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Congress of the United States
House of Representatives
COMMITTEE ON WAYS AND MEANS
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 14, 2001

The Honorable Tommy Thompson
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Secretary Thompson:

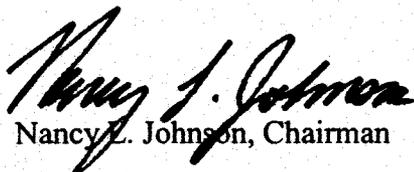
We share your commitment to strengthening and improving the Medicare program so that all beneficiaries have better access to quality health care. Many changes to the program that we think are necessary, such as integrating a prescription drug benefit, require legislative action. However, a number of modernizations can be made administratively. There is no reason to delay sensible changes which will make Medicare more responsive to beneficiaries and the providers that serve them, if they can be implemented immediately.

The Ways and Means Health Subcommittee has held five Medicare modernization hearings this session. We have solicited, listened to, and evaluated suggestions to make Medicare less bureaucratic and more workable.

We believe that the attached administrative changes will strengthen the Medicare program. We hope that you will give these suggestions full consideration and implement them as quickly as possible. Certainly, as we obtain more information and recommendations that merit administrative action, we will bring those proposals to your attention.

We also look forward to working with you as we begin to develop legislation to strengthen Medicare and make it a program that serves seniors even better than it has in the past.

Sincerely,


Nancy L. Johnson, Chairman


Pete Stark, Ranking Member

Attachment

ADMINISTRATIVE CHANGES

1. HCFA Management

Accountability In The HCFA Structure

Issue:

One of the recurring frustrations raised by Members and providers relates to inconsistencies in regional interpretations of central office policies on issues ranging from coverage decisions to program integrity. In addition, Secretary Thompson and the Office of Inspector General have both expressed disbelief that HCFA has not yet developed a modern, integrated dual entry accounting system for accounts receivable.

Proposal:

- C A direct point of accountability within HCFA should be established for oversight of regional office activities. This individual should be charged explicitly with reviewing regional activities to identify inconsistencies that may need policy attention.

- C A dual entry accounting system should be a top priority with a specific deadline for completion and implementation.

A Systematic Regulatory Process

Issue:

Providers have expressed frustration with many aspects of the regulatory process, especially with respect to the continuous stream of rules with which they are expected to comply.

Proposals:

- C Regular schedule for release of all program guidance, including program memoranda, notices of proposed rulemaking, interim final rules, and final

rules. These regulatory announcements would be made every 6 months, unless either the Secretary identified a compelling need for more timely action or earlier action is needed to comply with statutory requirements.

- C Regular and adhered to time line for the progression from proposed rules to interim final rules (as appropriate) to final rules.
- C Thorough review of all Medicare policies, including regulations and program manual instructions, to ensure consistency and to promote simplicity.
- C System of formal consultation with congressional committees of jurisdiction to ascertain whether regulations are consistent with legislative intent prior to release of notices of proposed rulemaking, consistent with the Administrative Procedures Act.
- C System of formal consultation with beneficiaries, provider groups, and other interested parties to solicit their input and guidance prior to release of notices of proposed rulemaking, consistent with the Administrative Procedures Act.

Expanding Outreach for Provider Education

Issue:

A more aggressive system of education and technical assistance must be developed to facilitate compliance with the numerous and complicated regulations confronting Medicare providers. This effort should make assistance available to providers to help them interpret and comply with all new laws, regulations, program memoranda, instructions to regional offices, and fiscal intermediary and carrier manual instructions related to billing, coding, cost reporting, and documentation. This will require additional funding, which we will discuss with you as we move forward with legislative initiatives we are developing in this arena.

Proposals:

- C HCFA contractors should offer technical experts to visit providers and work with them to evaluate systems to determine compliance and to suggest more efficient or more effective means of fulfilling program obligations.

