

Member Question(s) Submitted for the Record

Witness Name: Dr. Donald Berwick

Hearing Date: Feb. 10, 2011

General Committee Questions:

Dr. Berwick, as you may know, as part of the 2003 Medicare Modernization Act, Congress required Part D plans to utilize Medication Therapy Management (MTM) programs to help beneficiaries improve prescription drug adherence and minimize adverse drug interactions. Can you please detail how many beneficiaries each year since 2006 have participated under MTM programs, and the total yearly management or dispensing fees paid by Part D Plans in relation to MTM programs. Further, according to CMS' 2010 Medicare Part D Medication Therapy Management Programs Fact Sheet, the agency noted that it is "exploring meaningful performance measures" for MTM programs. Can you please detail the performance measures that are under consideration by CMS?

Question 1: Can you please detail how many beneficiaries each year since 2006 have participated under MTM programs?

Answer 1: Based on plan-reported data, there have been approximately 9.1 million beneficiaries participating in MTM programs across five years from 2006 through 2010. This is not a count of distinct beneficiaries – if a beneficiary participated each year, he or she is counted for each year in which the beneficiary participated in an MTM program. We only have numbers in aggregate. The number of beneficiaries identified by plans as participating in MTM in any given year ranged from 1.3 million to 2.8 million between 2006 and 2010.

Year	# of MTM Participants
2006	1,385,382
2007	2,649,354
2008	2,824,330
2009	2,328,720
2010	2,598,351
Total	9,136,783

Question 2: What is the total yearly management or dispensing fees paid by Part D Plans in relation to MTM programs?

Answer 2: MTM is part of a plan's administrative costs in its bid and thus these costs are not reimbursed by CMS on a service level or broken out separately to CMS.

Question 3: Can you please detail the performance measures that are under consideration by CMS?

Answer 3: CMS has been working with and monitoring MTM measures that are in development in the Pharmacy Quality Alliance (PQA). The PQA is a consensus-based alliance committed to improving medication use and medication related services across the health care system. The PQA measures around MTM are currently going through data validation and testing. One measure of particular interest to CMS is the percentage of MTM-eligible beneficiaries who received a Comprehensive Medication Review (CMR).

Questions on behalf of Mr. McDermott:

Hearing on the Health Care Law's Impact on the Medicare Program and its Beneficiaries

Topic

Discussion of the new End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and the transition adjustor

Background

On January 1, 2011, CMS initiated a new ESRD Prospective Payment System (PPS) for dialysis facilities. The new reimbursement is called a "bundled" payment since it reflects all of the costs of providing care to dialysis patients, except for oral drugs, and is widely believed to be the forerunner for the manner in which CMS will pay other providers. Because the "bundled" payment is new and very different from the manner in which dialysis facilities were being reimbursed before January 1, the law creating the program (Medicare Improvements for Patients and Providers Act) provided that each facility could choose to opt into the new program or phase-in over a four year period.

To remain budget neutral during this four-year transition period, the Agency devised a transition adjustment that would be driven by the number of dialysis facilities that opt out of the transition period and receive payment solely under the new PPS. In the final regulation, CMS estimated that only 43 percent of the facilities would opt into the new program; however, the reality is that 98 percent of the facilities opted into the new system. Based on the faulty estimate, CMS will be reducing payments by 3.1 percent or \$6.75 per treatment in 2011. This reduction is much higher than necessary given the actual number of facilities choosing to enter the new program.

The Northwest Kidney Centers, which operates multiple dialysis facilities within my district, serves more than 1,400 patients in western Washington. Like most other dialysis facilities, the Northwest Kidney Centers opted to move directly into the new ESRD bundle system. Under the 3.1 percent transition adjustment proposed by CMS, the Northwest Kidney Centers estimates it will lose \$1.1 million in 2011 for the 1,050 Medicare insured patients they serve because the transition adjustor has not been modified.

Question 1: It is vital that CMS move quickly to substitute the actual number of facilities that will be paid under the new ESRD PPS system for the estimated number it is currently using. Can you explain why CMS has not yet calculated the transition adjustor using the actual number of facilities that moved into the bundle earlier this year? When does the

Agency plan to correct the adjustor? Is CMS willing to take action to waive the rulemaking requirement and recalculate the transition adjustment based upon the actual number of facilities that have opted out of the transition period?

Answer 1: When adopting a new payment system under Medicare, CMS is often statutorily required to ensure that aggregate payments (with the exception of any applicable inflation update) are the same as those under the previous payment system. In this case, we were required to ensure that payments under the new ESRD prospective payment system (PPS) were, in aggregate, 98 percent of the total payments that would have been made under the previous basic case-adjusted composite payment system. In order to meet this requirement, we applied a transition budget neutrality adjustment factor of 3.1 percent to ESRD payments in the calendar year (CY 2011) ESRD PPS final rule.

