limit the current medical practice at the Hospital. Thus, we find that the CMP would apply to the Proposed Arrangement. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that

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[8]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

the Proposed Arrangement is not having an adverse impact on clinical care.[9]

Third, the payments under the Proposed Arrangement are based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in catheterization laboratory practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Cardiology Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[10]

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[9]We have had the Proposed Arrangement reviewed by a government medical expert who concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

[10]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in procedures, we believe that patient satisfaction surveys would not be effective.

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Cardiology Group's profits are distributed to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).
- The individual actions that would give rise to the savings are not identified with specificity.
- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."
- The quality of care indicators are of questionable validity and statistical significance.
- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide

sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Cardiology Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Group. Specifically, the Proposed Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologist would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to cardiologists already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Cardiology Group or its cardiologists. The Cardiology Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiologist; no surgeons or other physicians are members of the Cardiology Group or share in its profit distributions. Within the Cardiology Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. The recommendations in the Practice Patterns Report represent a change in catheterization laboratory practice, for which the cardiologist is responsible and will have liability exposure. The product standardization and limitation on use of vascular closure devices each carry some increased liability risk for the physicians. It is not unreasonable for the cardiologist to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments

under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twelve recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Cardiology Group.[11] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

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[11]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly

discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 18, 2005

Posted: February 25, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-06**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction

or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgical Group. [Name redacted] (the "Surgical Group") is a professional association composed exclusively of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital.[1] The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgical Group's compensation under the Proposed Arrangement.

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[1] The Surgical Group performs the majority of cardiac surgery cases at the Hospital. The surgeons in the Surgical Group also practice at one other hospital in the region.

[2] The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgical Group a share of the first year cost savings directly attributable to specific changes in the Surgical Group's operating room practices, including standardization of certain cardiac devices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-seven specific cost-savings opportunities. The results of the Program Administrator's study of the Surgical Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Surgical Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgical Group change current operating room practices to curb inappropriate use or waste of medical supplies. The twenty-seven recommendations can be roughly grouped into four categories.

The first category consists of two recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies.

The second category, involving three recommendations, is similar and involves limiting the use of certain surgical supplies, such as gelfoam, surgicel, and vancomycin paste, to an as needed basis (hereafter, the "use as needed" recommendations). The Requestors have certified that the individual surgeon will make a patient-by-patient determination as to whether these items are clinically indicated and that the surgical supplies will still be readily available to the surgeons. The Requestors have further certified that any resulting limitations on the use of these products will not adversely affect patient care.

The third category, involving eleven recommendations, consists of the substitution, in whole or in part, of less costly items for items currently being used by the surgeons (hereafter, the "product substitution" recommendations). In this case, the substitutions involve types of items and services for which a product substitution will have no appreciable clinical significance (e.g., substituting disposable head supports, disposable k-thermia blankets, and instrument pouches). For example, currently a foam donut is used in each surgical case to support the patient's head. Under the Proposed Arrangement, surgeons would be asked to utilize a less expensive reusable head support that has similar characteristics to the surgeons' historic preference.

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[3]The Practice Patterns Report for the Surgical Group, dated October 2004, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

The final category, involving eleven recommendations, consists of product standardization of certain cardiac devices and supplies where medically appropriate. For this category, the Surgical Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products.[4] The Surgical Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Surgical Group. For example, surgicel is currently utilized on 28% of the cases specified under the Proposed Arrangement. According to the Program Administrator, national data indicates a best practice usage of 5% for surgicel. Thus, the Program Administrator has set a 5% floor for this recommendation. The Surgical Group will receive no share of any savings resulting from the reduction in use of surgicel beyond the 5% floor. With respect to the product substitution recommendations in the Proposed Arrangement, as the identified substitutions[5] will have no appreciable clinical significance, no floors are set.[6]

Importantly, with respect to the product standardization recommendations, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate devices and supplies and the availability of the full range of these items will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices and supplies after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-seven recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]The Practice Patterns Report clearly identifies with specificity each substitution recommendation under this category.

[6]We note that for product substitution recommendations that are of clinical significance, we would require additional safeguards, such as the establishment of quality thresholds beyond which no cost savings would be credited.

The Hospital will pay the Surgical Group 50% of the cost savings achieved by implementing the twenty-seven recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-seven recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgical Group. This payment will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Proposed Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-seven recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "current year costs"[7]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[8]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgical Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgical Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

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[7]The current year will be the twelve-month term of the contract for which the Surgical Group will be compensated under the Proposed Arrangement.

[8]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

- The aggregate payment to the Surgical Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Surgical Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgical Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgical Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-seven individual recommendations, we conclude that, except for the unopened surgical tray items and the product substitutions (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the "use as needed" surgical supplies and the product standardization, the Proposed Arrangement constitutes an inducement to reduce or limit

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[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items and product substitutions, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. With respect to the specific product substitution recommendations, the identified substitutions will have no appreciable clinical significance; therefore, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items and the specific product substitutions do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving limitations on use of certain surgical supplies and product standardization. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[11]

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the

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[11]We have had the Proposed Arrangement reviewed by a government medical expert who concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgical Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of cardiac devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgical Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[12]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgical Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician

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[12]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in operating rooms, we believe that patient satisfaction surveys would not be effective.

that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).
- The individual actions that would give rise to the savings are not identified with specificity.
- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."
- The quality of care indicators are of questionable validity and statistical significance.
- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible

"kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgical Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgical Group or its surgeons. The Surgical Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgical Group or share in its profit distributions. Within the Surgical Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, limitation on use of certain surgical supplies and product standardization each carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-seven recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.[13] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

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[13]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed

Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: November 9, 2006

Posted: November 16, 2006

[names and addresses redacted]

Re: OIG Advisory Opinion No. 06-22

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' elimination of waste and use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or

limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgeon Group. [Name redacted] (the "Surgeon Group") is a professional association composed exclusively of cardiac surgeons who are licensed in the State of [name redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgeon Group is the only group of cardiac surgeons that practices at the Hospital.[1]

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgeon Group's compensation under the Proposed Arrangement.

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[1]Surgeons in the Surgeon Group also practice at two other hospitals in the region.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgeon Group a share of the first year cost savings directly attributable to specific changes in the Surgeon Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-four specific cost-savings opportunities. The results of the Program Administrator's study of the Surgeon Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Surgeon Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgeon Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The Practice Patterns Report identifies twenty-four specific recommendations that can be roughly grouped into the following three categories.

The first category consists of five recommendations that involve limiting the use of certain surgical supplies (hereafter, the "use as needed" recommendations). The Requestors have certified that the individual surgeon will make a patient-by-patient determination as to whether these items are clinically indicated and that the surgical supplies will still be readily available to the surgeons. The Requestors have further certified that any resulting limitations on the use of these products will not adversely affect patient care. Included in this category is a recommendation to limit use of Aprotinin – a medication currently given to many surgical patients pre-operatively to prevent hemorrhaging – to patients that are at higher risk of perioperative hemorrhage as indicated by objective clinical standards.

The second category, involving nine recommendations, consists of the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons. The substitutions involve types of items and services for which a product substitution will have no appreciable clinical significance (e.g., substituting reusable hyperthermia blankets, reusable gel pad, and ace bandages). For example, currently a disposable warming blanket is used on all open heart cases to maintain body temperature. Under the Proposed Arrangement, surgeons would be asked to utilize reusable warming blankets.

The final category, involving ten recommendations, consists of product standardization of certain cardiac devices where medically appropriate. For this category, the Surgeon Group would be required to work in conjunction with the Hospital to evaluate and clinically

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[3]The Practice Patterns Report for the Surgeon Group, dated June 2, 2006, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

review vendors and products.[4] The Surgeon Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the use as needed recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Surgical Group. For example, with respect to Aprotinin, the Proposed Arrangement uses specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Hospital and its patient population to determine medical appropriateness.[5] Currently, Aprotinin is used in approximately 48% of the cases specified under the Proposed Arrangement. According to the Program Administrator, national data indicates a best practice usage of 20% for Aprotinin. Under the Proposed Arrangement, savings from reduced use of Aprotinin will not be credited to the Surgeon Group if the savings result from utilization of Aprotinin in less than 20% of cases or if the savings result from failure to use Aprotinin in a case that meets the clinical indicators. All surgical cases – including cases in which Aprotinin is not administered – will be reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether Aprotinin was used appropriately.

With respect to the product substitution recommendations in the Proposed Arrangement, as the identified substitutions[6] will have no appreciable clinical significance, no floors are set.[7]

Importantly, with respect to the product standardization recommendations, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate cardiac device and the availability of the full range of cardiac devices will not be compromised by the product standardization. The Requestors have further

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]The objective clinical indicators used in the Proposed Arrangement to determine when Aprotinin is administered appropriately are cited in medical literature. Lemmer et al., ATS 62: 1659-68 (1996).

[6]The Practice Patterns Report clearly identifies with specificity each substitution recommendation under this category.

[7]We note that for product substitution recommendations that are of clinical significance, we would require additional safeguards, such as the establishment of quality thresholds beyond which no cost savings would be credited.

certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-four recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will pay the Surgeon Group 50% of the cost savings achieved by implementing the twenty-four recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-four recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgeon Group. This payment will constitute the entire compensation paid to the Surgeon Group for services performed under the contract memorializing the Proposed Arrangement between the Surgeon Group and the Hospital. For purposes of calculating the payment to the Surgeon Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-four recommendations when used by surgeons in the Surgeon Group during the specified surgical procedures (the "current year costs"[8]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[9]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgeon Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgeon Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgeon Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal

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[8]The current year will be the twelve-month term of the contract for which the Surgeon Group will be compensated under the Proposed Arrangement.

[9]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Surgeon Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Surgeon Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgeon Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgeon Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following:
(i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in

exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[10] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[11]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or

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[10]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[11]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-four individual recommendations, we conclude that, except for the product substitutions (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the "use as needed" surgical supplies, Aprotinin, and the product standardization, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding specific product substitution recommendations, the identified substitutions will have no appreciable clinical significance; therefore, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

In sum, while the recommendations for the specific product substitutions do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving limitations on use of certain surgical supplies, Aprotinin, and product standardization. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[12]

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[12]We have had the Proposed Arrangement reviewed by a government medical expert. The medical expert has concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgeon Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of cardiac devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgeon Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgeon Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory

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[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

Many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgeon Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgeon Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgeon Group or its surgeons. The Surgeon Group is the sole participant in the

Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgeon Group or share in its profit distributions. Within the Surgeon Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, product standardization, for example, carries some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-four recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgeon Group.[14] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the

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[14]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

Attachment A [Redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 28, 2007

Posted: January 14, 2008

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 07-22

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement in which a hospital has agreed to share with a group of anesthesiologists a percentage of the hospital's cost savings arising from the anesthesiologists' implementation of a number of cost reduction measures related to anesthesia services provided during cardiac surgical procedures (the "Arrangement"). The cost savings are measured based on the anesthesiologists' reduction of waste and use of specific devices and supplies during designated cardiac surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to an anesthesiologist to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the anesthesiologist's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Anesthesiology Group. [Name redacted] (the "Anesthesiology Group") is a professional corporation comprised only of anesthesiologists who are licensed in [state redacted], have active medical staff privileges at the Hospital, and whose practice includes the provision of cardiac anesthesia services. The Anesthesiology Group is the only group administering cardiac anesthesia at the Hospital. The Anesthesiology Group's practice is limited to the administration of anesthesia ancillary to procedures performed by other physicians. It does not furnish pain management or similar free-standing professional services or order or furnish any separately billable Hospital services. The Anesthesia Group bills and collects its own professional fees; it does not reassign such fees to the Hospital.

The Program Administrator. The Hospital engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data

and analyzed and managed the Arrangement.[1] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Anesthesiology Group's compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agreed to pay the Anesthesiology Group a share of cost savings directly attributable to specific changes in the Anesthesiology Group's anesthesia practices. The Requestors implemented the Arrangement – and the Anesthesiology Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Hospital has not paid amounts owed to the Anesthesiology Group under the Arrangement pending the outcome of this opinion.[2] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

The Program Administrator conducted a study of the historic anesthesia practices at the Hospital's cardiac surgery department and identified five specific cost-savings opportunities. The results of the Program Administrator's study of the Anesthesiology Group and the specific cost-savings opportunities are summarized in a document entitled "Executive Summary of Value Share for Cardiac Anesthesia" (the "Executive Summary").[3] The Hospital and the Anesthesiology Group reviewed the recommendations and conclusions outlined in the Executive Summary for medical appropriateness, and each adopted them.

In general, the Executive Summary recommended that the Anesthesiology Group change its operating room practices to curb the inappropriate use or waste of medical supplies. The

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[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

[2]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[3]The Executive Summary for the Anesthesiology Group is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts set forth in the Executive Summary. Similar cost savings recommendations involving different facts could produce a different result.

Executive Summary identified five specific recommendations that can be roughly grouped into the following three categories.

- "*Use as Needed" Items*. The Anesthesiology Group was to eliminate the routine use in the specific cardiac procedures covered by the Arrangement of (i) a specific drug and (ii) a device used to monitor patients' brain function (when the reduction occured in conjunction with compensating changes in clinical practice) (hereafter, the "use as needed" recommendations).[4] The Requestors have certified that the individual anesthesiologists made patient-by-patient determinations as to whether the items were clinically indicated in particular procedures and that the items remained readily available to the anesthesiologists. The Requestors further certified that any change in the use of these items did not adversely affect patient care.[5]

- *Product Substitution*. The Anesthesiology Group was to substitute, in whole or in part, less costly items for items currently being used by the anesthesiologists during the covered cardiac procedures (hereafter, the "product substitution" recommendations). Specifically, one recommendation involved the use of a specific catheter, and the other involved a nasogastric tube made with a less expensive material.

- *Product Standardization*. The Anesthesiology Group was to standardize the use of certain fluid warming hot lines where medically appropriate. For this category, the Anesthesiology Group was required to work with the Hospital to evaluate and clinically review vendors and products.[6] The Anesthesiology Group agreed to use the selected product where medically appropriate, which might have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. The Executive Summary clearly identified with specificity each "use as needed" and product substitution recommendation. For the catheter substitution recommendation, the Arrangement used objective historical and clinical measures

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[4]The Executive Summary identified with specificity the products at issue.

[5]In the case of the device, the Requestors indicate its use in the covered procedures is not supported by medical literature and that the American Society of Anesthesiology has issued a practice advisory stating that its routine use is not indicated. With respect to the drug, the Requestors indicate that its routine use is not supported by evidence and that its use significantly increases costs without proven increases in benefits.

[6]The Executive Summary identified with specificity the type of product at issue.

reasonably related to the practices and the patient population at the Hospital, and, in some cases, data at comparable hospitals to establish thresholds beyond which no savings accrued to the Anesthesiology Group. The Executive Summary indicated that a less expensive catheter could appropriately be used in 90% of cases; accordingly, the savings achievable by using less expensive catheters was limited to 90% of cases. The Anesthesiology Group will receive no share of cost savings attributable to using less expensive catheters in more than 90% of cases.[7]

Further, the Program Administrator tracked and measured the Hospital's performance of the covered cardiac procedures against the quality indicators established by the Society of Thoracic Surgeons ("STS") throughout the base year and contract year (as defined below). According to the Requestors, the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Anesthesiology Group for procedures involving reductions in historical STS quality indicators.

Importantly, with respect to the recommendation to standardize fluid warming hot lines, the Requestors have certified that the individual anesthesiologists made patient-by-patient determinations of the most appropriate fluid warming hot lines, and the availability of the full range of lines was not compromised by the product standardization. The Requestors have further certified that individual anesthesiologists still had available the same selection of lines after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of warming hot lines.

Finally, the Requestors have certified that all items covered by the Arrangement remained readily available for use by the anesthesiologists after implementation of the Arrangement.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the five recommendations presented substantial cost

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[7]The Arrangement did not include comparable objective utilization thresholds for recommendations to eliminate use of the brain function monitor and to use a nasogastric tube made of a less expensive material in the covered cardiac procedures. The Requestors have certified that the former recommendation was consistent with a practice advisory issued by the American Society of Anesthesiology and that the latter recommendation was consistent with the routine standard of care for the covered procedures.

savings opportunities for the Hospital without any adverse impact on the quality of patient care.

The Hospital intends to pay the Anesthesiology Group 50% of the cost savings achieved by implementing the five recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each of the five recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization reduced below the set targets, as applicable, were not credited to the Anesthesiology Group. The payment, when made, will constitute the entire compensation paid to the Anesthesiology Group for services performed pursuant to the contract memorializing the Arrangement between the Anesthesiology Group and the Hospital. For purposes of calculating the payment to the Anesthesiology Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year for the items specified in the five recommendations when used by anesthesiologists in the Anesthesiology Group during the specified surgical procedures (the "contract year costs"[8]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[9]). The current year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary or in connection with reductions in the STS quality indicators. The payment to the Anesthesiology Group was calculated to be 50% of the difference between the adjusted contract year costs and base year costs.

The Hospital is obligated to make an aggregate payment to the Anesthesiology Group, which distributes its profits to each of its members on a per capita basis. Calculation of the payments to the Anesthesiology Group was also subject to the following limitations:

- If the Anesthesiology Group's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

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[8]The current year was the twelve-month period for which the Anesthesiology Group is to be compensated under the Arrangement.

[9]The "base year" will be the twelve months preceding the current year of the arrangement. For purposes of this opinion, the Arrangement is limited to a one-year term; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

- To minimize the potential for steering of more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

- The Executive Summary identified projected cost savings, and the aggregate payment to the Anesthesiology Group, when made, will not exceed 50% of those amounts.