- Working with various provider associations, HCFA should develop an agreed upon system of information dissemination and training.
- Carriers, intermediaries and contractors shall conduct outreach to providers with fewer than 25 employees to implement education programs tailored to their needs.
- On-going technical assistance should include a convenient process of consultation to allow providers to seek help regarding a claim prior to its submission. All government or contractor employees should provide callers with either their name or other unique identifier to promote accountability.
- Full review and explanation of findings of audits should be made available to providers by HCFA and its auditors to make sure providers understand the findings. Providers should also be informed of their appeal rights.
- Frequently asked provider questions and HCFA's answers to those questions should be made publicly available to all providers over the internet. We understand this request is currently being implemented by the agency, and we encourage you to make sure the internet site is easily accessible.
- Providers will have 30 days after the receipt of direct notice of policy changes from carriers and intermediaries to comply with such changes as may be necessary.

Medicare Contractor Oversight

Issue:

The Health Care Financing Administration has experienced poor performance with its intermediaries and contractors, resulting in increased frustration from providers over inaccurate provider education and late delivery on changes the providers must make in billing systems. In the last several years, HCFA has made substantial improvements in its oversight of the contractors, such as using the same teams from central office to evaluate intermediaries and carriers as well as the development of management reporting. However, HCFA should undertake further

refinement -- building on prior improvements -- in its internal management of the contractors.

ISO 9000 (ISO is a free standing acronym) are international standards used for quality management. Many major corporations and government agencies (such as NASA) have adopted ISO 9000. The Malcolm Baldrige National Quality Award, which was established by Congress in 1987 to enhance competitiveness and promote quality awareness in manufacturing, service, small business, education and health care, uses ISO as one the measures of operational effectiveness and efficiency. We agree that HCFA needs to be able to significantly reform its contracting system and will support legislation to accomplish these reforms

Proposal:

- HCFA should investigate and examine adopting the relevant standards from the best private industry practices for improving their processes for procurement and supervision of contractors.
- HCFA should identify any legislative or regulatory barriers that exist in their ability to adopt these processes and work with the Congress to resolve any roadblocks.

Release of Information

Issue:

Historically, HCFA has released only aggregate facility level data on the impact of changes in rate-setting. Providers and their representatives need access to the underlying information, such as Minimum Data Set and claims data, used in rule-making to analyze and benchmark their own performance as well as to look at quality improvement.

Proposal:

- HCFA should establish processes to release detailed information and the assumptions underlying the rates used to reimburse providers. The process should ensure that the privacy of beneficiaries is clearly protected and there is industry consensus on the release of data. This is not intended to affect the release of facility specific-data on quality.

2. Strengthening Fee-For-Service

Coverage of Self-Administered Drug and Biologicals

Issue:

The Benefits Improvement and Protection Act (BIPA) included a provision related to the coverage of drugs and biologicals under Part B of the Medicare program, changing coverage policy so that rather than covering “services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered,” now such drugs and biologicals will be covered if they “are not usually self-administered by the patient.” However, no program memorandum has been issued to implement the new policy and accordingly the carriers are not making the necessary change.

Proposal:

C HCFA should issue the necessary program memorandum as soon as possible.

Compendia of FDA-Approved Drugs and Biologicals

Issue:

Section 1861(t)(1) of the Social Security Act defines drugs and biologicals as including “only such drugs and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia (USP), the National Formulary (NF), or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein) or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.”

A number of these compendia have changed significantly since this provision was enacted 35 years ago. The USP and the NF have merged. The USP- Dispensing Information compendia now contains the information formerly contained in the USP - providing dispensing information to pharmacists and physicians.

Beginning in the summer of 2000, HCFA has required new drugs and biologicals to be listed in the merged United States Pharmacopoeia/National Formulary

compendium, in addition to the USP-Dispensing Information compendium, in order to secure coverage under Medicare. Manufacturers are concerned that securing listing in the USP/NF can take several months, delaying Medicare beneficiaries access to new covered products. They argue, persuasively, that listing in USP-DI is consistent with the original statutory requirement because other compendia have been deemed successors to documents no longer in existence.