As described in the final rule, CMS' calculation of this factor was based on the best available data to estimate payments during the transition period. At the same time, we acknowledged that the adjustment may not reflect actual choices made by the ESRD facilities regarding opting out of the ESRD PPS transition. However, we noted that the adjustment would be updated each year of the transition (CY 2012 and CY 2013) to reflect actual data on providers electing to opt-out of the transition.

As a result of the information available to CMS on the number of facilities opting out of the transition, on April 1, 2011, CMS issued an interim final rule revising the ESRD transition budget-neutrality adjustment finalized in the CY 2011 ESRD PPS final rule to reflect the actual election decisions of ESRD facilities to receive 100 percent payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. This revision will result in an increase in payments by replacing a negative 3.1 percent adjustment with a zero percent adjustment for renal dialysis services furnished April 1, 2011 through December 31, 2011.

Topic

Discussion of the new End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and the transition adjustor

Background

The Centers for Disease Control and Prevention's National Guidelines for the Prevention of Catheter Infections state that patients living with catheters must maintain their hygiene, and when doing so must cover their catheters with secure, impermeable waterproof dressings that keep the catheter dry while they shower or bathe. Medicare has always covered these types of dressings for catheter patients under Part B as a home supply benefit.

Question 2: Last July, CMS began denying this cost- and life-saving benefit to fragile Medicare beneficiaries on dialysis. Why was this change made under Part B?

I also understand that a clarification was recently issued to say that these waterproof dressings are covered under the dialysis composite rate payment. But Medicare's written

policy states that the composite rate covers costs associated with the dialysis treatment, which it defines as the period of three to four hours over which dialysis occurs.

Patients do not shower or bathe during dialysis. Additionally, the list of codes that are covered by the dialysis composite rate expanded bundle does not include any code for the waterproof dressings recommended by the CDC. This clarification seems in contradiction to the policy it aims to clarify.

Therefore I would like to inquire what Medicare is doing to ensure that patients receive these dressings that save lives and possibly millions in preventable costs?

Answer 2: CMS shares your commitment to ensuring that ESRD patients receive quality care under the Medicare program. Through various initiatives, including the new ESRD prospective payment system (PPS), the ESRD quality incentive program, and the collection of data on infection control, CMS has worked actively to implement reforms that support quality of care in this critical area of the Medicare program.

With regard to this specific issue, we considered this matter carefully. Our analysis included a review of Medicare policies as they relate to dressings used for showering and bathing, meetings with a leading manufacturer of these items, and, most importantly, thoughtful consideration of patients' clinical needs.

As you know, beginning January 1, 2011, ESRD facilities are paid for all renal dialysis items and services that patients require, including renal dialysis items and services that are used in the home, based on full payment under the new ESRD PPS or through a blended payment reflecting both the previous composite payment system and the new ESRD PPS. To the extent that waterproof dressings are determined to be medically necessary, an ESRD facility would provide them and be paid by Medicare in this way. Paying for these items through a separate code under Part B would represent duplicate payment. To provide further clarification on this issue for ESRD facilities, CMS issued a manual revision on January 28, 2011, stating that all medically-required dressings or protective coverings used during or after dialysis to protect a dialysis patient's access site, including for example, coverings used for day to day activities such as bathing, are considered to be ESRD related items, and included in the payment under the PPS.

Questions on behalf of Mr. Pascrell:

Dr. Berwick, regarding health care reform's ability to improve the quality of care for seniors, I want to bring up the topic of healthcare-associated infections. As you know, the Department of Health and Human Services acknowledged this problem and proposed a series of recommendations through the 2009 HHS Action Plan to prevent healthcare-associated infections. Congress included these recommendations in the initial phase of Hospital Value Based Purchasing (VBP) program that begins in fiscal year 2013.

However, the recent CMS proposed rule on Hospital Value Based Purchasing only includes one of the seven measures from the HHS Action Plan.

Question 1: Can you share with me CMS' timeline for incorporating the remaining six measures into the VBP program?

Answer 1: As required by law, the measures used to gauge hospital performance under VBP must be those that are part of the hospital Inpatient Quality Reporting (IQR) program, as well as the HCAHPS survey. The IQR measure set includes both process measures and outcome measures, and hospitals are familiar with them because they have been reporting them for a number of years. A measure must be included on Hospital Compare for one year prior to its being selected for use under the hospital VBP program.

Incorporation of the Healthcare-Associated Infections (HAI) Action Plan measures into the Hospital IQR program and subsequently, into the Hospital VBP program is a high priority of the Agency, and we are working to do this as soon as possible.