The Hospital and the Anesthesiology Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Anesthesiology Group disclosed the Arrangement to patients, including the fact that the Anesthesiology Group's compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were in writing, and patients had an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed at the hospital.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physicians' judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient

referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[10] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[11]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A

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[10]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[11]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

threshold inquiry is whether the Arrangement might have induced the anesthesiologists in the Anesthesiology Group to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the five individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and will continue to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[12]

Third, the amount to be paid under the Arrangement has been calcuated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Arrangement applied were not disproportionately performed on Federal health care program

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[12]We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Anesthesiology Group. The Requestors have certified that the baseline measure establishing a "floor" for reduced use of the particular catheter was reasonably related to the Hospital's or comparable hospitals' practices and patient populations, and that the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices; the indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Anesthesiology Group where there were reductions in historical STS quality indicators.

Fifth, the product standardization recommendation protected against inappropriate reductions in services by ensuring that individual anesthesiologists still had available the same selection of fluid warming hot lines after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Anesthesiology Group provided written disclosures of their involvement in the Arrangement to patients whose care may have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because the Anesthesiology Group distributes profits to its members on a per capita basis, any incentive for an individual anesthesiologist to generate disproportionate cost savings is mitigated.

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[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also

initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Anesthesiology Group was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

As with any compensation arrangement between a hospital and a physician potentially in a position to generate business, directly or indirectly, for the hospital, we are concerned that the Arrangement could have been used to disguise remuneration from the Hospital to the Anesthesiology Group or its anesthesiologists. Under the Arrangement, the anesthesiologists would receive not only their professional fees, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more anesthesia services an anesthesiologist furnishes at the Hospital, the more money he or she is likely to receive under the Arrangement. Thus, the Arrangement will generate remuneration for the anesthesiologists.

Typically, anesthesiologists are less likely to generate business for hospitals than many other types of physicians, although some anesthesiologists perform procedures themselves (e.g., pain management procedures), order additional items or services for existing patients, or otherwise generate Federally payable business for hospitals. Thus, depending on the facts, anesthesiologists may be in a position, directly or indirectly, to generate Federal health care program business, and purposeful payments to induce such business would run afoul of the statute. Here, it appears unlikely that the anesthesiologists in the Anesthesiology Group are in a position to generate Federal health care program business for the Hospital. The nature of the specific services furnished by the Anesthesiology Group at the Hospital, as well as the nature of the relationship between the parties (including the fact that the anesthesiologists do not reassign their right to payment to the Hospital),

substantially limit the opportunities for the Anesthesiology Group to generate Federal health care program business for the Hospital.[14]

The structure of the Arrangement adequately addresses any residual risk of improper referral payments.

First, participation in the Arrangement was limited to anesthesiologists already on the medical staff, thus limiting the likelihood that the Arrangement would have attracted other anesthesiologists to the Hospital. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract year for which payments were calculated was limited to one year, reducing any incentive for anesthesiologists to switch facilities to earn cost sharing payments, and patient admissions were monitored for changes in severity, age, or payor to ensure that the Arrangement did not result in inappropriate changes in referral patterns. Thus, while the incentive to generate business was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement was used to reward physicians who referred patients to, or otherwise generated business for, the Hospital, the Anesthesiology Group, or its anesthesiologists. The Anesthesiology Group is the sole participant in the Arrangement and is composed entirely of anesthesiologists; no cardiologists, cardiac surgeons, or other physicians are members of the Anesthesiology Group or share in its profit distributions. Within the Anesthesiology Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual anesthesiologist to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments were based. The recommendations in the Executive Summary represented a change in operating room practice, for which the anesthesiologist was responsible and had liability exposure. It is not unreasonable for the anesthesiologist to receive compensation for the increased risk from the changes in practice. Moreover, the payments to be made represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the

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[14]Moreover, we note that the typical anti-kickback concern about arrangements between hospitals and anesthesiologists is the risk of remuneration flowing from the anesthesiologists to the hospital in return for hospital business.

anesthesiologists to implement the five recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Anesthesiology Group.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

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[15]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we made an independent fair market value assessment.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this

advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 28, 2007

Posted: January 14, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 07-21

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement in which a hospital has agreed to share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Arrangement"). The cost savings are measured based on the surgeons' reduction of waste and use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is

limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgical Group. [Name redacted] (the "Surgical Group") is a limited liability company comprised only of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgical Group is the only group of cardiac surgeons that practices at the Hospital and performs 100% of the Hospital's cardiac surgery.

The Program Administrator. The Hospital engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data

and analyzed and manages the Arrangement.[1] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Surgical Group's compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agreed to pay the Surgical Group a share of cost savings directly attributable to specific changes in the Surgical Group's operating room practices. The Requestors implemented the Arrangement – and the Surgical Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Hospital has not paid amounts owed to the Surgical Group under the Arrangement pending the outcome of this opinion.[2] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-five specific cost-savings opportunities. The Program Administrator summarized the results of the study of the Surgical Group and the specific cost-savings opportunities in a document entitled [title redacted] (the "Executive Summary").[3] The Hospital and the Surgical Group reviewed the Executive Summary for medical appropriateness, and each adopted its recommendations and conclusions.

In general, the Executive Summary recommended that the Surgical Group change its operating room practices to curb the inappropriate use or waste of medical supplies. The

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[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

[2]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[3]The Executive Summary for the Surgical Group is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors or measurable quality indicators set for each recommendation) set forth in the Executive Summary. Similar cost savings recommendations involving different facts could produce a different result.

Executive Summary identified twenty-five specific recommendations that can be grouped roughly into the following four categories.

- *Disposable Cell Saver Components*. This category involved one recommendation that the Surgical Group refrain from opening disposable components of the cell saver unit until a patient experiences excessive bleeding, and, at the same time, that the Surgical Group implement specific alternative clinical practices. The Requestors have certified that the resulting delay in cell saver readiness did not exceed two to five minutes and did not adversely affect patient care.

- *"Use as Needed" Supplies*. For the second category, involving eight recommendations, the Surgical Group was to limit the use of certain surgical supplies to an as needed basis (hereafter, the "use as needed" recommendations). The Requestors have certified that the individual surgeons made patient-by-patient determinations as to whether these items were clinically indicated and that the surgical supplies remained readily available to the surgeons. The Requestors have further certified that any resulting limitations on the use of these products did not adversely affect patient care. Included in this category was a recommendation to limit use of Aprotinin– a medication given to many surgical patients pre-operatively to prevent hemorrhaging – to patients at higher risk of perioperative hemorrhage as indicated by objective clinical standards, as well as recommendations to eliminate the use of Vancomycin and Triple Antibiotic Ointment for particular procedures covered by the Arrangement.

- *Product Substitutions*. For the third category, involving eleven recommendations, the Surgical Group was to substitute, in whole or in part, less costly items for items then being used by the surgeons (hereafter, the "product substitution" recommendations). Some of the identified substitutions[4] would have no appreciable clinical significance (e.g., elbow pads, wrist splints, or skin staplers). For example, under one recommendation, surgeons were asked to utilize a reusable blanket instead of a disposable blanket. Other product substitutions involved pharmacy items and supplies that may have had appreciable clinical significance. With respect to these substitutions, the Requestors certified that the individual surgeon made a patient-by-patient determination whether the item or supply was clinically indicated and that all of the items and supplies remained readily available to the surgeons. The Requestors further certified that none of the identified product substitutions adversely impacted patient care.

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[4]The Executive Summary identified with specificity the product substitution recommendations.

- *Product Standardization*. For the fourth category, involving five recommendations, the Surgical Group was to standardize the use of certain cardiac devices and supplies where medically appropriate. For this category, the Surgical Group was required to work with the Hospital to evaluate and clinically review vendors and products.[5] The Surgical Group agreed to use the selected products where medically appropriate, which might have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. For many of the recommendations, the Arrangement used objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and, in some cases, national data to establish "floors" below which no savings would accrue to the Surgical Group. For example, the cell saver was previously being set up for 100% of the cardiac procedures specified under the Arrangement, but was not actually used in all cases. The Arrangement established a 30% "floor" based upon best practice utilization. The Surgical Group has not been credited with any savings resulting from any reductions in cell saver use below this 30% floor. In other words, if cell saver use dropped below 30% of cases, no cost savings were allocated to the surgeons. Similarly for Aprotinin, the Arrangement established a 10% "floor" based upon national best practice data.[6] Under the Arrangement, savings from reduced use of Aprotinin have not been credited to the Surgical Group if the savings resulted from utilization of Aprotinin in fewer than 10% of cases or if the savings resulted from failure to use Aprotinin in a case that met the clinical indicators. All surgical cases – including cases in which Aprotinin was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators.

For some recommendations, no "floors" were set because the identified substitutions had no appreciable clinical significance (e.g., use of blankets) or because eliminating usage of a pharmaceutical or supply comported with national best practice data and other quality indicators. However, to ensure that these recommendations did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital's performance of the covered cardiac procedures against the quality indicators established by the Society of Thoracic Surgeons ("STS") throughout the base year and contract year (as defined below). According to the Requestors, the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines

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[5]The Executive Summary identified with specificity the products at issue.

[6]According to the Requestors, the 10% floor represented a change in the national best practice baseline from an earlier 20% floor.

and incorporate specificity sufficient to correlate outcomes with operating room practices. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Surgical Group for procedures involving reductions in historical STS quality indicators.

Importantly, with respect to the product standardization recommendations for cardiac devices and supplies, the Requestors have certified that the individual surgeons made patient-by-patient determinations of the most appropriate device and the availability of the full range of cardiac devices was not compromised by the product standardization. The Requestors have further certified that individual physicians still had available the same selection of devices under the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-five recommendations presented substantial cost savings opportunities for the Hospital without any adverse impact on the quality of patient care.

Under the Arrangement, the Hospital intends to pay the Surgical Group 50% of the cost savings achieved by implementing the twenty-five recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each of the twenty-five recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization reduced below the set targets, as applicable, were not credited to the Surgical Group. The payment, when made, will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year[7] for the items specified in the twenty-five recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "contract year costs") from the historic costs for the same items when used during comparable surgical procedures in the base year[8] (the "base year costs"). The contract year costs were adjusted to account for any

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[7]The contract year was the twelve-month term for which the Surgical Group would be compensated under the Arrangement.

[8]The "base year" was the twelve months preceding the contract year term. For purposes of this opinion, the Arrangement was limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any renewal or extension of the

inappropriate reductions in use of items beyond the targets set in the Executive Summary or in connection with reductions in the STS quality indicators. The payment to the Surgical Group was calculated to be 50% of the difference between the adjusted contract year costs and base year costs. Under the Arrangement, the Hospital is obligated to make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a *per capita* basis.

Calculation of the payment to the Surgical Group was also subject to the following limitations:

- If the Surgical Group's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a surgeon had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the surgeon at issue would have been terminated from participation in the Arrangement. No surgeons were terminated.

- The Executive Summary identified projected cost savings, and the aggregate payment to the Surgical Group, when made, will not exceed 50% of those amounts.

The Hospital and the Surgical Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgical Group disclosed the Arrangement to patients, including the fact that the Surgical Group's compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had

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Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement would need to have incorporated updated base year costs.

an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to

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[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement might have induced physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-five individual recommendations, we conclude that, except for a limited number of the identified product substitutions,[11] the recommendations implicated the CMP. Simply put, with respect to all but a handful of the recommendations, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Hospital.[12] We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

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[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

[11]As described in Section I.B of this opinion, a few of the product substitution recommendations involved actions that should have had no appreciable clinical significance, such as substituting a reusable blanket for a disposable one. For these recommendations, we believe there would be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

[12]This is true even though the Hospital has not yet paid the Surgical Group.

Notwithstanding, several features of the Arrangement, in combination, provided sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and continues to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[13]

Third, the amount to be paid under the Arrangement has been calculated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Arrangement applied were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds (or similar benchmarks) beyond which no savings accrued to the Surgical Group. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. Moreover, the Requestors have certified that the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices; the indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific

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[13]We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

changes in operating room practices. No cost sharing amounts were allocated to the Surgical Group where there were reductions in historical STS quality indicators.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies under the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

Sixth, the Hospital and the Surgical Group provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[14]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because Surgical Group distributes profits to its members on a *per capita* basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely

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[14]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Surgical Group was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

As with any compensation arrangement between a hospital and a physician who admits or refers patients to the hospital, we are concerned that the Arrangement could have been used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group or its surgeons. Specifically, the Arrangement could have encouraged the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performed at the Hospital, the more money he or she was likely to receive under the Arrangement.

While we believe the Arrangement might have resulted in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduce the likelihood that the Arrangement was used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to surgeons already on the medical staff, thus limiting the likelihood that the Arrangement would attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract year for which payments were calculated was limited to one year, reducing any incentive for physicians to switch facilities to earn cost savings payments, and patient admissions were monitored for changes in severity, age, or payor to ensure that the Arrangement did not result in inappropriate changes in referral patterns. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement might have been used to reward cardiologists or other physicians who refer patients to the Surgical Group or its surgeons. The Surgical Group is the sole participant in the Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgical Group or share in its profit distributions. Within the Surgical Group, profits are

distributed to its members on a *per capita* basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments are based. While many of the recommendations in the Executive Summary are simple common sense, they did represent a change in operating room practice, for which the surgeon was responsible and has liability exposure. While most of the recommendations appear to present minimal risk, the preparation of the cell saver, limiting the use of certain surgical supplies, product substitution of pharmacy items and supplies, and product standardization each carried some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that could be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twenty-five recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific

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[15]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments owed under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: July 31, 2008

Posted: August 7, 2008

To: ATTACHED DISTRIBUTION LIST

Re: OIG Advisory Opinion No. 08-09

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement under which a medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Arrangement"). The cost savings are measured based on the surgeons' reduction of waste and use of specific medical devices and supplies during designated spine fusion surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") will not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Medical Center. [Name redacted] Medical Center (the "Medical Center") is an academic medical center in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including spine fusion surgery services. The Medical Center is a participating provider in the Medicare and Medicaid programs.

The Orthopedic Surgery Groups. [Names redacted] (the "Orthopedic Surgery Groups") are group medical practices that employ only orthopedic surgeons. The members of the Orthopedic Surgery Groups participating in the Arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[1] They refer patients to the Medical Center for inpatient and outpatient hospital services. Both groups entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Neurosurgery Group. [Name redacted] (the "Neurosurgery Group") employs only neurosurgeons. The members of the Neurosurgery Group participating in the arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[2] The Neurosurgery Group refers patients to the

[1]The Orthopedic Surgery Groups include members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Orthopedic Surgery Groups.

Medical Center for inpatient and outpatient hospital services. The Neurosurgery Group entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Program Administrator. The Medical Center engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data and analyzed and manages the Arrangement.[3] The Medical Center paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or to the compensation of the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement.

B. The Arrangement

Under the Arrangement, the Medical Center agreed to pay the Orthopedic Surgery Groups and the Neurosurgery Group a share of the first year cost savings directly attributable to specific changes made in the Orthopedic Surgery Groups' and the Neurosurgery Group's operating room practices. The Requestors implemented the Arrangement – and the Orthopedic Surgery Groups and the Neurosurgery Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Medical Center has not paid amounts owed to the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement pending the outcome of this opinion.[4] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Medical Center will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

To develop the Arrangement, the Program Administrator conducted a study of historic practices in spine fusion surgery by the Orthopedic Surgery Groups and the Neurosurgery Group at the Medical Center and identified thirty-six specific cost-savings opportunities. The Program Administrator summarized the results of the study of the historic practices of the Orthopedic Surgery Groups and the Neurosurgery Group and the specific cost-

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[2]The Neurosurgery Group includes members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Neurosurgery Group.

[3]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis.

[4]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

savings opportunities in a document entitled, "Executive Summary [name redacted] Valueshare for Spine Surgery" (the "Executive Summary").

The Medical Center, the Orthopedic Surgery Groups and the Neurosurgery Group reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.[5]

In general, the Executive Summary recommended that the Orthopedic Surgery Groups and the Neurosurgery Group change their operating room practices to standardize the use of spine fusion devices and supplies. The Executive Summary identified thirty-six specific recommendations that can be roughly grouped into the following two categories.

- *"Use as Needed" Biological*. The first category, containing a single recommendation, involved limiting the use of Bone Morphogenetic Protein ("BMP") to an as needed basis. The Requestors have certified that the individual surgeon made patient-by-patient determinations as to whether BMP was clinically indicated and that the biological remained readily available to the surgeons. The Requestors further certified that any resulting limitation on the use of BMP did not adversely affect patient care.

- *Product Standardization.* For the second category, involving thirty-five recommendations, the Orthopedic Surgery Groups and the Neurosurgery Group were to standardize the use of certain spine fusion devices and supplies where medically appropriate. For this category, the Orthopedic Surgery Groups and the Neurosurgery Group were required to work in conjunction with the Medical Center to evaluate and clinically review vendors and products.[6] The Orthopedic Surgery Groups and the Neurosurgery Group agreed to use the selected products where medically appropriate, which may have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. With respect to the use as needed recommendation, the Arrangement utilized objective historical and clinical measures reasonably related to the

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[5]The Executive Summary, dated December 31, 2006, is attached to this advisory opinion as Appendix A. The approaches of the orthopedic surgeons and the neurosurgeons to spine fusion surgery overlap, often making use of same methods, devices, and supplies. No distinctions are made in the Executive Summary between the two types of surgeons in terms of past practices or gainsharing recommendations.