Last year, we adopted two of the HAI measures into our hospital reporting system that can be included in the Hospital Value-Based Purchasing program once they have been on the Hospital Compare website for one year. The first is on central line-associated bloodstream infections, for which reporting began in January of this year. The second is on Surgical site infections, which hospitals will begin reporting in January of 2012. In addition, in the proposed rule on the Medicare hospital inpatient prospective payment system (IPPS) for FY 2012 that was issued on April 19th, we are proposing to require hospital reporting of four additional HAI measures from the HHS Action Plan:

- Catheter Associated Urinary Tract Infection
- Central Line Insertion Practices Adherence Percentage
- C. Difficile
- Methicillin-resistant Staphylococcus aureus (MRSA)

If these measures are incorporated in the Inpatient Quality Reporting Program in the final rule issued later this year, they can also be included in the Hospital VBP program after they have been reported on Hospital Compare for one year.

HAIs are among the leading cause of death in the United States. In the coming years, we will work to enhance and strengthen the HAI measure set and to include them in the hospital VBP program. Our intent is for this measure set to play a strong and vital role in the future determination of value-based incentive payments.

Second, Dr. Berwick, as you may know in 2005, CMS created the imputed wage index floor for states, like New Jersey, that are considered by the federal government to be all-urban states for Medicare payment purposes through regulation.

This floor corrected years of unequal treatment for New Jersey's hospitals by providing them with benefits similar to those granted to healthcare institutions in 49 other states through the rural hospital wage index floor.

This floor is set to expire this year and I believe that this floor needs to be made permanent. Other states have a permanent floor in place, except NJ. This is about equity, fairness, and leveling the playing field with other states.

Question 2: Do you support making this floor permanent this year?

Answer 2: Current law requires that the area wage index for any hospital that is located in an urban area of a State may not be less than the area wage index for hospitals located in rural areas in that State. This provision is commonly known as the “rural floor.” While there is a statutory requirement for the *rural* floor, there is no such requirement for the *imputed* rural floor. Concerns have been expressed, as I understand it, that both the rural floor and the imputed rural floor policies create a benefit for a minority of States that is funded by a majority of States, including States that are overwhelmingly rural in character. I would be happy to discuss with you any concerns you may have about the imputed rural floor policy generally, and its specific impact on New Jersey hospitals.

Finally, Dr. Berwick, as you may know nationally, the skilled nursing sector employs 1.7 million Americans and generates over \$200 billion in economic activity. In my state, skilled nursing facilities employ more than 53,000 people and generate nearly \$10 billion annually in economic activity, which makes the skilled nursing sector the nation’s second largest health employer.

Also, as you know, Medicare and Medicaid have a significant impact on the skilled nursing sector.

Question 3: Recognizing the fiscal pressures at the state level to reduce Medicaid funding to these health care providers, is there any way you can assure these providers that there are no additional cuts that will come from CMS in the next year?

Answer 3: CMS recognizes the important contribution of skilled nursing facilities (SNFs) to the economy and also understands that there are fiscal pressures at the state level to reduce Medicaid funding to SNFs. Further, we will continue to act as responsible stewards of the Medicare Trust Funds and make sure that SNFs are receiving accurate payment for the beneficiaries they are serving. At the same time, at its December 2, 2010 public meeting, the Medicare Payment Advisory Commission (MedPAC) reviewed many factors, including indicators of beneficiary access, the volume of services, the supply of providers, access to capital, and 2009 data showing that the aggregate Medicare margin for freestanding SNFs was 18.1 percent. Based on this information, MedPAC determined that Medicare payments to SNFs appear more than adequate.

Questions on behalf of Dr. Price:

Question 1: During the hearing, I asked you the following question: "Who ought to make that final decision about what treatment that patient receives?" to which you responded, "The doctor and the patient." How do you see increased government control of the physician-patient relationship as fitting into the patient-centered model?

Answer 1: There are two parts to your question.

First, in terms of the government's role and the law – the Affordable Care Act is built to protect and strengthen the system of private insurance in this country. It is built on the foundation of our current system. And it is designed to be implemented in full partnership with the States. The Secretary – who is a former governor- says that unlike most Federal laws that tell States to do things and don't make them partners or give resources, this is an exceptionally state-friendly law.

It strengthens public programs like Medicare. These changes, like lower prescription drug costs, and more preventive services, are strongly supported by beneficiaries.

Second, I strongly oppose any proposal that would place the government between the doctor and the patient. Unfortunately, care controls are present in the health system today. Insurance companies ration care based solely on costs. Arbitrary coverage limits reduce quality and shift costs to American families and health care providers. Low payments or lack of coverage can block access to life-saving treatments. This situation is economically and morally wrong.

I strongly oppose arbitrary limits on the care Americans receive. The Affordable Care Act gives states and consumers tools to stop these kinds of limits on care. For example, since September 23, 2010, insurers can no longer deny children with pre-existing conditions health care coverage in this country or attach arbitrary limits on what they would and wouldn't pay for.

Question 2: There are numerous provisions in the bill that would provide for the creation of quality measures. These provisions often give the Secretary of Health and Human Services wide discretion when developing the measures. First, how is the government best suited to foster the development and selection of these measures? What steps will you take and what protections will be put into place to ensure that physicians are behind the development and selection of these measures?

Some examples of these provisions include:

*** Section 10407 provides for the creation of a National Diabetes Report Card that will, in part, include information on quality of care. The Secretary is only required to consult with the Director of the Centers for Disease Control and Prevention.**

*** Section 10331 provides for the creation of a "Physician Compare" website that will provide for the reporting of performance information. To the extent practicable, PPACA requires the information to include an assessment of patient health outcomes, an assessment of the continuity and coordination of care transitions, an assessment of efficiency, and an assessment of the safety, effectiveness, and timeliness of care. Although the bill specifies that these measures must be "scientifically sound", the Secretary is only required to "take into consideration" input from multi-stakeholder groups.**

Answer 2: We have a number of exciting initiatives underway in the Department. In Medicare, we are working on a value based purchasing agenda by integrating measures into Medicare

payment systems for the end stage renal disease and inpatient hospital contexts. In Medicaid, for adults, CMS recently released a proposed core set of adult quality measures for public comment, as required by the Affordable Care Act. The adult quality measures are for voluntary reporting by Medicaid and are to be finalized by January 1, 2012. CMS will work with States to report data on these measures. For children, on February 14, 2011, CMS released a letter to State Health Officials and written guidance for voluntary reporting of the core set of child quality measures that were published in January 2010. This effort is funded through the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA). CMS is also working with States to report data on these measures.

But much more needs to be done to advance quality initiatives and improve the quality of care patients receive. We need a more coordinated focus on quality, which is what the National Strategy for Health Care Quality would provide. The Secretary developed this Strategy through a participatory, transparent, and collaborative process that reached out to a range of stakeholders, including provider groups, for comment. This process culminated in a request for public comment on a proposed approach to the effort and a draft set of principles and priorities. More than 300 groups, organizations, and individuals provided comments, representing all sectors of the health care industry and the general public. We also need better outcomes data to be able to identify gaps and monitor progress, in which the new health reform law invests. And we need an additional focus on provider reporting and payment based on performance, which the bills prioritize.

Information and transparency are key to the quality initiative, to measure the quality of the health care we are currently receiving, and over time, how it improves. Patient safety in health care settings is a key priority and focus for CMS. We are evaluating policies and options related to Healthcare Acquired Conditions and hospital readmissions, as well as overall patient safety issues, to determine the best way to address these concerns. We are also consulting with other agencies within the Department to develop a coordinated approach to improve patient care. Additionally, through the Interagency Working Group for Health Care Quality, there is now a common platform for collaboration, cooperation, and consultation among relevant Federal agencies regarding quality initiatives, as a means to ensure alignment and coordination of quality efforts in the public sector and with private sector initiatives.

Question 3: At a rally in Holmdel, New Jersey on July 16, 2009, President Obama said, "Let me be exactly clear about what health care reform means to you. First of all, if you've got health insurance, you like your doctors, you like your plan, you can keep your doctor, you can keep your plan. Nobody is talking about taking that away from you." During the hearing, when I asked whether individuals that like their coverage will be able to keep it, you responded, "[T]here is turnover always in what's available to the beneficiaries." Your own actuary, Richard Foster, estimates that by 2017 enrollment in Medicare Advantage plans will be lower by about 50 percent due to "reductions in the value of MA benefit packages because of the lower rebate levels [which] are expected to significantly reduce the attractiveness of many MA plans relative to fee-for-service Medicare." Would you define a 50 percent reduction in enrollment over seven years as "turnover"?

Answer 3: This Administration has embarked on a path to strengthen and improve Medicare Advantage. Despite the CMS Actuary's estimates and projections last year, I'm happy to report that the actual enrollment data for Medicare Advantage in 2011 shows a 6 percent increase in enrollment this year, with more than 190,000 new Medicare Advantage enrollees in the program.

Question 4: There are provisions in the bill that will threaten patient-centered care. Specifically, Section 6301 of PPACA creates the Patient Centered Outcomes Research Institute. The bill states that the Secretary will not be prevented "from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under such title based upon a comparison of the difference in the effectiveness of alternative health care treatments in extending an individual's life due to that individual's age, disability, or terminal illness." If this research can be used to determine coverage and reimbursement, how will this not directly interfere with the physician-patient ability to determine which treatment is best for the patient?