[6]The Executive Summary identified with specificity the vendors and products at issue.

practices and the patient population at the Medical Center to establish a "floor" beyond which no savings would accrue to the Orthopedic Surgery Groups or the Neurosurgery Group. The Arrangement used specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Medical Center and its patient population to determine medical appropriateness.

Before the implementation of the Arrangement, BMP had been used in approximately 15% of patients undergoing spine fusion procedures by the Orthopedic Surgery Groups and the Neurosurgery Group. The Program Administrator determined through analysis of national data that it was reasonable to reduce the use of BMP on these cases to 11% of patients and that this reduction would not adversely impact patient care. Under the Arrangement, savings from reduced use of BMP were not credited to the Orthopedic Surgery Groups and the Neurosurgery Group if the savings resulted from utilization of BMP in less than 11% of cases or if the savings resulted from failure to use BMP in a case that met the clinical indicators. All surgical cases – including cases in which BMP was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether BMP was used appropriately.

Importantly, with respect to the product standardization recommendations, the Requestors certified that the individual surgeons made a patient-by-patient determination of the most appropriate spine fusion devices and supplies and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty-six recommendations presented substantial cost savings opportunities for the Medical Center without adversely impacting the quality of patient care.

Under the Arrangement, the Medical Center intends to pay each of the Orthopedic Surgery Groups and the Neurosurgery Group individually for 50% of the cost savings achieved by the respective group when implementing the thirty-six recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each group and for each of the thirty-six recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization beyond set targets, as applicable were not credited to the Orthopedic Surgery Groups or the Neurosurgery Group.

The payments, when made, to the Orthopedic Surgery Groups and Neurosurgery Groups, respectively, will constitute the entire compensation paid to the Orthopedic Surgery Groups and the Neurosurgery Group for services performed under the contracts memorializing the Arrangement between the respective groups and the Medical Center. For purposes of calculating the payments to the Orthopedic Surgery Groups and the Neurosurgery Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year[7] for the items specified in the thirty-six recommendations when used by surgeons in each respective group, as applicable, during the specified surgical procedures (the "contract year costs") from the historic costs for the same items when used by the particular group during comparable surgical procedures in the base year (the "base year costs"[8]). The contract year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary. The payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will be 50% of the difference between each respective group's adjusted current year costs and the base year costs less 50% of the costs incurred by the Medical Center to administer the Arrangement.

Under the Arrangement, the Medical Center is obligated to make aggregate payments to the practices which comprise the Orthopedic Surgery Groups and the Neurosurgery Group, each of which distributes its respective profits among its members on a per capita basis.

Calculation of payments to the Orthopedic Surgery Groups and the Neurosurgery Group was subject to the following limitations:

- If the volumes of procedures payable by a Federal health care program performed by each of the three physician groups in the gainsharing year exceeded that individual group's volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of

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[7]The contract year was the twelve-month term for which the Orthopedic Surgery Groups and the Neurosurgery Group were compensated under the Arrangement.

[8]The "base year" was the twelve months preceding the effective date of the contracts. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a surgeon had altered his or her referral patterns in a manner beneficial to the Medical Center as a result of the Arrangement, the surgeon at issue would have been terminated from participation in the Arrangement. No surgeons were terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will not exceed 50% of the group's share of projected cost savings; each group, furthermore, will be compensated solely for its own savings under the Arrangement.

The Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group disclosed the Arrangement to the patients, including the fact that compensation of the Orthopedic Surgery Groups and the Neurosurgery Group was based on a percentage of the Medical Center's cost savings. The disclosure was made to the patient before the patient was admitted to the Medical Center for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and

more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

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[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty-six individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Medical Center. [11] We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applied to the recommendations for the standardization of devices and supplies, and limiting the use of BMP. Notwithstanding, several features of the Arrangement, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allows for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[12]

Third, the amount to be paid under the Arrangement was calculated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal

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[11] This is true even though the Medical Center has not yet paid the Orthopedic Surgery Groups and the Neurosurgery Group.

[12] We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

health care program procedures. Moreover, the surgical procedures to which the Arrangement applies were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated from the Medical Center's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Orthopedic Surgery Groups or the Neurosurgery Group. The Requestors have certified that these baseline measures were reasonably related to the Medical Center's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

Sixth, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Medical Center (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because the Orthopedic Surgery Groups and the Neurosurgery Group distribute profits to their respective members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory

[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

Bulletin on "Gainsharing Arrangements and CMPs for Medical Center Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from many "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

Many "gainsharing" plans present substantial risks for both patient and program abuse – risks that were not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Orthopedic Surgery Groups and the Neurosurgery Group was calculated on a percentage basis, and thus the compensation could not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

We are concerned that the Arrangement, like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, could be used to disguise remuneration from the Medical Center to reward or induce referrals by the Orthopedic Surgery Groups or the Neurosurgery Group. Specifically, the Arrangement could have encouraged the surgeons to admit Federal health care program patients to the Medical Center, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Medical Center's payment, depending on cost savings. In other words, the more procedures a surgeon performed at the Medical Center, the more money he or she is likely to have received under the Arrangement.

While we believe the Arrangement might have resulted in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement was used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to surgeons already on the medical staff, thus limiting the likelihood that the Arrangement would attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the participating physicians' prior year's admissions of Federal health care program beneficiaries. Finally, the contracts' terms were limited to one year, reducing any incentive to switch facilities, and admissions were monitored for changes in severity, age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement might be used to reward surgeons or other physicians who refer patients to the Orthopedic Surgery Groups, the Neurosurgery Group, or their surgeons. The Orthopedic Surgery Groups and the Neurosurgery Group, the only participants in the Arrangement, were composed entirely of surgeons who perform spine fusion surgery; no other types of physicians were members of the Orthopedic Surgery Groups or the Neurosurgery Group, or shared in their profit distributions. Within each of the three practices, profits were distributed to members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations represented a change in operating room practice, for which the surgeon was responsible and had liability exposure. Product standardization and limiting the use of BMP each carried some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that could be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the thirty-six recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Orthopedic Surgery Groups and the Neurosurgery Group.[14] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately

[14]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG will not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/
Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: **October 6, 2008**

Posted: **October 14, 2008**

Re: OIG Advisory Opinion No. 08-15

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital shares with groups of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain procedures (the "Arrangement"). The cost savings are measured based on the cardiologists' use of specific supplies during designated cardiac catheterization laboratory procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Name redacted] ("Group A") is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group A refers patients to the Hospital for inpatient and outpatient hospital services. [Name redacted] ("Group B") is another limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group B also refers patients to the Hospital for inpatient and outpatient hospital services (Group A and Group B are herein referred to, individually, as "a Cardiology Group" and, in combination, as "the Cardiology Groups").[1] The Cardiology Groups perform nearly all of the cardiac catheterization laboratory services at the Hospital. Occasionally a case is completed by another group or by solo practitioners.

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[1]Groups A and B both have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in Groups A and B.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collects data and analyzes and manages the Arrangement.[2] The Hospital pays the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee is not tied in any way to cost savings or the Cardiology Groups' compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agrees to pay each Cardiology Group a share of three years of cost savings directly attributable to specific changes in that particular group's cardiac catheterization laboratory practices. The Requestors have implemented the three-year Arrangement under which payments are owed to each of the Cardiology Groups at the end of each year (as described in greater detail below). The Cardiology Groups have initiated the specific changes in cardiac catheterization laboratory procedures and the Arrangement is still on-going. The Hospital has not paid amounts owed to the Cardiology Groups under the Arrangement, however, pending the outcome of this opinion.[3] The Requestors have certified that the Hospital will make payments owed under the Arrangement should the Requestors receive a favorable advisory opinion. The Cardiology Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices of the Cardiology Groups at the Hospital's cardiac catheterization laboratory and identified thirty specific cost savings opportunities. The results of the Program Administrator's study and the specific cost savings opportunities were summarized in a document entitled, "Executive Summary [name redacted] Valueshare for Cardiology" (the "Executive Summary").[4] The Hospital and the Cardiology Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

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[2]The Program Administrator's software product that measures cost, quality, and utilization on a national basis is certified by the American College of Cardiology.

[3]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[4]The Executive Summary is attached to this advisory opinion as Appendix A.

In general, the Executive Summary recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to standardize use of medical devices and supplies and to curb the inappropriate use or waste of medical devices and supplies. The thirty recommendations can be roughly grouped into three categories.

- *Product Standardization.* For the first category, involving twenty-five recommendations, the Executive Summary recommends that the Cardiology Groups standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators) they employ.[5] The Cardiology Groups are required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

- *"Use as needed" Devices.* The second category, consisting of four recommendations, involves limiting the use of specific vascular closure devices to an "as needed" basis (hereinafter, the "use as needed" recommendations) for coronary and peripheral interventional procedures and diagnostic procedures. The Requestors certified that the cardiologists make patient-by-patient determinations as to whether the devices are clinically indicated, and that any resulting limitation in use of these devices does not adversely affect patient care. The Requestors further certified that the specific vascular closure devices remain readily available in the procedure room.

- *Product Substitution*. The third category involves a single recommendation to substitute, as appropriate, less costly anti-thrombotic medication for other products being used by the cardiologists (hereafter, the "product substitution"). This recommendation may have an appreciable clinical significance. The Requestors certified that the identified product substitution does not adversely impact patient care.

The Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, in connection with the product standardization, product substitution, and use as needed recommendations, the Requestors certified that the

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[5]We note that the Executive Summary identifies with specificity the vendors and products at issue.

individual cardiologists make a patient-by-patient determination of the most appropriate device or supply, and the availability of the full range of devices and supplies is not compromised by the product standardization, product substitution, and use as needed recommendations. The Requestors further certified that individual physicians still have available the same selection of devices and medications after implementation of the Arrangement as before, and that the economies gained through the Arrangement result from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

With respect to the use as needed recommendations for vascular closure devices, the Arrangement utilizes objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish "floors" beyond which no savings accrue to the Cardiology Groups. For example, according to the Requestors, vascular closure devices for peripheral interventional cases had previously been utilized at the Hospital on 40% of the cases specified under the Arrangement. The Program Administrator determined through analysis of national data that it would be reasonable to reduce the use of vascular closure devices on these cases to 15% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Groups receive no share of any savings resulting from the reduction of use of vascular closure devices for peripheral intervention beyond the 15% floor.

For the product substitution, no "floors" were set because substituting usage of the anti-thrombotic medication comported with national guidelines and other quality indicators. However to ensure that this recommendation does not adversely affect the quality of care at the Hospital, the Program Administrator is tracking the Hospital's performance of the covered cardiac procedures against quality indicators established by the American College of Cardiology ("ACC") throughout the base years and contract years. (See infra definitions notes 6 and 7.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in catheterization lab practices. The ACC indicators incorporate enough specificity to permit correlation of outcomes with catheterization lab practices. No cost sharing amounts are allocated to the Cardiology Groups for procedures involving reductions in historical ACC quality indicators.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Cardiology Groups separately for 50% of the yearly savings achieved by the particular group when implementing the thirty recommendations in the Executive Summary. At the end of each year of the three-year Arrangement, cost savings are calculated separately for each group and for each of the thirty recommendations; this precludes shifting of cost savings and ensures that savings generated by utilization beyond the set targets, as applicable, are not credited to the Cardiology Groups.

The sum of all three annual payments to each Cardiology Group, when made, will constitute the entire compensation paid to the particular group for services performed under the contract memorializing the Arrangement between that Cardiology Group and the Hospital. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the thirty recommendations when used by cardiologists in the particular Cardiology Group during the specified procedures (the "current year costs"[6]) are subtracted from the costs for the same items when used during comparable procedures in the respective base year (the "base year costs"[7]). The Requestors are rebasing the Arrangement at the end of each year so that the Cardiology Groups will not receive duplicate payments for savings achieved in prior years. Specifically, at the end of the first year, the Requestors calculated the amounts owed to the Cardiology Groups as described above. The Requestors then reset the base year so that the first year of the Arrangement became the base year for the second year of the Arrangement. The same rebasing will occur for the third year. This annual rebasing method removes earlier accomplished savings from the accounting.

The current year costs for each of the three years are adjusted to account for any inappropriate reductions in the use of items beyond the targets set in the Executive

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[6]The term "current year costs" used here represents the actual costs incurred during each of the three twelve-month periods which comprise the Arrangement. Current year costs were calculated for year one of the Arrangement, recalculated for year two, and will be recalculated again for year three.

[7]Figures for three successive "base years" have been calculated from historical costs during the twelve months immediately preceding the contracts' year one, year two, and year three, respectively. For purposes of this opinion, the Arrangement is limited to the three-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated current year and base year costs.

Summary. After receipt of a favorable advisory opinion, year-end payments will separately be made to the groups for 50% of the difference between their respective adjusted current year costs and base year costs for the first, second, and third years, if any. Under the Arrangement, the Hospital is obligated to make these aggregate payments to the Cardiology Groups, both of which distribute profits among members on a per capita basis.

Calculation of payments to the Cardiology Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year which preceded it, there is no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement are monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a cardiologist had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the cardiologist at issue would have been terminated from participation in the Arrangement. No cardiologists have been terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Cardiology Group, when made, will not exceed 50% of that group's share of the projected cost savings identified in the initial base year. Each group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Cardiology Groups document the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups disclose the Arrangement to the patients, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure is made to the patient before the patient is admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure is made before the patient consents to the procedure. The disclosures are in writing, and patients have an opportunity, if they desire, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct

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[8] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty recommendations, we conclude that the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding the standardization of devices and supplies, the limitations on the use of vascular closure devices, and product substitution of the anti-thrombotic medication, the Arrangement might induce physicians to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for the standardization of devices, limiting the use of vascular closure devices, and product substitution of the anti-thrombotic medication. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings have been clearly and separately identified. The transparency of the Arrangement has allowed for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The

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[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

transparency of the incentives for specific actions and specific procedures has also facilitated accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations does not adversely affect patient care. The Arrangement has been periodically reviewed by the Requestors to confirm that the Arrangement does not have an adverse impact on clinical care.[10]

Third, the amounts to be paid under the Arrangement have been based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applies have not been disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated based on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement has protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures have been reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards have been action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization laboratory practices.

Fifth, the product standardization portion of the Arrangement has further protected against inappropriate reductions in services by ensuring that individual physicians still have available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

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[10]We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

Sixth, the Hospital and the Cardiology Groups have provided written disclosures of their involvement in the Arrangement to patients whose care might be affected by the Arrangement and have provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosures offer some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Arrangement have been reasonably limited in duration and amount.

Eighth, because each of the Cardiology Groups distributes its profits to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items and medications used in cardiac catheterization laboratory procedures, we believe that patient satisfaction surveys would not be effective.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment to be owed the Cardiology Groups is to be calculated on a percentage basis, and thus the aggregate compensation is not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

Multiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once. The resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent. The annual rebasing method adopted by the Requestors removes earlier accomplished savings from the accounting and thereby avoids improper duplication of physician payments, reducing the accompanying risk of kickbacks.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement have reduced the likelihood that the Arrangement is being used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement has been limited to cardiologists already on the medical staff, thus limiting the likelihood that the Arrangement attracts other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries have been capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments are calculated has been limited to one year (and the Arrangement is rebased annually as described above), and the overall amount of available cost savings payments over the entire three-year term of the contract has been capped, reducing any incentive to switch facilities. Finally, admissions have been monitored for changes in severity, age, or payor. Thus, while the incentive to refer has not necessarily eliminated, it has been substantially reduced.

Second, the structure of the Arrangement has eliminated the risk that the Arrangement is used to reward cardiologists or other physicians who refer patients to the Cardiology Groups, or their cardiologists. The Cardiology Groups have been the sole participants in the Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in their profit distributions. Within the

Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Arrangement has set out with specificity the particular actions that generate the cost savings on which the payments are based. The recommendations in the Executive Summary have represented a change in catheterization laboratory practice, for which the cardiologist is responsible and has liability exposure. The product standardization, limitation on use of vascular closure devices, and product substitution have each carried some increased liability risk for the physicians. It is not unreasonable for the cardiologists to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made represent portions of three years' worth of cost savings and have been limited in amount (i.e., the rebasing and aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions that have been required of the physicians to implement the thirty recommended actions, the specificity of the payment formula, the annual rebasing, and the cap on total remuneration to the Cardiology Groups.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: **October 6, 2008**

Posted: **October 14, 2008**

Re: OIG Advisory Opinion No. 08-15

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital shares with groups of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain procedures (the "Arrangement"). The cost savings are measured based on the cardiologists' use of specific supplies during designated cardiac catheterization laboratory procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Name redacted] ("Group A") is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group A refers patients to the Hospital for inpatient and outpatient hospital services. [Name redacted] ("Group B") is another limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group B also refers patients to the Hospital for inpatient and outpatient hospital services (Group A and Group B are herein referred to, individually, as "a Cardiology Group" and, in combination, as "the Cardiology Groups").[1] The Cardiology Groups perform nearly all of the cardiac catheterization laboratory services at the Hospital. Occasionally a case is completed by another group or by solo practitioners.