Answer 4: Let me be clear. I strongly oppose any proposal that would place the government in between the doctor and the patient. I strongly oppose arbitrary limits on the care Americans receive.

This provision will enhance the physician-patient ability to determine which treatment is best for the patient, not interfere with it. Section 6301(c) of the Affordable Care Act states clearly that the Secretary is not authorized "to deny coverage of items or services... solely on the basis of comparative clinical effectiveness research." This research will be publicly available and widely disseminated so that it can aid physicians in guiding appropriate care for patients, helping them to prescribe care based on the benefit that patients might gain. For example, if doctors learn from this research that a brand name drug works as well as a similar type of generic, or a procedure associated with many side effects works nearly as well as a different procedure with fewer side effects, they can use this information to help patients make choices that are right for their unique health care needs.

Question 5: I sent a letter to your office on December 2, 2010 asking for clarification on how an August 27, 2010 DMEPOS final rule would affect the use of "consignment closets." I wanted to follow up and see if you could provide an answer to this letter.

Answer 5: Thank you for your letter. Consignment closet arrangements involve a physician, or other provider, giving patients supplies at the physician's or provider's location without requiring ownership of the supplies. These arrangements have not been affected by the DMEPOS final rule, and are not expressly prohibited, provided such arrangements comply with the DMEPOS supplier standards, as well as applicable Medicare laws, rules, and regulations. We will provide clarifying guidance through the Web site of our DMEPOS enrollment contractor, the National Supplier Clearinghouse. This guidance will confirm that nothing in the aforementioned regulation prevents DMEPOS suppliers from entering into consignment closet arrangements that comply with applicable Medicare laws, rules, and regulations.

Questions on behalf of Mr. Reichert:

Question 1: Last year as part of your 2011 hospital outpatient prospective system (HOPPS) proposed rule your agency determined that OPSS costs incurred by the Dedicated Cancer Centers exceed the OPSS costs provided at other PPS hospitals. As required under the Affordable Care Act, CMS was directed to make an “appropriate adjustment” for Cancer Centers to reflect those higher costs. I was pleased to see CMS recognize these Cancer Centers are underpaid for their services. However, I am concerned that CMS failed to bring real parity to these Cancer Centers as compared to other PPS hospitals. Specifically, I understand CMS did not take into account the significant Medicare outpatient concentrations as compared to that of other PPS hospitals. Since the inception of HOPPS, Congress has afforded these dedicated Cancer Centers permanent “hold harmless” protection under this payment system. It would be my hope that CMS will consider the high outpatient concentration and set these Cancer Centers reimbursement at a more appropriate level moving forward. Treatment in the outpatient setting is better for patients and less costly than inpatient care. The centers should not incur large losses by doing the right thing for patients and the Medicare program.

Answer 1: CMS is extremely concerned about the impact that the steep rise in healthcare costs has on all Americans, especially the impact these costs have on Medicare beneficiaries and Medicaid recipients. During the comment period for the Hospital Outpatient Prospective Payment System (OPSS) proposed rule for CY 2011, many commenters pointed out the likelihood of much greater cost-sharing for Medicare beneficiaries seeking care at these institutions should we finalize our cancer hospital adjustment as proposed. However, with few exceptions, the statute requires that the beneficiary co-payment apply to OPSS payment to a hospital, including any enhanced OPSS payment received by a cancer hospital under Section 3138.

Section 3138 of the Affordable Care Act requires the Secretary to first study cost differences with respect to ambulatory payment classification groups under the OPSS between the 11 designated cancer hospitals and other Medicare-participating hospitals. The Secretary shall make an appropriate adjustment under the statute, if the Secretary determines that the cost incurred by those cancer hospitals with respect to the ambulatory payment classification groups exceed those costs incurred by other hospitals under the OPSS. During the rule’s comment period, CMS received a great volume of thoughtful comments on our study of cancer hospitals’ costs and the proposed adjustment. In response to these comments, CMS agreed to study the issue for another year and will again discuss the issue in our CY 2012 rulemaking cycle.

Question 2: It is vital that CMS move quickly to substitute the actual number of facilities that will be paid under the new ESRD PPS system for the estimated number it is currently using. Can you explain why CMS has not yet calculated the transition adjustor using the actual number of facilities that moved into the bundle earlier this year? When does the Agency plan to correct the adjustor? Is CMS willing to take action to waive the rulemaking requirement and recalculate the transition adjustment based upon the actual number of facilities that have opted out of the transition period?