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[1]Groups A and B both have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in Groups A and B.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collects data and analyzes and manages the Arrangement.[2] The Hospital pays the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee is not tied in any way to cost savings or the Cardiology Groups' compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agrees to pay each Cardiology Group a share of three years of cost savings directly attributable to specific changes in that particular group's cardiac catheterization laboratory practices. The Requestors have implemented the three-year Arrangement under which payments are owed to each of the Cardiology Groups at the end of each year (as described in greater detail below). The Cardiology Groups have initiated the specific changes in cardiac catheterization laboratory procedures and the Arrangement is still on-going. The Hospital has not paid amounts owed to the Cardiology Groups under the Arrangement, however, pending the outcome of this opinion.[3] The Requestors have certified that the Hospital will make payments owed under the Arrangement should the Requestors receive a favorable advisory opinion. The Cardiology Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices of the Cardiology Groups at the Hospital's cardiac catheterization laboratory and identified thirty specific cost savings opportunities. The results of the Program Administrator's study and the specific cost savings opportunities were summarized in a document entitled, "Executive Summary [name redacted] Valueshare for Cardiology" (the "Executive Summary").[4] The Hospital and the Cardiology Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

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[2]The Program Administrator's software product that measures cost, quality, and utilization on a national basis is certified by the American College of Cardiology.

[3]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[4]The Executive Summary is attached to this advisory opinion as Appendix A.

In general, the Executive Summary recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to standardize use of medical devices and supplies and to curb the inappropriate use or waste of medical devices and supplies. The thirty recommendations can be roughly grouped into three categories.

- *Product Standardization.* For the first category, involving twenty-five recommendations, the Executive Summary recommends that the Cardiology Groups standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators) they employ.[5] The Cardiology Groups are required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

- *"Use as needed" Devices.* The second category, consisting of four recommendations, involves limiting the use of specific vascular closure devices to an "as needed" basis (hereinafter, the "use as needed" recommendations) for coronary and peripheral interventional procedures and diagnostic procedures. The Requestors certified that the cardiologists make patient-by-patient determinations as to whether the devices are clinically indicated, and that any resulting limitation in use of these devices does not adversely affect patient care. The Requestors further certified that the specific vascular closure devices remain readily available in the procedure room.

- *Product Substitution*. The third category involves a single recommendation to substitute, as appropriate, less costly anti-thrombotic medication for other products being used by the cardiologists (hereafter, the "product substitution"). This recommendation may have an appreciable clinical significance. The Requestors certified that the identified product substitution does not adversely impact patient care.

The Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, in connection with the product standardization, product substitution, and use as needed recommendations, the Requestors certified that the

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[5]We note that the Executive Summary identifies with specificity the vendors and products at issue.

individual cardiologists make a patient-by-patient determination of the most appropriate device or supply, and the availability of the full range of devices and supplies is not compromised by the product standardization, product substitution, and use as needed recommendations. The Requestors further certified that individual physicians still have available the same selection of devices and medications after implementation of the Arrangement as before, and that the economies gained through the Arrangement result from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

With respect to the use as needed recommendations for vascular closure devices, the Arrangement utilizes objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish "floors" beyond which no savings accrue to the Cardiology Groups. For example, according to the Requestors, vascular closure devices for peripheral interventional cases had previously been utilized at the Hospital on 40% of the cases specified under the Arrangement. The Program Administrator determined through analysis of national data that it would be reasonable to reduce the use of vascular closure devices on these cases to 15% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Groups receive no share of any savings resulting from the reduction of use of vascular closure devices for peripheral intervention beyond the 15% floor.

For the product substitution, no "floors" were set because substituting usage of the anti-thrombotic medication comported with national guidelines and other quality indicators. However to ensure that this recommendation does not adversely affect the quality of care at the Hospital, the Program Administrator is tracking the Hospital's performance of the covered cardiac procedures against quality indicators established by the American College of Cardiology ("ACC") throughout the base years and contract years. (See infra definitions notes 6 and 7.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in catheterization lab practices. The ACC indicators incorporate enough specificity to permit correlation of outcomes with catheterization lab practices. No cost sharing amounts are allocated to the Cardiology Groups for procedures involving reductions in historical ACC quality indicators.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Cardiology Groups separately for 50% of the yearly savings achieved by the particular group when implementing the thirty recommendations in the Executive Summary. At the end of each year of the three-year Arrangement, cost savings are calculated separately for each group and for each of the thirty recommendations; this precludes shifting of cost savings and ensures that savings generated by utilization beyond the set targets, as applicable, are not credited to the Cardiology Groups.

The sum of all three annual payments to each Cardiology Group, when made, will constitute the entire compensation paid to the particular group for services performed under the contract memorializing the Arrangement between that Cardiology Group and the Hospital. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the thirty recommendations when used by cardiologists in the particular Cardiology Group during the specified procedures (the "current year costs"[6]) are subtracted from the costs for the same items when used during comparable procedures in the respective base year (the "base year costs"[7]). The Requestors are rebasing the Arrangement at the end of each year so that the Cardiology Groups will not receive duplicate payments for savings achieved in prior years. Specifically, at the end of the first year, the Requestors calculated the amounts owed to the Cardiology Groups as described above. The Requestors then reset the base year so that the first year of the Arrangement became the base year for the second year of the Arrangement. The same rebasing will occur for the third year. This annual rebasing method removes earlier accomplished savings from the accounting.

The current year costs for each of the three years are adjusted to account for any inappropriate reductions in the use of items beyond the targets set in the Executive

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[6]The term "current year costs" used here represents the actual costs incurred during each of the three twelve-month periods which comprise the Arrangement. Current year costs were calculated for year one of the Arrangement, recalculated for year two, and will be recalculated again for year three.

[7]Figures for three successive "base years" have been calculated from historical costs during the twelve months immediately preceding the contracts' year one, year two, and year three, respectively. For purposes of this opinion, the Arrangement is limited to the three-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated current year and base year costs.

Summary. After receipt of a favorable advisory opinion, year-end payments will separately be made to the groups for 50% of the difference between their respective adjusted current year costs and base year costs for the first, second, and third years, if any. Under the Arrangement, the Hospital is obligated to make these aggregate payments to the Cardiology Groups, both of which distribute profits among members on a per capita basis.

Calculation of payments to the Cardiology Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year which preceded it, there is no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement are monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a cardiologist had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the cardiologist at issue would have been terminated from participation in the Arrangement. No cardiologists have been terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Cardiology Group, when made, will not exceed 50% of that group's share of the projected cost savings identified in the initial base year. Each group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Cardiology Groups document the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups disclose the Arrangement to the patients, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure is made to the patient before the patient is admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure is made before the patient consents to the procedure. The disclosures are in writing, and patients have an opportunity, if they desire, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct

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[8] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty recommendations, we conclude that the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding the standardization of devices and supplies, the limitations on the use of vascular closure devices, and product substitution of the anti-thrombotic medication, the Arrangement might induce physicians to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for the standardization of devices, limiting the use of vascular closure devices, and product substitution of the anti-thrombotic medication. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings have been clearly and separately identified. The transparency of the Arrangement has allowed for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The

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[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

transparency of the incentives for specific actions and specific procedures has also facilitated accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations does not adversely affect patient care. The Arrangement has been periodically reviewed by the Requestors to confirm that the Arrangement does not have an adverse impact on clinical care.[10]

Third, the amounts to be paid under the Arrangement have been based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applies have not been disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated based on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement has protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures have been reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards have been action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization laboratory practices.

Fifth, the product standardization portion of the Arrangement has further protected against inappropriate reductions in services by ensuring that individual physicians still have available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

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[10]We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

Sixth, the Hospital and the Cardiology Groups have provided written disclosures of their involvement in the Arrangement to patients whose care might be affected by the Arrangement and have provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosures offer some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Arrangement have been reasonably limited in duration and amount.

Eighth, because each of the Cardiology Groups distributes its profits to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items and medications used in cardiac catheterization laboratory procedures, we believe that patient satisfaction surveys would not be effective.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment to be owed the Cardiology Groups is to be calculated on a percentage basis, and thus the aggregate compensation is not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

Multiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once. The resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent. The annual rebasing method adopted by the Requestors removes earlier accomplished savings from the accounting and thereby avoids improper duplication of physician payments, reducing the accompanying risk of kickbacks.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement have reduced the likelihood that the Arrangement is being used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement has been limited to cardiologists already on the medical staff, thus limiting the likelihood that the Arrangement attracts other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries have been capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments are calculated has been limited to one year (and the Arrangement is rebased annually as described above), and the overall amount of available cost savings payments over the entire three-year term of the contract has been capped, reducing any incentive to switch facilities. Finally, admissions have been monitored for changes in severity, age, or payor. Thus, while the incentive to refer has not necessarily eliminated, it has been substantially reduced.

Second, the structure of the Arrangement has eliminated the risk that the Arrangement is used to reward cardiologists or other physicians who refer patients to the Cardiology Groups, or their cardiologists. The Cardiology Groups have been the sole participants in the Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in their profit distributions. Within the

Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Arrangement has set out with specificity the particular actions that generate the cost savings on which the payments are based. The recommendations in the Executive Summary have represented a change in catheterization laboratory practice, for which the cardiologist is responsible and has liability exposure. The product standardization, limitation on use of vascular closure devices, and product substitution have each carried some increased liability risk for the physicians. It is not unreasonable for the cardiologists to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made represent portions of three years' worth of cost savings and have been limited in amount (i.e., the rebasing and aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions that have been required of the physicians to implement the thirty recommended actions, the specificity of the payment formula, the annual rebasing, and the cap on total remuneration to the Cardiology Groups.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: **November 25, 2008**

Posted: **December 8, 2008**

To: **Attached Distribution List**

Re: **OIG Advisory Opinion No. 08-21**

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital has agreed to share with four cardiology groups and one radiology group a percentage of the hospital's cost savings arising from the physicians' implementation over two years of a number of cost reduction measures in certain cardiac catheterization procedures[1] (the "Arrangement"). The cost savings are measured based on the physicians' use of specific medical devices and supplies during designated cardiac catheterization procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

[1]We note that the request refers to cardiac catheterization laboratory and special procedures laboratory procedures, services, practices, etc. For purposes of this opinion, we will refer to them collectively as "cardiac catheterization" procedures, services, practices, etc.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Name redacted] is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. [Name redacted] is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. [Name redacted] is a professional medical corporation that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the

Hospital. [Name redacted] is a professional medical corporation that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] who have active medical staff privileges at the Hospital. These practice groups are herein referred to, individually, as a "Cardiology Group" and, in combination, as the "Cardiology Groups." The Cardiology Groups refer patients to the Hospital for inpatient and outpatient hospital services. Each Cardiology Group entered into a separate contract with the Hospital that set forth the projected savings opportunities available to that practice.

The Radiology Group. [Name redacted] (the "Radiology Group") is a limited liability company that employs exclusively interventional radiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. The Radiology Group refers patients to the Hospital for inpatient and outpatient hospital services. The Radiology Group entered into a separate contract with the Hospital that set forth the projected savings opportunities available to the practice.

In combination, the Cardiology Groups and the Radiology Group, herein referred to, individually, as a "Group" and, in combination, as the "Groups," perform nearly all of the cardiac catheterization services at the Hospital.[2] Occasionally a case is completed by another group or by solo practitioners.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator has collected data and analyzed and manages the Arrangement.[3] The Hospital has paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee has not been tied in any way to cost savings or the Groups' compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital has agreed to pay each Group a share of cost savings directly attributable to specific changes in that particular Group's cardiac catheterization

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[2]The Groups have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the physicians in the Groups.

[3] The Program Administrator has developed a software product that measures cost, quality, and utilization on a national basis. The product is certified by the American College of Cardiology.

practices over two years. The Requestors implemented the Arrangement – and the Groups began performance of the specific changes in cardiac catheterization practices – prior to requesting this advisory opinion. The Hospital has not paid amounts owed to the Groups under the Arrangement, however, pending the outcome of this opinion.[4] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion. The Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historical practices of the Groups with respect to cardiac catheterization procedures performed at the Hospital and identified twenty-three specific cost savings opportunities. The Program Administrator summarized the results of its study and the specific cost savings opportunities in a document entitled, "EXECUTIVE SUMMARY [NAME REDACTED] VALUESHARE FOR CARDIOLOGY" (the "Executive Summary").[5] The Hospital and the Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

In general, the Executive Summary recommended that the Groups change current cardiac catheterization practices to standardize their use of medical devices and supplies and to curb the inappropriate use or waste of medical devices and supplies. The Executive Summary identified twenty-seven specific recommendations that can be grouped roughly into the following three categories.[6]

- *Product Standardization.* For the first category, involving twenty-two recommendations, the Executive Summary recommended that the Groups standardize the types of cardiac catheterization devices and supplies (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices,

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[4]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[5]The Executive Summary is attached to this advisory opinion as Appendix A.

[6]While the Executive Summary contains twenty-three specific cost-savings opportunities, some of those opportunities include more than one recommendation and can therefore be classified in more than one category. Thus, the total number of recommendations exceeds the total number of cost-savings opportunities identified in the Executive Summary.

pacemakers, defibrillators and contrast agents) they employ.[7] The Groups were required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

- *"Use as needed" Devices.* The second category, consisting of three recommendations, involved limiting the use of certain vascular closure devices and cutting balloons to an "as needed" basis (hereinafter, the "use as needed" recommendations) for coronary interventional and diagnostic procedures. The Requestors further certified that the specific vascular closure devices and cutting balloons remained readily available in the procedure room.

- *Product Substitutions.* The third category involved two recommendations to substitute, as appropriate, less costly contrast agents and anti-thrombotic medications for other products being used by the physicians (hereafter, the "product substitutions"). These recommendations may have an appreciable clinical significance. The Requestors certified that neither of the identified product substitutions adversely impacted patient care.[8]

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. Importantly, with respect to the product standardization, use as needed recommendations, and product substitution, the Requestors certified that the individual physicians made a patient-by-patient determination of the most appropriate device or supply and the availability of the full range of devices and supplies was not compromised by the product standardization, use as needed recommendations, or product substitution. The Requestors have further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before, and that the economies gained through the Arrangement resulted

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[7]We note that the Executive Summary identified with specificity the vendors and products at issue.

[8]The Executive Summary identified with specificity the product substitutions.

from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

With respect to the use as needed recommendations and the product substitutions, the Arrangement utilized objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and in some cases, national averages to establish "floors" beyond which no savings accrued to any Group. For example, according to the Requestors, diagnostic vascular closure devices had previously been utilized at the Hospital on 88% of the cases specified under the Arrangement. The Program Administrator determined through analysis of national data that it would be reasonable to reduce the use of diagnostic vascular closure devices on these cases to 37% of coronary patients and that this reduction would not adversely impact patient care. Thus, the Groups receive no share of any savings resulting from the reduction of use of diagnostic vascular closure devices beyond the 37% floor.

With regard to the product substitution of contrast agents, the Program Administrator identified national averages and historical patterns of use at the Hospital or at hospitals with comparable practices and patient populations and established quality thresholds beyond which no cost savings will be credited. The Executive Summary indicated that certain less expensive contrast agents could be used in 68% of the cases without an adverse impact on patient care. Accordingly, any savings from using a less expensive contrast agent in more than 68% of the cases will not be credited to the Groups.

For the product substitution of anti-thrombotic medications, no "floors" were set because substituting usage of the medications comported with national guidelines and other quality indicators. However, to ensure that this recommendation did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital's performance of the covered cardiac catheterization procedures against the quality indicators established by the American College of Cardiology ("ACC") throughout the base years and contract years. (See infra definitions notes 9 and 10.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in cardiac catheterization practices. The ACC indicators incorporate enough specificity to permit correlation of outcomes with cardiac catheterization practices. No cost sharing amounts are allocated to the Groups for procedures involving reductions in historical ACC quality indicators.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-seven recommendations presented

substantial cost savings opportunities for the Hospital without any adverse impact on the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Groups separately for 50% of the yearly savings achieved by the particular group when implementing the applicable recommendations in the Executive Summary. At the end of each year of the two-year Arrangement, cost savings were calculated separately for each Group for each of the applicable recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization beyond the set targets, as applicable, were not credited to the Groups.

The sum of the two annual payments to each Group, when made, will constitute the entire compensation paid to the particular Group for services performed under the contract memorializing the Arrangement between that Group and the Hospital. The payment to each Group will be calculated using the same formula. For purposes of calculating the payment to each Group, the actual costs incurred for the items specified in the applicable recommendations when used by physicians of the particular Group during the specified procedures (the "current year costs"[9]) are subtracted from the historical costs for the same items when used during comparable procedures in the respective base year (the "base year costs"[10]). The Requestors rebased the Arrangement at the end of the first year so that the Groups will not receive duplicate payments for savings achieved in the first year. Specifically, at the end of the first year, Requestors calculated the amounts owed to the Groups as described above. The Requestors then reset the base year so that the first year of the Arrangement became the base year for the second year of the Arrangement. This annual rebasing method removed earlier accomplished savings from the accounting.

The current year costs for each of the two years were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary. After receipt of a favorable advisory opinion, year-end payments will be made to the

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[9]The term "current year costs" used here represents the actual costs incurred during each of the two twelve-month periods that comprise the Arrangement. Current year costs were calculated for year one of the Arrangement and recalculated at the start of year two.

[10]Figures for two successive "base years" were calculated from historical costs during the twelve months immediately preceding the contracts' year one, and year two, respectively. For purposes of this opinion, the Arrangement is limited to the two year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated current year and base year costs.

Groups for 50% of the difference between their respective adjusted current year costs and base year costs for the first and second years, if any. Under the Arrangement, the Hospital is obligated to make these aggregate payments to each Group, each of which distributes profits among members on a per capita basis.

Calculation of payments to the Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the current year exceeded the volume of like procedures payable by a Federal health care program performed in the base year which preceded it, there is no sharing of cost savings for the additional procedures.