Answer 2: When adopting a new payment system under Medicare, CMS is often statutorily required to ensure that aggregate payments (with the exception of any applicable inflation update) are the same as those under the previous payment system. In this case, we were required to ensure that payments under the new ESRD prospective payment system (PPS) were, in aggregate, 98 percent of the total payments that would have been made under the previous basic case-adjusted composite payment system. In order to meet this requirement, we applied a transition budget neutrality adjustment factor of 3.1 percent to ESRD payments in the calendar year (CY 2011) ESRD PPS final rule.

As described in the final rule, CMS' calculation of this factor was based on the best available data to estimate payments during the transition period. At the same time, we acknowledged that the adjustment may not reflect actual choices made by the ESRD facilities regarding opting out of the ESRD PPS transition. However, we noted that the adjustment would be updated each year of the transition (CY 2012 and CY 2013) to reflect actual data on providers electing to opt-out of the transition.

As a result of the information available to CMS on the number of facilities opting out of the transition, on April 1, 2011, CMS issued an interim final rule revising the ESRD transition budget-neutrality adjustment finalized in the CY 2011 ESRD PPS final rule to reflect the actual election decisions of ESRD facilities to receive 100 percent payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. This revision will be applied prospectively and results in an increase in payments by replacing a negative 3.1 percent adjustment with a zero percent adjustment for renal dialysis services furnished April 1, 2011 through December 31, 2011.

Questions on behalf of Mr. Roskam:

Question 1: Dr. Berwick, you have stated there will be no guaranteed benefit cuts to Medicare. However, according to Mr. Foster and the CMS Actuaries, Medicare reimbursement will be lower than Medicaid reimbursement in just over ten years. In 75 years, Medicare payments will be one-third of what they are presently. Will new Medicare beneficiaries have their access to healthcare services jeopardized because of unsustainable Medicare cuts in PPACA? Are these Medicare "savings" sustainable?

Answer 1: CMS is working to make the "best care" in America the norm in health care, for everyone. We are implementing several Affordable Care Act provisions designed to improve the quality of care for those enrolled in our programs. The Affordable Care Act contains provisions designed to help avoid preventable hospital readmissions by linking financial incentives to readmission rates and by providing assistance and support to hospitals to improve transitional care processes. It also requires CMS and providers to focus on the prevention of infections, conditions, and other complications that patients acquire from the care that is supposed to help them.

We believe that providing productivity adjustments that will bring hospitals and doctors in line with other aspects of our economy in terms of growth rates is a reasonable and fiscally responsible step to take, and the Affordable Care Act allows us to do that.

Medicare participation rates have been historically very high – well above 90 percent. In 2010, the total Medicare provider participation rate was 95.8 percent (932,737 providers). This is the highest participation rate in the history of the Medicare program, and represents an increase of 0.4 percent from 2009. Additionally, the physician participation rate for Medicare FFS in 2010 was 97.1 percent. The vast majority of States, according to 2006 data, have a provider participation rate of 90 percent or better.

CMS will continue to monitor participation levels and other indicators of access to care to ensure Medicare beneficiaries have access to the care they need.

Question 2: Dr. Berwick, the Medicare actuaries also stated that 15% of Medicare Part A providers will be unprofitable within ten years and jeopardize access to care absent legislative intervention. This equates to 725 hospitals, 2,352 nursing homes, and 1,587 home health agencies. I represent a hospital that is part of an even more vulnerable subset of this group of providers. A number of Illinois hospitals are significantly dependent on Medicare – over 60% and do not receive any special add-on payments, such as DSH or IME. Not only are these hospitals disproportionately impacted by the market basket and productivity adjustments, but these hospitals will not be able to make up the difference with newly insured patients because Medicare is clearly their predominant payor. I am very concerned about the viability of these hospitals and beneficiary access to these important communities. Does CMS share the concern about this subset of hospitals? Does CMS have administrative tools to fix this access and viability problem or will it rely on Congressional intervention? If Congress must intervene to prevent the cuts in a manner similar to the “doc fix,” will the promised spending (insurance subsidies and Medicaid expansion) contribute to the deficit?

Answer 2: I recognize the challenging environment that hospitals are currently facing. The Affordable Care Act contains a number of provisions that will help hospitals improve care and lower costs, including efforts related to hospital readmissions, value based purchasing, and hospital acquired conditions. Moreover, by expanding coverage, the Affordable Care Act will dramatically reduce the amount of uncompensated care that hospitals currently absorb, and will ensure that patients are able to appropriately access hospital services. Improvements in care and coverage from these provisions will benefit hospitals’ bottom line, will benefit the health care system as a whole – and most importantly, will benefit our beneficiaries.

Question 3: Dr. Berwick, in your written testimony it says, “CMS is currently integrating predictive modeling as part of an end-to-end solution that is transparent, measurable, and triggers effective, timely administrative actions. Innovative risk scoring technology applies a combination of behavioral analyses, network analyses, and predictive analyses that are proven to effectively identify complex patterns of fraud and improper claims and billing schemes. Given the changing landscape of Medicare and Medicaid fraud, any successful technology will need to be nimble and flexible, identifying and adjusting to new schemes as

they appear.” I tried to improve the original healthcare bill, HR 3200, with a fraud mitigation amendment using predictive modeling but it was rejected on a partisan basis in this Committee. It is encouraging to see CMS moving towards this method of fraud detection and prevention in public programs. I would like to see the technology moved pre-payment more quickly. What significant systems changes will be needed to move this process pre-payment? What can Congress do to assist CMS in this process? What is the timeline for (a) post-payment review and (b) pre-payment review of claims?

Answer 3: CMS is expanding its Integrated Data Repository (IDR) which is currently populated with five years of historical Part A, Part B and Part D paid claims, to include near real time pre-payment stage claims data; this additional data will provide the opportunity to analyze previously undetected indicators of aberrant activity throughout the claims processing cycle. CMS intends to develop shared data models and is pursuing data sharing and matching agreements with the Department of Veterans Affairs, the Department of Defense, the Social Security Administration, and the Indian Health Service to identify potential waste, fraud, and abuse throughout Federal health care programs. Also, the Affordable Care Act requirement that States report an expanded set of data elements from their Medicaid Management Information System (MMIS) will strengthen CMS’ program integrity work both within State Medicaid programs and across CMS. This robust State data set will be harmonized with Medicare claims data in the IDR to detect potential fraud, waste and abuse across multiple payers.

CMS will implement an innovative risk scoring technology that applies effective predictive models to Medicare. Innovative risk scoring technology applies a combination of behavioral analyses, network analyses, and predictive analyses in order to identify complex patterns of fraud and improper claims and billing schemes. CMS is integrating the advanced technology as part of an end-to-end solution that will trigger effective, timely administrative actions by CMS as well as referrals to law enforcement when appropriate. Prior to applying predictive models to claims prepayment, CMS will rigorously test the algorithms to ensure a low rate of false positives, allowing payment of claims to legitimate providers without disruption or additional costs to honest providers; confirm that the algorithms do not diminish access to care for legitimate beneficiaries; and identify the most efficient analytics in order to appropriately target resources to the highest risk claims or providers. Given the changing landscape of health care fraud, any successful technology will need to be nimble and flexible, identifying and adjusting to new schemes as they appear.

Further, the Small Business Jobs Act of 2010 provided \$100 million, beginning in FY 2011 to phase-in the implementation of predictive analytics in Medicare FFS. The Small Business Jobs Act of 2010 additionally provides that the Secretary shall start to phase-in the use of predictive analytics technologies to Medicaid and CHIP beginning April 1, 2015. The new predictive modeling technology will incorporate lessons learned through pilot projects. For example, in one pilot, CMS partnered with the Federal Recovery Accountability and Transparency Board (RATB) to investigate a group of high-risk providers. By linking public data found on the Internet with other information, like fraud alerts from other payers and court records, we uncovered a potentially fraudulent scheme. The scheme involved opening multiple companies at the same location on the same day using provider numbers of physicians in other states. The

data confirmed several suspect providers who were already under investigation and, through linkage analysis, identified affiliated providers who are now also under investigation.

Question 4: In the summer of 2009, the DuPage County State's Attorney's Office (SAO) entered into an agreement with the Illinois Department of Public Health (IDPH) to begin a new program designed to protect residents of long-term residential healthcare facilities and nursing homes in DuPage County from criminal abuse, neglect, and financial exploitation. The agreement with IDPH supplemented IDPH's existing administrative investigations and Illinois State Police's criminal investigation procedures such that IDPH provided copies of any complaints that it received to the SAO so that the office could screen the complaints for possible criminal investigation. After screening a complaint and determining that a criminal investigation was warranted, the SAO would request (and receive) copies of any follow-up reports done by IDPH investigators. Upon receipt, prosecutors and investigations reviewed these follow-up reports for law enforcement purposes and took whatever steps were appropriate based, in part, on the findings of the IDPH's investigators.

This program was working and effective until CMS intervened. In late summer of 2010, CMS informed the IDPH that it was no longer allowed to release the records sought by the SAO even though the records were sought for law enforcement purposes. After months of communication and conversation, CMS acknowledged that the Federal Administrative Code allows the release of these reports for the purpose sought by the SAO [45 CFR Subtitle A §5.9(b)(7)]. However, CMS has asserted that it is not permitted to authorize the release of these reports because CMS does not "have a policy in place" to facilitate the process. In the meantime, the SAO has not been able to review IDPH's reports of abuse and neglect for several months. It is my understanding that IDPH only requires that CMS grant permission to resume providing copies of its reports to the SAO. Can we quickly work together with the DuPage County State's Attorney's Office to resolve this dilemma and protect residents of long-term residential facilities and nursing homes from abuse, neglect, and financial exploitation?