- To minimize the physicians' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Group, when made, will not exceed 50% of the Group's share of the projected cost savings identified in the initial base year. Each Group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Groups documented the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Groups disclosed the Arrangement to the patients, including the fact that the Groups' compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the procedure. The disclosures were in writing, and each patient had an opportunity, if they desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[11] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct

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[11] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[12]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

Having reviewed the twenty-seven recommendations, we conclude that all of the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding standardization of devices and supplies, limiting use of specific vascular closure devices and cutting balloons, and substitution of contrast agent and anti-thrombotic medication, the Arrangement might induce physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for the product standardization, limiting use of devices and supplies, and product substitution. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and continues to allow, for public

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[12]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[13]

Third, the amounts to be paid under the Arrangement have been calculated based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applied were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Groups. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization practices.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections

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[13]We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

Sixth, the Hospital and the Groups provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[14]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because each of the Groups distributes profits to its members on a per capita basis, any incentive for an individual physician to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We iterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of any savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that were not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program

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[14]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in cardiac catheterization procedures, we believe that patient satisfaction surveys would not be effective.

abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment owed to the Groups was calculated on a percentage basis, and thus the aggregate compensation was

not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Groups. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to the Hospital, since the physicians receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a physician performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

Multiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once. The resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent. The annual rebasing method adopted by the Requestors removes earlier accomplished savings from the accounting and thereby avoids improper duplication of physician payments, reducing the accompanying risk of kickbacks.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement has been used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to physicians already on the medical staff, thus limiting the likelihood that the Arrangement would attract other physicians. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments have been calculated was limited to one year (and the Arrangement was rebased at the end of the first year), and the overall amount of available cost savings payments over the entire two year term of the contract has been capped, reducing any incentive to switch facilities. Finally, admissions were monitored for changes in severity, age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it has been substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement has been used to reward surgeons or other physicians who refer patients to the Groups or their physicians. The Groups were the sole participants in the Arrangement and were composed

entirely of cardiologists and interventional radiologists; no surgeons or other physicians are members of the Groups or will share in their profit distributions. Within the Groups, profits are distributed to members on a per capita basis, mitigating any incentive for an individual physician to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations in the Executive Summary represented a change in cardiac catheterization practice, for which the physicians were responsible and had liability exposure. The product standardization, limitation on use of devices and supplies, and product substitution each carried some increased liability risk for the physicians. It is not unreasonable for the physicians to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made represent portions of two years' worth of cost savings and are limited in amount (i.e., the rebasing and aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twenty-seven recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Groups.[15] We caution that payments of 50% in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we iterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened

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[15]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

- This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: June 23, 2009

Posted: June 30, 2009

To: Attached Distribution List

Re: OIG Advisory Opinion No. 09-06

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital has agreed to share with a cardiology group, a vascular surgical group, and an interventional radiology group a percentage of the hospital's cost savings arising from the physicians' implementation of a number of cost-reduction measures in certain cardiac catheterization procedures[1] (the "Arrangement"). The cost savings are measured based on the physicians' use of specific medical devices and supplies during designated cardiac catheterization procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

[1] The request refers to cardiac catheterization laboratory and special procedures laboratory procedures, services, and practices. For purposes of this opinion, we will refer to these collectively as "cardiac catheterization procedures."

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. At all times relevant to this advisory opinion, [name redacted] (the "Hospital") was an acute care hospital in [city and state names redacted] that offered a broad range of inpatient and outpatient hospital services, including cardiac catheterization procedures, and was a participating provider in the Medicare and Medicaid programs.[2]

The Cardiology Group. [Name redacted] (the "Cardiology Group") is a professional corporation that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Cardiology Group referred patients to the Hospital for

[2] After the contract year (see infra definition note 8), there was a restructuring and the Hospital became an outpatient facility.

inpatient and outpatient hospital services. The Cardiology Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

The Interventional Radiology Group. [Name redacted] (the "Interventional Radiology Group") is a professional corporation that employs exclusively interventional radiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Interventional Radiology Group referred patients to the Hospital for inpatient and outpatient hospital services. The Interventional Radiology Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

The Vascular Surgical Group. [Name redacted] (the "Vascular Surgical Group") is a professional corporation that employs exclusively vascular surgeons who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Vascular Surgical Group referred patients to the Hospital for inpatient and outpatient hospital services. The Vascular Surgical Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

In combination, the Cardiology Group, the Interventional Radiology Group, and the Vascular Surgical Group, herein referred to, individually, as a "Group" and, collectively, as the "Groups," perform nearly all of the cardiac catheterization procedures at the Hospital.[3] Occasionally a procedure is performed by another group or by solo practitioners.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator has collected data and analyzed and manages the Arrangement.[4] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Groups' compensation under the Arrangement.

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[3] The Groups have members who also practice at other hospitals in the region; however, at all times relevant to this advisory opinion, the Hospital was the primary practice location for most of the physicians in the Groups.

[4] The Program Administrator has developed a software product that measures cost, quality, and utilization on a national basis. The product is certified by the American College of Cardiology ("ACC").

B. The Arrangement

Under the Arrangement, the Hospital has agreed to pay each Group a share of the cost savings directly attributable to specific changes in that particular Group's cardiac catheterization procedures. The Requestors implemented the Arrangement—and the Groups began performance of the specific changes in cardiac catheterization procedures—prior to requesting this advisory opinion. The Hospital has not paid amounts owed to the Groups under the Arrangement, however, pending the outcome of this opinion.[5] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion. The Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historical practices of the Groups with respect to cardiac catheterization procedures performed at the Hospital and identified twenty-one specific cost-savings opportunities. The Program Administrator summarized the results of its study and the specific cost-savings opportunities in a document entitled, "EXECUTIVE SUMMARY [NAME REDACTED] VALUESHARE FOR CARDIOLOGY" (the "Executive Summary").[6] The Hospital and the Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

The Executive Summary identified twenty-one specific recommendations that can be grouped roughly into the category of product standardization. The Executive Summary recommended that the Groups change current cardiac catheterization procedures to standardize the types of cardiac catheterization devices and supplies (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) they employ.[7] The Groups were required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter

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[5] Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[6] The Executive Summary is attached to this advisory opinion as Appendix A.

[7] The Executive Summary identified with specificity the products at issue.

did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. Importantly, the Requestors certified that the individual physicians made a patient-by-patient determination of the most appropriate device or supply and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors have further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before, and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

In addition, to ensure that the recommendations did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital's performance of the covered cardiac catheterization procedures against the quality indicators established by the ACC throughout the base year and contract year. (See infra definitions notes 8 and 9.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in cardiac catheterization procedures. The ACC indicators incorporate enough specificity to permit correlation of outcomes with cardiac catheterization procedures. The Hospital will not allocate any cost-sharing amounts to the Groups if the cardiac catheterization procedures performed by the Groups involve reductions in the Hospital's quality as measured against the ACC quality indicators.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-one recommendations presented substantial cost-savings opportunities for the Hospital without any adverse impact on the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Groups separately for 50% of the savings achieved by the particular Group when implementing the applicable recommendations in the Executive Summary. At the end of the applicable year (the "contract year"[8]), cost savings were calculated separately for each Group for each of the applicable recommendations; this precluded shifting of cost savings and ensured that

[8] The contract year was the twelve-month period for which the Groups will be compensated under the Arrangement.

savings generated by procedures involving reductions in historical ACC quality indicators were not credited to the Groups.

The payments to each Group, when made, will constitute the entire compensation paid to the particular Group for services performed under the contract memorializing the Arrangement between that Group and the Hospital. The payment to each Group will be calculated using the same formula. For purposes of calculating the payment to each Group, the actual costs incurred during the contract year for the items specified in the applicable recommendations when used by physicians of the particular Group during the specified procedures (the "contract year costs") are subtracted from the historical costs for the same items when used during comparable procedures in the base year[9] (the "base year costs"[10]).

After receipt of a favorable advisory opinion, payments will be made to the Groups for 50% of the difference between their respective contract year costs and base year costs, if any. Under the Arrangement, the Hospital is obligated to make aggregate payments to each Group, each of which distributes profits among members on a per capita basis.

Calculation of payments to the Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there is no sharing of cost savings for the additional procedures.

- To minimize the physicians' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

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[9] The base year was the twelve-month period immediately preceding the contract year.

[10] Figures for the base year costs were calculated from historical costs during the base year. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Group, when made, will not exceed 50% of the Group's share of the projected cost savings identified in the base year. Each Group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Groups documented the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Groups disclosed the Arrangement to the patients, including the fact that the Groups' compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the procedure. The disclosures were in writing, and each patient had an opportunity, if they desired, to review details of the Arrangement, including the specific cost-savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost-saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost-savings programs to foster physician loyalty and to attract more referrals.

Hospital cost-savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care

program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[11] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act ("CMP") establish a civil monetary penalty against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for civil monetary penalties of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[12]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

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[11] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[12] Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

Having reviewed the twenty-one recommendations, we conclude that all of the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding standardization of devices and supplies, the Arrangement might induce physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for product standardization. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and continues to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[13]

Third, the amounts to be paid under the Arrangement have been calculated based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applied were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

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[13] We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost-savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications, and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Groups. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization procedures.

Fifth, the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

Sixth, the Hospital and the Groups provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost-savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[14]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because each of the Groups distributes profits to its members on a per capita basis, any incentive for an individual physician to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or

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[14] Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in cardiac catheterization procedures, we believe that patient satisfaction surveys would not be effective.

Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We iterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of any savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse—risks that are not present in the Arrangement. The limited duration and scope of the Arrangement, in combination with the other safeguards described above, provided sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment owed to the Groups was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Groups. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to the Hospital, since the physicians receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a physician performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement has been used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to physicians already on the medical staff, thus limiting the likelihood that the Arrangement would attract other physicians. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments were calculated was limited to one year, and the overall amount of available cost-savings payments over the one-year term of the contracts was capped, reducing any incentive to switch facilities. Finally, admissions were monitored for changes in severity,

age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement has been used to reward surgeons or other physicians who refer patients to the Groups or their physicians. The Groups were the sole participants in the Arrangement and each was composed entirely of physicians in a single specialty (i.e., cardiology, interventional radiology, and vascular surgery, respectively); no surgeons or other physicians are members of the Groups or will share in their profit distributions. Within the Groups, profits are distributed to members on a per capita basis, mitigating any incentive for an individual physician to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations in the Executive Summary represented a change in cardiac catheterization procedures, for which the physicians were responsible and had liability exposure. The product standardization carried some increased liability risk for the physicians. It is not unreasonable for the physicians to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent portions of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twenty-one recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Groups.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost-savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

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[15] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

III. CONCLUSION

Notwithstanding the foregoing, we iterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

- This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted], with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted], with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]

May 14, 2014

The Honorable Kevin Brady
Chairman
Subcommittee on Health
Committee on Ways and Means
Washington, DC 20515

The Honorable Jim McDermott
Ranking Member
Subcommittee on Health
Committee on Ways and Means
Washington, DC 20515

Dear Chairman Brady and Ranking Member McDermott:

On behalf of the millions of AARP members, and the millions more who rely on Medicare, thank you for holding the hearing on April 30, 2014, regarding ideas to improve oversight to reduce Medicare waste, fraud, and abuse. While Medicare is just one segment of the larger health care system, improving program integrity is essential to lowering overall health care costs. Waste, fraud, and abuse increase the overall cost of health care and may harm patients, either by providing them unneeded care or by withholding necessary care. AARP is committed to improving the efficiency and cost-effectiveness of our nation's health care system, and we share the Committee's interest in combating fraudulent and wasteful practices.

Congress has already taken positive steps to reduce waste, fraud, and abuse in recent health care reform legislation. For instance, funding for the Medicare and Medicaid Health Care Fraud and Abuse Control Fund has been increased substantially over the past decade. This increased funding has been coupled with more rigorous oversight and enforcement by the Centers for Medicare and Medicaid Services (CMS), Department of Justice (DOJ), and the Internal Revenue Service (IRS). Considering that the return on investment for program integrity efforts is approximately $8.10 for every $1 spent[1], maintaining adequate funding is both crucial and cost-effective.

Similarly, the Affordable Care Act has increased scrutiny of providers and suppliers in federal health programs, increased transparency requirements for compliance programs, as well as other provisions to reduce conflicts of interest. Enhanced screening measures, such as background checks, help root out program abusers. Likewise, reporting requirements reduce the influence of a provider's personal financial interests on the choice of care provided or offered. These steps are already yielding results, and deserve Congress's continued support.

However, there is still room for improvement. Enhancements made to Medicare can serve as a catalyst for the health care system at large. AARP suggests the Committee consider the following policy changes as options to better improve Medicare program integrity:

- **Prioritize spending:** A portion of funds recovered from federal and state fraud and abuse control efforts should be spent on further enforcement activities. If recovered money is not needed for further fraud and abuse control, the excess funds should be redirected to health care programs at CMS, and not be redirected to non-health programs at DOJ or IRS. Moreover, activities that provide the greatest net benefit to society should be prioritized.

- **Better education:** Health care providers should be better educated regarding compliance and to prevent or correct unintended errors. Innocent billing errors should not be prosecuted as intentional fraud. Similarly, consumers should be better educated to appropriately identify and report instances of fraud. Further resources should go to raising consumer awareness, as well. For instance, the Senior Medicare Patrol (SMP) program raises awareness and understanding of healthcare programs among

[1]The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program, "Annual Report for Fiscal Year 2013", page 8, https://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf

seniors. This knowledge helps seniors to protect themselves from the economic and health-related consequences of Medicare and Medicaid fraud, error, and abuse.

- **Practice guidelines:** Linking payment to best practices, as part of larger delivery-system reform, could reduce overutilization by incentivizing more efficient care. Through established practice guidelines, states and the federal government should assess resource use and efficiency in conjunction with quality, so that doctors, hospitals, and other providers are fairly evaluated, and consumers have useful information about the value of care they receive.

Additionally, there are several legislative measures introduced in Congress that would help reduce waste, fraud, and abuse in Medicare and Medicaid. In particular, these bills promote safer, more secure programs, as well as address beneficiary identity theft.

S. 1123/H.R. 2305 – The Preventing and Reducing Improper Medicare and Medicaid Expenditures Act
The PRIME Act would strengthen many existing programs by improving data sharing across federal agencies and programs in a way that would ensure more real-time sharing to discourage and prevent payment of fraudulent or duplicate claims. The bipartisan legislation would also include additional penalties for people who illegally distribute Medicare, Medicaid, or CHIP beneficiary identification information or provider billing privileges. In addition, the bill would improve upon the Senior Medicare Patrol (SMP), which helps educate beneficiaries to detect and report Medicare waste, fraud, and abuse. SMP projects also work to resolve beneficiary complaints of potential fraud in partnership with consumer protection entities at both the state and federal level.

H.R. 3616 – The Protecting Seniors from Health Care Fraud Act
This bill directs the Department of Health and Human Services and Department of Justice to report annually to Congress and the public on health care fraud schemes targeted to seniors and steps being taken to combat such schemes and to educate seniors about them.

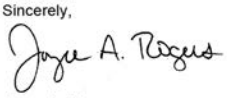
H.R. 3024 – The Medicare Common Access Card Act
This bill would establish a pilot program in order to utilize smart card technology for Medicare beneficiary and provider identification cards. The smart cards would provide greater security for beneficiaries' personal information, thereby reducing the possibility for identity theft. The technology would also enable more responsive claims tracking and adjudication, as well as reduce provider administrative burden.

H.R. 2925 – The Strengthening Medicare Anti-Fraud Measures Act
This bill excludes persons or entities affiliated with previously convicted or penalized entities from participating in federal health care programs.

S. 612 – The Social Security Number Protection Act
This bill ensures that the Medicare identification card does not display or electronically store (in an unencrypted format) a Medicare beneficiary's Social Security account number.

Combating fraud and abuse is about more than just saving money. It is about protecting beneficiaries' ability to get the right care at the right time. By strengthening program integrity efforts, we can reduce overutilization, lower costs, and ensure beneficiary identity security. AARP looks forward to working with the Committee as you address this important issue. If you have any questions, please feel free to contact me or have your staff contact Ariel Gonzalez of our Government Affairs staff at 202-434-3770 or agonzalez@aarp.org.

Sincerely,



Joyce A. Rogers
Senior Vice President
Government Affairs

Proper Payments
The American Coalition for Healthcare Claims Integrity

April 29, 2014

The Honorable Kevin Brady
United States House of Representatives
Chairman, House Ways & Means Subcommittee on Health
1101 Longworth HOB,
Washington, D.C. 20515

Dear Chairman Brady,

Our coalition appreciates the opportunity to contribute recommendations on ways to combat Medicare waste, fraud and abuse. In advance of the health subcommittee's hearing on this topic and in support of our mission to eliminate improper payments, I want to share the facts about the Recovery Audit Contractor (RAC) program, which is a vital tool for fighting waste in Medicare:

Solution to a Program Plagued by Improper Payments

- Medicare loses more money to waste than any other federal program. According to the Department of Health and Human Services (HHS) FY2013 Agency Financial Report, since 2011, the rate of improper payments has risen steadily from 8.6% to 10.1%.[i] In addition, in FY2013, providers overbilled Medicare by $45.6 billion.[ii] Due to this alarming trend, the Medicare Board of Trustees estimates that the Medicare Trust Fund will be insolvent by 2026.[iii]

- In 2003, Congress mandated the creation of a program to combat rampant Medicare waste. In 2009, the Centers for Medicare and Medicaid Services (CMS) implemented the permanent RAC program to identify improper payments and recover misused taxpayer funds. Since then, **RACs have recovered over $8.9 billion, while reviewing less than 2% of medical records**.