Answer 4: Thank you for your commitment to protecting residents of long-term care facilities and for raising this concern. The Centers for Medicare & Medicaid Services (CMS) is happy to work quickly with you, the State, and the County to resolve this concern.

CMS has been working with the State to resolve this issue and put in place a data use agreement (DUA) for the Federal complaint records it is seeking. As you may know, currently CMS does not have a DUA with the DuPage County State's Attorney's Office (SAO) or with the Illinois Department of Public Health (IDPH) to share data under the new program mentioned, nor is CMS a party to such a DUA to provide copies of any Federal complaint records that it received to the SAO so that the office could screen the records for possible criminal investigation.

In addition, written CMS guidance to States on this matter is forthcoming.

Questions on behalf of Mr. Tiberi:

Dr. Berwick, I have several concerns and request information as it pertains to the competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), as required by the Medicare Modernization Act of 2003. Specifically, I am concerned about the impact this program will have on small independent providers and the number of jobs that will be lost.

As you know, CMS initiated its DMEPOS Competitive Bidding program for Medicare Beneficiaries and Contract Suppliers on January 1, 2011.

Question 1: For each month in CYs 2010 and 2011, what was the total number of DME supplier claims in each Durable Medical Equipment Regional Carrier (DMERC)?

Answer 1: Thank you for your interest in the DMEPOS competitive bidding program. We have instructed our contractors to extract the data you have requested. We anticipate that we will have such data within the next two weeks and will provide it to you under separate cover as soon as it is available.

Question 2: For each month in CYs 2010 and 2011, what was the total number of beneficiary DME claims in each DMERC?

Answer 2: As mentioned above, we have instructed our contractors to extract the data you have requested. We anticipate that we will have such data within the next two weeks and will provide it to you under separate cover as soon as it is available.

Question 3: For each month in CYs 2010 and 2011, what is the total number of active DME provider numbers in each DMERC?

Answer 3: As mentioned above, we have instructed our contractors to extract the data you have requested. We anticipate that we will have such data within the next two weeks and will provide it to you under separate cover as soon as it is available.

Question 4: When ACO's are implemented under the law, how will ACO's operate as intended with so few DME suppliers following implementation of Competitive Bidding.

Answer 4: The Medicare Shared Savings Program is intended to encourage providers of services and suppliers (e.g., physicians, hospitals and others involved in patient care) to create a new type of health care entity, known as an “accountable care organization” (ACO) that agrees to be held accountable for improving the health and experience of care for individuals and improving the health of populations. Studies have shown that better care often costs less, because coordinated care helps to ensure that the patient receives the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. The goal of an ACO is to deliver seamless, high quality care for Medicare beneficiaries, instead of the fragmented care that has so often been part of fee-for-service health care.

The intent of the Medicare DMEPOS Competitive Bidding Program is to set more appropriate payment amounts for DMEPOS items, which will result in reduced beneficiary out-of-pocket expenses and savings to taxpayers and the Medicare program. The program does not affect the beneficiary's choice of physician or treating practitioner. Rather, under the program, suppliers of durable medical equipment, prosthetics, orthotics, and supplies compete to become Medicare contract suppliers. All contract suppliers were required to comply with Medicare enrollment rules, be licensed and accredited, and meet financial standards. Further, in determining how many contract suppliers would be needed to meet beneficiary demand, CMS used conservative estimates, over-estimating the number of needed contract suppliers to meet such demand. Accordingly, during Round 1 of the program, CMS awarded 1,217 contracts to suppliers to furnish certain medical equipment and supplies in the nine competitive bidding areas. While we continue to monitor the implementation of Round 1, we are pleased to report that implementation of the program is going very smoothly.

Question on behalf of Mr. Berg:

Question 1: According to the Medicare Actuaries' April 22 report on the health care law, 7.4 million seniors would lose their plan by 2017 as a result of the \$206 billion in cuts to Medicare Advantage. This will be a 50 percent reduction from what enrollment was expected to be before the law was enacted. Doesn't this mean that seniors won't be able to keep the plan they have and like?

Answer 1: This Administration has embarked on a path to strengthen and improve Medicare Advantage. Despite the CMS Actuary's estimates and projections last year, I am happy to report that the actual enrollment data for Medicare Advantage in 2011 shows a 6 percent increase in enrollment this year, with more than 190,000 new Medicare Advantage enrollees in the program.