A Highly Effective Weapon Against Waste

- According to CMS, the RAC program works. In its annual RAC report released March 25, 2014, CMS says, "In accordance with the President's initiative to eliminate waste and improper payments across Federal programs, the Medicare FFS **Recovery Audit Program has proven to be a valuable tool to reduce improper payments.**"[iv]

- By the end of FY2013, the RAC program was returning over $1 billion per quarter to the Medicare Trust Fund.[v]

- In April 2014, the HHS Office of Inspector General named the RAC program the 'most improved' healthcare integrity initiative with a $1.4 billion increase in recoveries from FY2012 to FY2013.[vi]

A Legacy of Accuracy

- According to CMS, the existing RAC pay structure and penalties promote accuracy above all. As CMS explains: "If an improper payment determination is overturned at any level of appeal, the Recovery Auditor contingency fee must be returned to CMS. **This process helps ensure the accuracy of the Recovery Auditors' reviews**."[vii] Furthermore, RACs invest significant front-end resources to ensure accuracy, including using teams of certified coders, nurses and other clinicians to review hundreds of medical records. As a result, **RACs have an average accuracy rating of 96%**, according the report released last week.[viii]

- According to CMS, few RAC decisions are overturned on appeal. In FY2012, only 7% of RAC decisions were appealed and overturned. And in the recent budget justification, CMS explained that the RAC program's consistently low rates of appeal show the agency has been "effective in ensuring that only valid claims are denied by the Recovery Auditors."[ix]

- According to CMS, RAC program oversight is robust and effective. From the FY2015 budget justification: "**CMS has several policies in place to oversee and limit Recovery Auditor actions.** Many of these requirements have been in place since the national program began. First, CMS approves all RAC review methodologies prior to allowing RACs to identify improper payments. […] Second, an independent validation contractor then selects a random sample of claims, from each RAC, on a monthly basis. The results of these validation reviews are compiled to create an annual "accuracy" score for each RAC, which is published in the Recovery Audit Programs' Report to Congress."[x]

This hearing comes at a critical time for the Medicare Trust Fund. In February, CMS decided to bar recovery auditors from requesting medical records from providers while the agency transitions to the new RAC program contracts, effectively halting all oversight. CMS anticipates auditing will resume when the new RAC contracts are awarded, however the status and start dates for the new contracts are unknown. Given the significant financial implications of this pause in oversight, our coalition urges the committee to request that CMS expedite the contract-awarding process.

Our coalition strongly supports the ongoing improvement to Medicare oversight. In its five-year existence, the RAC program has been a critical partner to CMS in bolstering Medicare integrity and promoting program oversight. Furthermore, our coalition encourages the committee to consider strategies that strengthen the RAC program and healthcare integrity overall.

On behalf of program integrity contractors and the nearly 50 million seniors who rely on Medicare every day, thank you for your consideration and for your efforts to improve oversight of our nation's marquee healthcare program.

Sincerely,

Rebecca Reeves
The American Coalition for Healthcare Claims Integrity

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[i] *The Department of Health and Human Services, FY2013 Agency Financial Report, December 2013, Page 15:* http://www.hhs.gov/afr/2013-hhs-agency-financial-report.pdf

[ii] *The Department of Health and Human Services, FY2013 Agency Financial Report, December 2013, Page 161:* http://www.hhs.gov/afr/2013-hhs-agency-financial-report.pdf

[iii] *The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, May 31, 2013, Page 6:* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2013.pdf

[iv] *Centers for Medicare & Medicaid Services, FY2012 RAC Report to Congress, March 2014, Page 11:* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Report-To-Congress-Recovery-Auditing-in-Medicare-and-Medicaid-for-Fiscal-Year-2012_013114.pdf

[v] *Centers for Medicare and Medicaid Services, Medicare Fee for Service National Recovery Audit Program Quarterly Newsletter, September 2013,* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-Recovery-Audit-Program-4th-Qtr-2013.pdf

[vi] *Department of Health and Human Services Office of Inspector General, U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 But Did Not Fully Comply for Fiscal Year 2013, April 2014, Page 9:* http://oig.hhs.gov/oas/reports/other/17145?000.pdf

[vii] *Centers for Medicare & Medicaid Services, FY2010 RAC Report to Congress, Oct. 2012, Page 11:* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY2010ReportCongress.pdf

[viii] *Centers for Medicare & Medicaid Services, FY2011 RAC Report to Congress, Oct. 2012, Page 32:* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY2011-Report-To-Congress.pdf

[ix] *Centers for Medicare & Medicaid Services. Justification of Estimates for Appropriations Committees, March 2014, Page 219:* http://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2015-CJ-Final.pdf

[x] *Centers for Medicare & Medicaid Services. Justification of Estimates for Appropriations Committees, March 2014, Page 338:* http://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2015-CJ-Final.pdf

Statement for the Record
by the

American Federation of State, County and Municipal Employees (AFSCME)

for the Hearing
on

Ideas to Improve Medicare Oversight to Reduce Waste, Fraud and Abuse

Before the

Subcommittee on Health
Committee on Ways and Means

U.S. House of Representatives

April 30, 2014

Statement for the Record
by the
American Federation of State, County and Municipal Employees (AFSCME)
For the Hearing on
Ideas to Improve Medicare Oversight to Reduce Waste, Fraud and Abuse
Before the
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
April 30, 2014

This statement is submitted on behalf of the 1.6 million workers and retiree members of the American Federation of State, County and Municipal Employees (AFSCME) for the hearing held April 30, 2014 on combating and reducing waste, fraud and abuse in Medicare.

Medicare is an amazing success story. Thanks to Medicare, older Americans have access to modern medicine no matter what their health status or individual income. For nearly 50 years, it has helped generations of Americans to keep a foothold in the middle class as they age. Because of its guaranteed benefits, seniors and their families are protected from financial ruin due to the ravages of illness. However, as the largest payer for most health care services in our country, it is important that protecting Medicare from waste, fraud and abuse be a priority.

Fortunately, the Affordable Care Act (ACA) protects taxpayer and Medicare dollars against criminal actions by beefing up enforcement tools, ramping up detection and pursuing those who steal, waste or abuse Medicare dollars.

- The ACA increases federal sentencing guidelines making it easier to get tougher on criminals who steal from Medicare. The law requires the U.S. Sentencing Commission to increase the federal sentencing guidelines for health care fraud offenses by 20-50% for crimes that involve more than $1,000,000 in losses. The ACA makes obstructing a fraud investigation a crime. Thanks to the ACA, it will be easier for the federal government to recapture monies acquired through fraudulent practices. In FY 2013, fraud prevention and enforcement efforts recovered a record-breaking $4.3 billion in taxpayer dollars from those trying to cheat federal health programs serving seniors.

- The ACA beefs up data matching and integration for law enforcement agencies. This makes it easier to identify criminals and prevent fraud among federal agencies that pay for health care. As a result, as of September 2013, more than 225,000 providers lost the ability to bill Medicare. And, over 14,600 Medicare providers and suppliers had their ability to bill Medicare revoked because of felony convictions or noncompliance.

Regrettably, if the policy of ACA repeal were to become law, as called for in the House-passed budget, the new enforcement tools would disappear and likely lead to more criminals evading detection, prosecution and time in jail.

Congress should Change the Laws that Allow Pharmaceutical Companies to "Legally" Overcharge Medicare

We expect the hearing to explore improving our nation's efforts to combat and reduce illegal activities taken by Medicare providers to cheat Medicare through fraud and abuse. We urge Congress to consider also combatting the ways in which pharmaceutical manufacturers can overcharge Medicare. This "legal" waste, fraud and abuse is significant and undermines Medicare solvency. It also harms taxpayers and beneficiaries.

Medicare Part D coverage for prescription drugs is estimated to cost $80 billion in 2014 and is expected to double by 2022, in large part due to "legal" overpayments to drug manufacturers. We urge Congress to enact the following policies to curb the pharmaceutical industry's ability to "legally" overcharge Medicare.

- **End "legal" drug overcharges for low-income beneficiaries.**
  When Medicare Part D was implemented, the cost of providing medicines to millions of people on Medicaid shot up overnight. Medicaid gets far lower drug prices than Medicare. But Medicare Part D told the pharmaceutical industry they no longer had to provide the Medicaid discount for the same people who were shifted to Medicare Part D plans.

Ending this "legal" windfall for the drug industry would recover more money for Medicare than even record-breaking fraud recoveries. The Congressional Budget Office says that simply restoring the Medicaid discounts for Medicare's low-income beneficiaries would save $116 billion over 10 years.

- **Unleash the purchasing power of 50 million Medicare beneficiaries.**
  Current law forbids Medicare from using the purchasing power of nearly 50 million Medicare beneficiaries to negotiate directly with drug companies for lower prices. The discounts obtained by private Medicare Part D plans are three times less than the ones the government gets for Medicaid. Even modest concern over Medicare's solvency and the use of taxpayers' dollars should compel Congress to give Medicare tools to pursue lower drug prices for the program. Estimates are that Medicare could save more than $200 billion over 10 years.

- **Close the Part D coverage gap, sooner.**
  The ACA has helped nearly eight million people with Medicare save $10 billion on their medications due to the law's required prescription drug discounts to close the coverage gap for Medicare prescription drugs – known as the "donut hole." The ACA closes this coverage gap by 2021. Increasing the drug-maker discounts required by the ACA would shorten the donut hole phase-out period. If coverage gap was ended in 2016 it would help the sickest beneficiaries and save $7.9 billion for Medicare over 10 years.

- **Stop brand-name drug manufacturers from postponing generic entry into the market.**
  Many brand-name pharmaceutical manufacturers pay off generic drug companies to delay introducing a less expensive generic drug, which keeps brand name prices artificially high for Medicare and its beneficiaries. Authorizing the Federal Trade Commission to stop these anti-competitive and "legal" wasteful pay-for-delay agreements would save Medicare $9.1 billion over 10 years.

- **Stop allowing drug companies to charge more for new drugs that are not an improvement over current medicines.**
  Countries such as Germany, New Zealand and Australia have successfully used a review process to reduce spending on expensive new drugs. Under the administrative processes new brand name drugs that are no more effective than existing treatments do not receive additional payments from those countries' health care programs. This process encourages pharmaceutical companies to invest in innovative drugs that improve health outcomes.

Conclusion

Medicare provides health and financial security to millions of Americans, even during the worst economic crisis since the Great Depression. Thankfully, the health care law does much to combat waste, fraud and abuse in Medicare, but the greater threat to Medicare is not fraud – it is the House-passed budget and "legal" wasteful overcharges from drug companies.

The House-passed budget would expose Medicare to more waste, fraud and abuse and leave beneficiaries to be preyed upon by unscrupulous criminals because it would strip away longer sentences for Medicare fraud crimes and take away tools to detect and combat waste, fraud and abuse.

We urge Congress to consider also combating the ways in which pharmaceutical manufacturers can overcharge Medicare. These "legal" mechanisms for waste, fraud and abuse are significant and undermine Medicare solvency. They also harm taxpayers and Medicare beneficiaries and should not be allowed to continue.

AMCP Academy of Managed Care Pharmacy®

April 30, 2014

The Honorable Kevin Brady
Chairman
Subcommittee on Health
Committee on Ways & Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Brady:

Thank you for the opportunity to provide written comments related to the April 30, 2014, hearing entitled "Ideas to Improve Oversight to Reduce Waste, Fraud and Abuse." The Academy of Managed Care Pharmacy (AMCP) is pleased to have the opportunity to suggest additional approaches to stemming the growth of Medicare fraud.

The Academy of Managed Care Pharmacy is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. Some of the Academy's members work within managed care organizations in special investigative units to prevent Medicare fraud in the Medicare Part D drug benefit. Others work closely with law enforcement to combat Medicare fraud.

Federal and private-sector estimates of Medicare fraud range from three percent to 10 percent of total expenditures, amounting to between $68 billion and $226 billion annually. The substantial size of the dollars lost annually in fraud, waste and abuse in Medicare Parts A, B, C and D have prompted Medicare fraud to be one of the federal government's top priorities. Fraudulent activity within pharmacy benefits can take many forms, including patients acquiring prescriptions under false pretenses, providers writing illegitimate prescriptions and the trafficking of counterfeit drugs.

The Academy strongly supports the premise of stopping the cycle of "paying and chasing" fraudulent activity. The Academy appreciates the inclusion of Section 6402 in the Patient Protection and Affordable Care Act, P.L. 111-148, (the Affordable Care Act, or ACA) that permits the Secretary of the Department of Health and Human Services (HHS) to suspend payments to a provider of services or supplier pending an investigation of a credible allegation of fraud against the provider of services or supplier in Medicare Parts A and B, unless there is good cause not to suspend the payment. Pursuant to this provision, the

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Secretary is required to consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud.

The Academy strongly recommends that the Committee consider legislation that would extend the authority in the Affordable Care Act to suspend payment of claims wherein there is a credible allegation of fraud in Medicare Part D. Such legislation should provide for an expansion of time in which managed care organizations pay claims believed to be fraudulent. Attached is draft legislation to effectuate this change to Medicare Part D.

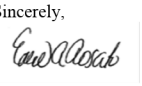
The problem faced by managed care pharmacy is exacerbated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) which adopted a reduced period in which prescription drug plans (PDP) are required to pay pharmacies. As a result, Part D plans are limited to a retrospective analysis of pharmacy claims and provider payment trends which are primarily directed at administration errors, i.e., coding errors, etc.

Generally, a seven to 10-day payment cycle is required to meet MIPPA's 14 day "prompt payment" standard. For instance, a two-day time period between the end of a payment cycle (run on day 11) and the production of payment (run on day 13) obviates any significant prospective opportunity to conduct analysis of claims and reimbursement data prior to payment being sent to the pharmacy provider. As a result, Part D plans must rely on a "pay and chase" approach to recovering suspected fraud once proven. One plan's experience is that since 2006, approximately 9% to 12% of retrospectively reviewed claims have been deemed outliers and warranted additional scrutiny and investigation. However, once the claim is paid, it is unlikely that it can be recovered.

Fraud, waste and abuse are unacceptable within any health care program, especially within health care programs that are financed through taxpayer dollars. In a time of diminishing financial resources, it is more important than ever that Medicare providers, including Part D plan sponsors, are effectively able to combat suspected fraud. AMCP recognizes the seriousness of this problem and is supportive of efforts that would reduce the instance of fraudulent activity.

The Academy would be pleased to work with you to develop legislative language that addresses fraudulent activity in the Medicare Part D drug benefit. Thank you again for the opportunity to provide these written comments. Please do not hesitate to contact Lauren L. Fuller, Vice President, Government Affairs, at 703-683-8416 ext. 625 or lfuller@amcp.org if we may be of further assistance.

Sincerely,



Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

cc: The Honorable Jim McDermott
Ranking Member

Attachments: Medicare Part D Anti-fraud Act, draft
Bill Summary

[Confidential Discussion Draft: May 21, 2013]

113TH CONGRESS H.R. _____

1ST SESSION

To amend title XVIII of the Social Security Act to permit prescription drug plan sponsors to withhold payments to pharmacies based on credible allegations of fraud, and for other purposes.

IN THE HOUSE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on

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A BILL

To amend title XVIII of the Social Security Act to permit prescription drug plan sponsors to withhold payments to pharmacies based on credible allegations of fraud, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare Prescription Drug Anti-Fraud Act of 2013".

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) The Secretary of Health and Human Services may suspend payments to any Medicare fee-for-service provider pending an investigation of a credible allegation of fraud under section 1862(o) of the Social Security Act.

(2) States may suspend payments to any Medicaid provider pending an investigation of a credible allegation of fraud under section 1903(i)(2)(C) of the Social Security Act.

(3) Medicare prescription drug plan sponsors may not suspend payments to any pharmacy pending a credible allegation of fraud because of prompt payment and any willing pharmacy contracting requirements.

(4) Medicare prescription drug plan sponsors can and should play an important role in fighting fraud, waste and abuse under the Medicare prescription drug program under part D of title XVIII of the Social Security Act.

(5) Greater involvement of prescription drug plan sponsors will reduce the incidence of fraud under the medicare program and result in savings for medicare beneficiaries and taxpayers.

(b) PURPOSES.—The purpose of this Act is to

reduce payments for fraudulent claims submitted

under part D of the medicare program under title XVIII of the Social Security Act by establishing procedures under which prescription drug plan sponsors may withhold payments to pharmacies based on credible allegations of fraud.

SEC. 3. AUTHORIZATION OF MEDICARE PRESCRIPTION DRUG PLANS TO SUSPEND PAYMENTS BASED ON CREDIBLE ALLEGATIONS OF FRAUD.

(a) IN GENERAL.—Section 1860D–12(b)(4) of the Social Security Act (42 U.S.C. 1395w–112(b)(4)) is amended by adding at the end the following new subsection:

"(H) AUTHORIZATION OF PDP SPONSORS TO SUSPEND PAYMENTS BASED ON CREDIBLE ALLEGATIONS OF FRAUD.—

"(i) IN GENERAL.—The Secretary shall establish procedures under which a PDP sponsor may report to the Secretary a credible allegation of fraud relating to a pharmacy or other supplier furnishing items and services under the PDP.

"(ii) CONSULTATION.—The procedures under clause (i) shall provide that the Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there

is a credible allegation of fraud

against a pharmacy or other supplier.

"(iii) AUTHORIZATION TO SUSPEND PAYMENTS.—If the Secretary determines there is a credible allegation of fraud, the Secretary may authorize the PDP sponsor to suspend payments to the pharmacy or other supplier pending an investigation of such allegation, unless the Secretary determines there is good cause not to suspend such payments.

"(iv) RELATION TO OTHER PAYMENT SUSPENSION AUTHORITIES.—In establishing procedures under this section, the Secretary shall consider the procedures established under sections 1862(o) and 1903(i)(2)(C).

"(v) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct post-claim payment review.".

(b) CONFORMING AMENDMENTS.—

(1) PROMPT PAYMENT REQUIREMENTS.—Section 1860D–12(b)(4)(A)(i) of the Social Security Act (42 U.S.C. 1395w–112(b)(4)(A)(i)) is amended by striking "Each contract" and inserting "Subject

to subparagraph (H), each contract".

(2) ANY WILLING PHARMACY REQUIREMENTS.—Section 1860D–4(b)(1)(A) of the Social Security Act (42 U.S.C. 1395w–104(b)(1)(A)) is amended by striking "A prescription drug plan" and inserting "Subject to section 1860D–12(b)(4)(H), a prescription drug plan".

(c) **EFFECTIVE DATE.**—The amendments made by this section shall apply to plan years beginning on or after January 1, 2015.

Academy of Managed Care Pharmacy

LEGISLATIVE SPECIFICATIONS

MEDICARE PRESCRIPTION DRUG ANTI-FRAUD ACT OF 2013

The Secretary of Health and Human Services, acting through the Centers for Medicare and Medicaid Services (CMS), should have similar authority to suspend payments under Medicare Part D to pharmacy providers based on credible allegations of fraud as the Secretary has to suspend payments under Medicare Parts A and B under section 1862(o) of the Social Security Act (with necessary adaptations identified below).

Amend Medicare Part D to add a new provision to section 1860D–12 of the Social Security Act as follows:

- Prescription Drug Plan (PDP) sponsors shall report to the Secretary any credible allegation of fraud relating to pharmacy providers and suppliers furnishing items and services under the PDP.

- The Secretary may authorize a PDP sponsor to suspend payments to a pharmacy provider or supplier pending an investigation of a credible allegation of fraud against the pharmacy provider or supplier, unless the Secretary determines there is good cause not to suspend such payments.

- The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a pharmacy provider or supplier.

- The process used to determine whether there is a credible allegation of fraud shall be similar to the process established for purposes of administering section 1862(o) of the Social Security Act.

- This provision would supersede the prompt payment requirements, the any willing pharmacy contracting requirements, and any other requirements to make Medicare payments to the subject pharmacy provider or supplier during the period of suspension.

- If the Secretary declines to pursue legal remedies, the Secretary may, in its discretion, establish procedures under which the subject pharmacy provider or supplier together with the PDP it serves may recommend a plan for the pharmacy to meet Medicare Part D requirements, and, if approved by the Secretary, would limit or end the payment suspension.

Bruce M. Gans, MD
Chair, AMRPA Board of Directors
Executive Vice President and Chief Medical Officer,
Kessler Institute for Rehabilitation
National Medical Director for Rehabilitation, Select Medical

May 14, 2014

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
Subcommittee on Health
United States House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

RE: *Ideas to Improve Medicare Oversight to Reduce Waste, Fraud, and Abuse* (April 30, 2014)

Dear Chairman Brady,

The American Medical Rehabilitation Providers Association (AMRPA) appreciates the opportunity to provide our recommendations and innovative solutions on how to more effectively prevent and combat fraud, waste, and abuse (FWA) in the Medicare program in connection with the Subcommittee's hearing held on April 30, 2014. AMRPA is the national trade association representing more than 500 freestanding inpatient rehabilitation hospitals, inpatient rehabilitation units of general hospitals (IRH/Us), outpatient rehabilitation service providers, skilled nursing facilities (SNFs) as well as a number of long-term care hospitals (LTCHs). AMRPA members work with approximately 600,000 patients per year to maximize patient health, functional skills, independence and participation in society.

AMRPA is supportive of eliminating fraud and abuse in the Medicare program. We appreciate the Subcommittee's efforts to bring together the federal agencies responsible for the execution and oversight of FWA initiatives including the Centers for Medicare and Medicaid Services (CMS), the Office of the Inspector General (OIG), and the Government Accountability Office (GAO) at the April 30 hearing to determine what steps they have taken to strengthen the integrity of the program while protecting Medicare beneficiaries and the Medicare Trust Fund. Members of the Subcommittee raised important questions about prevention of FWA including removal of the Social Security number from the Medicare identification card and strengthening the provider enrollment process to preclude fraudulent providers from enrolling in and billing the Medicare program. However, we remain extremely concerned that the current panoply of FWA programs is complex, redundant, overly burdensome, and inadvertently creates barriers to access to care for medical rehabilitation patients. We think it is critical that the Subcommittee host a second hearing featuring stakeholders from the provider and consumer communities to gain a better understanding of the challenges, both financial and administrative, of the audit and appeals process and to provide suggestions that will maintain the integrity of the Medicare program while preserving access to healthcare services. To ensure federal fraud and abuse resources are

appropriately targeted, AMRPA offers recommendations for the Subcommittee's consideration. Specifically:

I. Rehabilitative Care is Critically Important to Patients Working to Overcome Difficult—and Often Devastating—Conditions

Rehabilitative care is an essential component of the health care delivery system that works with patients to minimize physical and cognitive impairments, maximize functional ability, and restore lost functional capacity. The goal of rehabilitation is to return patients to home, work, or an active retirement. Individuals may require rehabilitative services for a variety of reasons including trauma, disease, or congenital deformity. Conditions treated by rehabilitation providers include, but are not limited to, spinal cord injuries, head and brain injuries, hip or other fractures, amputations, stokes, neurological disease, cardiovascular disease, pulmonary disease, and musculoskeletal disease.

In recent years, many have seen the dramatic impact of rehabilitation on the lives of people facing drastic changes in their lives because of illness or injury. After intense rehabilitation received in rehabilitation hospitals, former Representative Gabby Giffords (D-AZ), Senator Tim Johnson (D-SD) and Senator Mark Kirk (R-IL) have made incredible strides in their ability to walk, speak, carry out other activities of daily life, and return to their communities. While Senators Johnson and Kirk and Representative Giffords are public examples of the importance of rehabilitation treatment and the contributions of our nation's rehabilitation hospitals, there are hundreds of thousands of Americans each day who are fighting to regain their own ability to function through medical rehabilitation programs. Most of them succeed. More than 74 percent of our patients return to their communities.

II. Multiple Medicare Compliance Contractors Threaten Patient Access to Care, Burden Suppliers, and Do Not Effectively Address Fraud and Abuse

In the last decade, Congress and the Administration have created multiple entities designed to combat fraud and abuse in the Medicare program. These contractors include Medicare Administrative Contractors (MACs), Recovery Auditors (RAs), and Program Integrity Contractors such as Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs).The creation of these entities was rooted in the justifiable desire to protect Medicare resources. However, these entities have failed to protect the programs' resources while burdening patients and providers.

Medicare FWA contractors have been exceptionally active in denying claims for various, often confusing, reasons. These denials are ultimately overturned in the vast majority of cases. Government sources show a similar—if not a severe—pattern. A report issued by CMS in March 2011, entitled *A/B Medicare Administrative Contractor (MAC) Composite Benchmark Metric Report: March 31, 2011,* examined the effectiveness of the MACs based on certain benchmarks such as number of denials overturned on appeal. The report examined MAC performance for the first six months of 2010. Of note, approximately 42 percent of MAC denials for Part A services and 58 percent of denials for Part B services were overturned on the first level of appeal, the redetermination level. These statistics indicate that FWA resources are being

misspent on activities that do not effectively target actual fraud. In her testimony before the Subcommittee, Kathleen King, Director of Health Care for the GAO, noted that while CMS does conduct oversight of the MACs, these reviews are not timely and that mistakes can be made by these contractors before a problem is identified and corrected which calls into question the effectiveness of Medicare contractors in preventing and correcting FWA.

These denials, and the resulting appeals process that providers must undertake, impose significant burdens on providers. The traditional appeals process has four steps before a provider can appeal to a federal District Court. As a result, providers must slowly wind their way through the appeals process in a costly exercise that at best can take 18-24 months. However, in December 2013 the Office of Medicare Hearings and Appeals (OMHA) informed Medicare providers and beneficiaries that due to the high volume of appeals to the third level of the Medicare appeals process, hearings before the Administrative Law Judge (ALJ) would be delayed at least 28 months. According to OMHA, the average processing time for an ALJ appeal decision as of April 2014 was 346 days despite a statutory mandate that ALJ cases be decided within 90 days of the date the appeal is filed[1]. Recent studies and surveys on the implementation of the RA program demonstrate significant burdens on providers. The delay and cost of the Medicare appeals process is wholly unacceptable, in violation of the law, and creates a chilling effect for beneficiary access to care.

These burdens are widespread and cumulative. Each of the various contractors can contact a provider at the same time and request multiple documents. At times, the various contractors request the same documents, ensuring redundancy and inefficiency in the system. The multiplicity of contractors, the volume of requests and potential denials, and the lengthy appeals process is overwhelming—and excessively costly at multiple levels—for providers.

Some of the burden originates from misaligned incentives built in to the payment structures of certain contractors. Federal authorities have long said that health care consultants should avoid contingency payments due to the incentives for upcoding, misbilling, and other improper claims. This applies equally to contractors, who have incentives to improperly deny legitimate claims for the sake of maximizing the contractor's own profit. The incentives to identify "overpayments"- even those that are later overturned - are demonstrated by recent analysis of CMS data. Although RAs are authorized to identify and correct underpayments to providers, the clear focus of these contractors is on the identification of overpayments. According to a CMS report analyzing the first quarter 2014 results of RA activities, RAs found a total of $665 million in overpayments but only $71.5 million in underpayments.

Likewise, in identifying overpayments, seen as the primary mission of the contractors, these contractors themselves may be wasting federal dollars. For example, in a separate report analyzing the effectiveness of Medicaid Integrity Contractors, the Department of Health and Human Services (HHS) OIG found that "[f]ew of the audits assigned to Audit MICs from January through June 2010 identified overpayments."[2] Of the 370 audits assigned to Audit MICs, 81 percent either did not identify overpayments or are unlikely to identify overpayments.

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[1] 42 USC 1395ff(d)(1)(A)

[2] Office of the Inspector General, Department of Health and Human Services, Early Assessment of Audit Medicaid Integrity Contractors, OEI-05-10-00210 (Mar. 2012).

The skewed incentives that reward some contractors based on the number of claims they deny has created significant, unnecessary and costly problems.

Unfortunately, these administrative costs and burdens ultimately impact patient care. Clinical staff working on defending denials may be taken away from their direct patient care responsibilities to respond to voluminous and redundant documentation requests from multiple contractors. Additionally, providers may be hesitant to admit certain categories of clinical cases if these categories are subject to close to 100 percent review, no matter how successful the outcome of the final appeal. The negative impact to patient care and optimal patient treatment deserves further oversight and review.

While the work of contractors to combat fraud and abuse is vital, the cost of pursuing appeals, coupled with the high rate of success by providers on appeal, indicates that current fraud and abuse programs are not working effectively and are in need of reform. As discussed more fully below, Congress must immediately take several specific steps to begin to reform current FWA programs.

III. To Improve Federal Fraud, Waste, and Abuse Efforts, Congress Should Consolidate Contractors, Establish a Contractor Clearinghouse, Limit Records Requests, Penalize Inefficient Contractors, and Ensure Qualified Reviewers

Addressing these issues can be accomplished in a way that maintains the focus on preventing fraud while lessening burdens on providers and patients. Specifically, Congress can take the following actions to ensure FWA funds are being used effectively:

- Consolidate the number of Medicare compliance contractors, including claims processing and program integrity contractors, and clarify each contractor's responsibility, scope of authority to request records, and ability to deny payments;

- Establish a government-wide clearinghouse that coordinates the activities of these contractors, including all requests for records;

- Create reasonable absolute numbers of records that can be requested in any 60-day period;

- Increase transparency regarding the sources contractors use when adjudicating provider claims. When CMS contractors use proprietary, subscription-based services that interpret or reinterpret Medicare coverage and admission policies for purposes of making their own coverage or medical necessity determinations, they should be required to release those materials to the providers that are subject to claims review;

- Prohibit contingency payments to RAs and any other contractors seeking to identify and collect overpayments to eliminate the perverse incentives to deny claims inappropriately;

- Penalize contractors that trigger overpayment demands or denials that are overturned at high rates;

- Subject cases that MACs identify for review to prior authorization.[3] Providers that demonstrate a high degree of accuracy over time could ultimately be able to attest, without pre-authorization, that the services billed meet Medicare coverage guidelines;

- Assure that compliance contractors and others reviewing appeal requests utilize appropriately qualified staff and issue decisions in a timely fashion to prevent lengthy and unnecessary delays in the resolution of these appeals;

- Require that ALJ decisions comply with the statutory timeframes for issuing timely decisions; and

- Eliminate the Qualified Independent Contractor (QIC) level of appeals (the second level of the Medicare appeals process). These contractors appear to "rubber stamp" the decision made at the first level of appeal and a majority of these decisions are ultimately appealed to the ALJ. If this level of appeal was eliminated it would create at least a portion of the resources necessary to administer the ALJ level of appeal as intended by Congress.

AMRPA supports the letter signed by Senate Finance Committee Ranking Member Orrin Hatch (R-UT), Energy and Commerce Committee Chairman Fred Upton (R-MI), former Senate Finance Committee Chairman Max Baucus (D-MT), Energy and Commerce Committee Ranking Member Henry Waxman (D-CA), Senate Judiciary Committee Ranking Member Charles Grassley (R-IA), Senator Tom Coburn (R-OK), Representative Cliff Stearns (R-FL), Senator Tom Carper (D-DE), Representative Diane DeGette (D-CO), Representative Charles Boustany (R-LA), and Representative John Lewis (D-GA) to the GAO requesting a study on the coordination of contractor efforts to ensure that beneficiaries are receiving the care to which they are entitled and that contractors are working efficiently.[4]

IV. Providers with Pending Appeals Should Not Be Subject to False Claims Act Liability as a Result of the ACA's "60 Day Repayment Rule."

The Affordable Care Act requires a provider to report and repay overpayments or face potential False Claims Act liability.[5] Unfortunately, the provision does not address how this requirement interacts with the appeals process for providers contesting a contractor's decision to reject a claim. Congress and CMS should make clear that providers appealing a denied claim are not subject to the 60 day reporting requirement until the conclusion of the appeals process.

Under current practice, if a contractor reviews and then denies a claim, it issues a demand letter for the repayment. The provider may then respond in one of three ways: (1) repay the claim;

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[3] This prior authorization should be based on the existing inpatient rehabilitation hospital and unit medical necessity coverage guidelines found at 42 CFR 412. 622(a)(3) – (a)(5).

[4] Letter from Orrin Hatch (R-UT), Energy and Commerce Committee Chairman Fred Upton (R-MI), Senate Finance Committee Chairman Max Baucus (D-MT), et. al. to Gene Dodaro, Comptroller General of the United States (June 26, 2012).

[5] Patient Protection and Affordable Care Act, § 6402(a), 42 U.S.C. § 1320a-7k (2010).

(2) seek to have repayment delayed while it pursues the appeals process; or (3) follow the traditional appeals process and repay the claim. The traditional appeals process allows for a review of the contractor's decision to deny the claim. However, the process is extremely time-consuming. The appeals process involves five phases, and as noted, above can take well over a year.

AMRPA is concerned that Section 6402(a) of the Affordable Care Act may cause problems for providers seeking to pursue the appeals process. Section 6402(a) requires a person who has received an overpayment to report and return the overpayment within 60 days of its identification. On February 16, 2012, CMS published in the *Federal Register* a proposed rule entitled "Medicare Program: Reporting and Returning of Overpayments" implementing this requirement. The proposed rule does not acknowledge nor address the relationship among the appeals process, the recoupment process, and the requirement to repay overpayments within 60 days. The proposed rule does not specify whether the potential overpayment in question is to be identified by the provider or the contractor. If identified by the contractor, the 60-day window to repay to avoid a false claims determination does not appear to take into consideration provider appeal rights.

This presents providers with a difficult decision. The provider may wait to repay a potential overpayment until the appeals process is exhausted but in so doing risk additional penalties for filing a false claim for failure to repay these funds within 60 days. Alternately, the provider could repay the funds while simultaneously appealing and wait to be reimbursed if the denial is subsequently overturned during the appeals process. While we recognize overpayments should be returned in a timely fashion, providers should clearly have the ability to challenge denials and overpayment demands, using well-established administrative mechanisms, without fear of False Claims Act liability.

The proposed rule also authorizes a ten year look-back period which subjects any claim submitted within the last ten years to the 60-day repayment period. If finalized, the look-back period would create a significant administrative burden for providers. A provider could be required to review all claims from the last ten years of the type that a MAC or RA is reviewing to ensure an overpayment was not received.

Recommendation: Congress Should Allow Providers to Exhaust the Appeals Process Before Imposing False Claims Act Liability

To ensure that providers do not face inappropriate False Claims Act liability, Congress and CMS should:

- Make the appeals and recoupment processes available to providers prior to having to repay a claims that may fall within the scope of Section 6402 (a) of the ACA;
    - One approach is for CMS to address this concern in the definitions of "identification" and "reconciliation" in the final rule implementing this provision. These terms must be defined in such a way that a provider could avail itself of the recoupment and appeals processes and essentially stay repayment of the claim until the appeals process is exhausted; and

- Continue to monitor the response rate of the entity responsible for reviewing appeals at each level to guarantee that decisions are issued within the specified timeframes of the appeals process.

V. Contractors Often Deny Claims Based on Meaningless, Technical Compliance Problems and Overlook the Clinical Judgment of Physicians

AMRPA remains very concerned that the various contractors often overzealously search for minor, technical reasons to deny claims rather than concentrating on uncovering actual fraudulent activity. AMRPA recognizes that full and complete documentation of the patient's status and of the medical record is critical to assuring proper care for medical rehabilitation patients, starting with the point of referral and the preadmissions screening. In addition, AMRPA appreciate that payers can establish reasonable documentation requirements to ensure payment for services is appropriate. However, strict and completely rigid attention to the technical aspects of this documentation creates an unnecessary burden for providers and an inappropriate barrier for patients as providers are forced to spend time and effort meeting detailed contractor requirements.

AMRPA believes that in reviewing claims these technical aspects should be considered secondary to the overall clinical assessment and the needs of the patient. For example, denials have been issued for missing deadlines by as little as an hour. Rehabilitation providers are required to perform a post-admission evaluation within 24 hours of the patient's admission to the IRH/U. AMRPA has learned that contractors have denied claims if the physician signature was provided an hour late, even if the evaluation demonstrated that a patient needed an inpatient rehabilitation level of care. It appears that contractors are focusing on technical requirements and overlooking the clinical judgment of the physician and the needs of the patient.

Recommendation: Congress Should Protect Patient Care by Creating Standards that Penalize Consistently Non-Compliant Providers while Reducing the Focus on Technical Mistakes

To improve the efficiency of federal fraud, waste, and abuse efforts, Congress should ensure that contractors are focused upon providers with a history of non-compliance, not providers who have made minor, technical mistakes. Congress should work to:

- Create a "non-compliance threshold" that withholds payment to consistently non-compliant providers while not penalizing providers for infrequent, technical mistakes;
    - For example, a threshold might be set that denies payment for exceeding time requirements by more than 10 or 20 percent of the standard, or denies payment when a recurring pattern of non-compliance is observed during an audit (more than 30 percent of the records reviewed, for example); and

- Establish a "medical judgment" standard that recognizes the responsibility and authority of the physician to make medical determinations. As part of this standard, establish a

physician "compliance rate" such that contractors only deny payments when a certain threshold of denied claims is reached.

VI. Congress Should Immediately Act to Implement Fraud, Waste, and Abuse Reform

In conclusion, AMRPA appreciates the opportunity to share our concerns regarding fraud and abuse initiatives undertaken by the federal government and provide our recommendations. AMRPA strongly supports ensuring that taxpayer dollars are being spent appropriately and that Medicare beneficiaries are protected. AMRPA believes that current FWA programs are duplicative, burdensome, and ineffective and encourages Congress to reform the current initiatives to ensure a streamlined and timely process. Ultimately, such reforms will allow the government to prevent FWA and allow providers to focus on their core missions—ensuring their patients achieve the best clinical outcomes.

If you have any questions, please do not hesitate to contact Carolyn Zollar (czollar@amrpa.org), Sarah Warren (swarren@amrpa.org) or Martha Kendrick (mkendrick@pattonboggs.com).

Sincerely,

Bruce M. Gans, M.D.
Chair, AMRPA Board of Directors
Executive Vice President and Chief Medical Officer, Kessler Institute for Rehabilitation
National Medical Director for Rehabilitation, Select Medical

American Orthotic & Prosthetic Association

Statement of the American Orthotic and Prosthetic Association on Combating Fraud, Waste, and Abuse in the Medicare Program, April 30, 2014

The American Orthotic and Prosthetic Association (AOPA) is pleased to provide this statement concerning Medicare fraud and the delivery of care to Medicare beneficiaries who have suffered a loss of a limb or impaired use of a limb or the spine. AOPA, founded in 1917, is the largest orthotic and prosthetic trade association with a national membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss or limb impairment resulting from a chronic disease or health condition. Members include patient care facilities, manufacturers and distributors of prostheses, orthoses, and related products, plus educational and research institutions.

Annual Medicare spending for custom orthotics and all prosthetics is less than one percent of all Medicare spending. However, Medicare fraud has an outsized impact on the beneficiaries whose limb loss or impairment results in the need for orthotics or prosthetics. Patients treated by AOPA's members already are confronted with the trauma of limb loss or impairment, loss of mobility, diminished independence, and sometimes financial hardship. When seen by a fraudulent supplier, the patient also oftentimes experiences a financial loss after paying for a device that is inappropriate or never delivered. Additionally, a patient in this situation has to find another supplier and make another copayment, and he or she may lose important time in the rehabilitation process. Dobson-DaVanzo's research concluded that nearly one-third of the $3.62 billion CMS paid between 2007-2011 for orthotic and prosthetic services for Medicare beneficiaries went to unlicensed providers, as well as those who fail to meet the accreditation requirement legislated by Congress in 2000. Additional research by Dobson-DaVanzo tracking Medicare data has demonstrated the overall cost-effectiveness of O&P care. For example, the analytic work indicated that over the first eighteen months patients who receive spinal orthoses had total Medicare episode payments that were 0.3% lower than those who did not receive orthotic bracing for the comparable back ailment. These are important trends for saving Medicare dollars.

AOPA and its members believe the best way to fight fraud in the orthotics and prosthetics sector is to prevent fraud in the first place. We also believe that it is possible – and preferable – to combat fraud without punishing an entire healthcare sector because of the actions of a handful of bad actors. Regrettably, it seems that the Centers for Medicare and Medicaid Services (CMS) has opted for the latter approach, despite Congress having given the agency adequate authority to drive fraudulent suppliers from the Medicare program.

The Fraud-Fighting Tools CMS Has Not Used

Section 427 of the Beneficiary Improvement and Protection Act (BIPA) of 2000 requires CMS to ensure that Medicare payments for custom fabricated orthotics and all prosthetics are furnished by "qualified practitioners" and "qualified suppliers." The orthotics and prosthetics profession supported this effort and consistently has pushed to have this requirement implemented. Currently, 14 states have enacted

orthotics and prosthetics licensure statutes. In 2005, CMS issued Transmittal 656 to Medicare payment contractors specifying that contractors must have claims processing edits in place to make sure that in those states where prosthetics or orthotics must be provided by a licensed or certified orthotist or prosthetist, payments are made only to practitioners and suppliers that meet relevant state orthotics and prosthetics licensure laws. However, CMS has not taken concrete steps to enforce this requirement. For example, in 2009, a "60 Minutes" expose demonstrated that CMS was paying unlicensed providers for orthotic and prosthetic services. The amount of Medicare funds inappropriately paid by CMS was in the tens of millions. The fraud discussed in that report involved Florida, a state with orthotics and prosthetics licensure requirements.

Since Congress passed BIPA, AOPA and its members have met with CMS administrators and staff regarding implementation of the law, and in 2007, we were told that proposed regulations would be issued by the end of that year. We are still waiting. On June 25, 2013, AOPA shared with CMS the results of two studies that demonstrate that CMS had been paying unlicensed suppliers.

- In one study, the health economics and policy consulting firm Dobson-DaVanzo examined Medicare claims data from 2007-2011 and did not find significant changes in the distribution of payments to medical supply facilities with uncertified orthotics and prosthetics professionals on their staffs. We note that orthotist and prosthetist licensing requirements in most states track very closely with the typical certification requirements of training and education so that a person who is not certified will almost never meet eligibility for licensure. It is possible to be certified and not licensed, but it is virtually impossible to be licensed and not certified.

- In the other study, conducted in 2013, orthotics and prosthetics suppliers who were receiving Medicare payments were contacted in three licensure states and asked if they had a licensed orthotics and prosthetics professional on staff. This study revealed that 65 out of 78 surveyed suppliers by their own admission did not have a licensed professional on staff.

In a letter to AOPA dated August 2, 2013, CMS Administrator Marilyn Tavenner denied that CMS has been paying unlicensed orthotics and prosthetics suppliers. In the letter, Administrator Tavenner states that systematic claims edits have been in place since 2005 to deny claims submitted by unlicensed suppliers in nine states with orthotics and prosthetics licensure requirements (AL, FL, IL, NJ, OH, OK, RI, TX, and WA) and that the agency is implementing claims edits for the remaining five states with licensure requirements (AR, GA, KY, MS and TN). (This was reported in a Medicare Learning Network Matters article on the same day.) This amounts to an admission by the agency that it has been paying unlicensed suppliers in at least five licensure states (and CMS has omitted any reference to Pennsylvania and Iowa, both of which have enacted O&P licensure as well). Also, the effectiveness of the claims edits in the other nine states is questionable, in light of the fraud that has been documented in two of these states (FL and TX) since 2005 when these edits reportedly were implemented.

It is difficult to understand how the relative proportion of Medicare payments to non-certified orthotics and prosthetics suppliers is unchanged if unlicensed providers no longer are receiving payments in

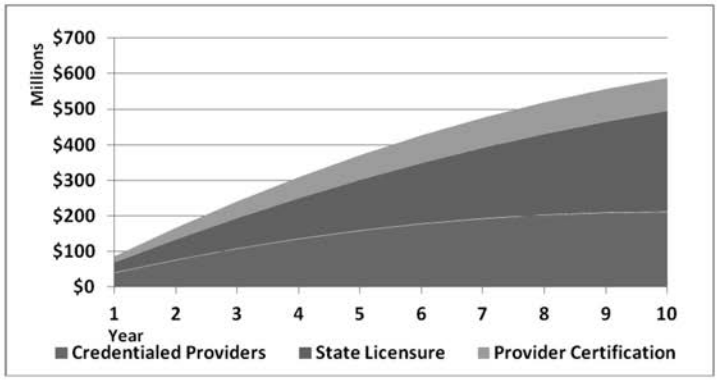
states where certification is required. We have seen evidence of only a small reduction in the proportion of payments to non-certified orthotics and prosthetics personnel since 2009. This also is supported by the results of the independent survey of orthotics and prosthetics suppliers, which showed that unlicensed, non-certified suppliers continue to provide and be paid for orthotics and prosthetics furnished to Medicare beneficiaries, even in states where licensure is required.

H. R. 3112, the Medicare Orthotics and Prosthetics Improvement Act, has been introduced in Congress and would build upon the fraud-fighting provisions included in BIPA. It would help reduce fraud, protect patients, and save Medicare funds by keeping out fraudulent providers in the first place. As the Dobson-DaVanzo report notes: "If CMS was to actively enforce that unlicensed providers cannot receive payment for providing orthotics and prosthetics services to Medicare beneficiaries within a licensure state, Medicare savings could be realized. Under such enforcement of limiting payments to providers with proven licensure and standards of training and experience, payments to unqualified providers would be eliminated. As the '60 Minutes' special suggested, allowing non-certified personnel to provide these services, especially in states with licensure, could lead to fraud and abuse in orthotics and prosthetics services, as well as expose patients who received these services to inappropriate or substandard care. Therefore, shifting payments to only certified providers could result in better care for beneficiaries and lower Medicare payments." An estimate of how much could be saved by implementation of these provisions is provided in the following excerpt from a 2009 report prepared by Morrison Informatics.

Table 1 – First Year Medicare Savings Estimated Range Following H.R. 2479 (now H.R. 3112) Provisions, with Amendment

Provision	Medicare Savings Range	Proportion of Savings
Credentialed Providers	$40 - $101	47%
State Licensure	$28 - $71	33%
Provider Certification	$18 - $44	20%
Total	$86 - $216	100%

Figure 1 – Minimum Cumulative 10-Year Medicare Savings Projection Following H.R. 2479 (now H.R. 3112) Provisions, with Amendment



Concerns about CMS's failure to implement BIPA Section 427 were brought to the agency's attention most recently in a letter from the Chair of the House Ways and Means Committee and the Chair of the Health Subcommittee. CMS's response, dated March 6, 2014, stated that CMS is developing a notice of proposed rulemaking and anticipates that it will be published in 2014. AOPA is skeptical, since we have been told by Ms. Tavenner and other CMS administrators in the past that proposed regulations were forthcoming. In its response, CMS also said that "when a state has enacted a new licensure law, CMS implements an edit that immediately limits payment to only those suppliers that have a specialty of orthotics and prosthetics on their enrollment applications. Then the [National Supplier Clearinghouse] determines whether all orthotic and prosthetic suppliers in the affected state have the required licenses or certifications." However, the National Supplier Clearinghouse generally scrutinizes a potential orthotics and prosthetics supplier only when the supplier seeks a new Medicare provider number and on a regular three year re-enrollment cycle thereafter. AOPA is not aware of actions taken by National Supplier Clearinghouse to monitor orthotics and prosthetics suppliers for licensure after granting a Medicare number.

In summary, CMS currently has several tools at its disposal to bolster its efforts to fight fraud in the orthotics and prosthetics field, yet it has failed to avail itself of its full arsenal. It has not issued any regulations to implement Section 427 of BIPA, and edits to prevent payment to unlicensed orthotics and prosthetics suppliers have not been implemented fully. These shortcomings were highlighted by the HHS Office of Inspector General in its October, 2012 report entitled, "CMS Has Not Promulgated Regulations to Establish Payment Requirements for Prosthetics and Custom-Fabricated Orthotics," but still no rules have been promulgated.

RAC Audits and the ALJ Appeals Backlog

Instead of using tools to keep bad actors from participating in the orthotics and prosthetics sector, CMS has ramped up the Recovery Audit Contractor (RAC) program, which has had the effect of punishing legitimate providers.

While CMS makes payments to unlicensed and unaccredited providers, contravening Congress's intention, legitimate suppliers have been subject to RAC and prepayment audits conducted by contractors who appear to play by their own set of rules. It also appears that RAC audits penalize suppliers for paperwork or documentation errors as often, or more often, than it catches those perpetrating fraud. This sometimes results in legitimate providers, especially those who are small businesses, suffering cash flow problems or going out of business. AOPA estimates that roughly 100 orthotics and prosthetics suppliers have gone out of business, at least in part due to these audit/recoupment related cash flow problems. The impact of these closings extends beyond economics and business—it directly and negatively affects individuals with limb loss, as they have been deprived of long-standing, clinically-beneficial relationships with their health care providers. We note that AOPA has sued the U.S. Department of Health and Human Services (HHS) over RAC audits and how they are being applied to orthotics and prosthetics suppliers.

We feel that certain actions by CMS have compromised the due process rights of orthotics and prosthetics suppliers. For example, CMS issued a "Dear Physician" letter on its website in August, 2011 that had the effect of establishing new policy for payment for artificial limbs, and it applied the new policy retroactively in RAC and prepayment audits as to claims for dates of service as much as two years before the policy was issued in the letter.

There has been an explosion in the number of RAC audit claims under Medicare Part B for artificial limbs that are appealed to the Administrative Law Judge (ALJ) level. Congress and CMS have provided some modest relief for Medicare Part A providers, but none of this relief has been extended to Part B claims for artificial limbs. While we appreciate the difficult task facing the Office of Medicare Hearings and Appeals (OMHA), timely redress of improperly denied payments is critical. Many suppliers, particularly in the orthotics and prosthetics field, are small businesses that do not have the luxury of waiting months for payment of services legitimately furnished. In fact, just last year, 35 Members of Congress wrote to HHS Secretary Kathleen Sebelius that well-intentioned efforts to reduce fraud and abuse in Medicare may be harming access for vulnerable Medicare beneficiaries and placing undue burdens on legitimate orthotic and prosthetic providers. In a context of increasingly aggressive CMS audits, OMHA's decision to suspend ALJ review of provider and supplier claims is devastating to suppliers who deliver Medicare services to over 40 million beneficiaries.

Congress showed that it understood the importance of timely processing of Medicare appeals when it included in BIPA a requirement that an ALJ issue a decision about a case within 90 days of the date when the appeal request was filed. However, by OMHA's own admission, the current wait time for a hearing before an ALJ has increased to 16 months. In some areas that wait is as long as 26 months, which is unacceptable.

At the February 12, 2014 OMHA public hearing on this issue, Judge Griswold gave an explanation of OMHA's position, but offered few if any short-term remedies that would restore the right of a timely ALJ hearing to providers. With ALJs siding fully with appellants in over half of all decisions, ALJ hearings realistically amount to a provider's primary means of challenging costly and often prejudicial CMS auditor decisions. As OMHA is leaving Medicare providers without an avenue of redress against auditors' payment denials, we believe it is only fair that CMS suspend these audits until an appropriate, timely, and statutorily required system providing due process to providers is restored.

Conclusion

In conclusion, AOPA wants to continue to work with Congress and CMS to ensure that those who prey on Medicare beneficiaries do not find the orthotics and prosthetics sector an easy place to establish and operate a fraud scheme. We offer our support for developing more effective means to fight Medicare fraud that does not punish legitimate suppliers who are playing by the rules. We believe that the fairest and most effective system is one that prevents fraud before it starts, and we hope that Congress will direct CMS to develop a system taking the pathways outlined in both Section 427 of BIPA 2000 and H.R. 3112 to deter fraud, promote program integrity, and protect the due process rights of legitimate orthotics and prosthetics suppliers.

AOPA appreciates the efforts of the Chairman of the Committee and of the Subcommittee on Health for working with us to find ways to better regulate our profession. We hope to continue to work with you to improve the quality of care we deliver to patients who need orthotics and prosthetics and to protect the integrity of the Medicare program.