Proposal:

- C HCFA should accept the USP-DI compendium as the successor to the AMA's New Drugs compendium, thereby allowing new products listed in USP-DI to be reimbursed as long as they meet Medicare's other coverage requirements.

Certification of Diabetes Self-Management Programs

Issue:

The Benefits Improvement and Protection Act of 2000 established Medicare coverage of medical nutrition therapy for beneficiaries with diabetes or a renal disease. Through a final rule promulgated on February 27th, 2001, all medical nutrition programs eligible for reimbursement under the new benefit must show proof of meeting the National Standards for Diabetes Self-Management Education Programs. But, the only way for a program to show proof that they meet national standards is through a credential offered by the American Diabetes Association.

Programs that do not hold the ADA's Education Recognition Program credential, the only designation acceptable to HCFA as proof of meeting National Standards, will no longer be available to Medicare beneficiaries. Programs holding existing state health department credentials will not be eligible for reimbursement.

Proposal:

- C HCFA should grandfather the state-level certifications currently in place in 10 states as valid for purposes of Medicare reimbursement. All new programs would still be subject to the ADA standard.

Simplifying Patient Assessment Instruments and Process

Issue:

Providers must operate with assessment instruments that require a considerable amount of nursing staff time due to the length of the form and the number of times the form must be given to the patient during an episode of care. The Medicare Payment Advisory Commission has recommended that “ the Secretary should minimize reporting burden and unnecessary complexity while assuring that only necessary data are collected for payment and quality.”

Changing the current situation will require the cooperation of all parties, including the patient advocacy groups and the states. For example, all of the states are statutorily required to collect the Minimum Data Set (MDS) information on nursing home patients and changing the form imposes costs on the states because it requires changing their computer software and data warehouses.

For the longer term, the Benefit Improvement and Protection Act (BIPA) required the Secretary to review the assessment instruments used for each type of provider and report back by January 1, 2005 on their recommendations for standardizing these instruments.

Proposals:

- **Home health agencies** -- HCFA should convene a Technical Experts Panel (TEP) of agency representatives, clinicians, and patient advocates to simplify the use of the Outcome and Assessment Information Set (OASIS) form and limit the time and number of individuals that are evaluated. The TEP should consider the effect of the length of the interview on the patient and avoid repetition without cause.
- **Skilled nursing facilities** -- HCFA should convene a Technical Experts Panel (TEP) of agency representatives, clinicians, patient advocates, and the states to revise and simplify the MDS.

The longer-term evaluation required in BIPA of the MDS should include the development and testing of new as well as existing quality measures.

Standardization of Local Medical Review Policies**Issue:**

Each carrier and intermediary sets its own local medical review policies (LMRPs.) These policies limit coverage (and thus payments) for services, based on data that show these services are overused or excessive in that area.

There are unintended consequences from the growth in LMRPs. First, in areas with multiple intermediaries and a separate carrier for physicians, some hospitals may have to comply with only one or two policies, other hospitals with several hundred policies, and the local physicians and ambulatory surgery centers have an entirely different set. Beneficiaries are confused because they cannot know what is or is not covered.

Second, the intersection of Emergency Medical Labor and Treatment Act (EMTALA) and the requirement for the Advanced Beneficiary Notice (ABN) leaves hospitals financially responsible for the costs of emergency services that have been restricted under LMRPs, which are not specifically developed to represent medically necessary care in an emergency encounter. Hospitals cannot give the patient an ABN until the patient has been screened and stabilized. However, hospitals cannot bill the patient, unless the patient has received an ABN notice in advance.

Proposals:

- HCFA should require the intermediaries and carriers to move to a single set of LMRPs for each state and for each metropolitan area that overlaps several states. This rationalization and simplification should be a high priority for the agency.
- HCFA should direct intermediaries and carriers to exclude emergency services that meet the prudent layperson standard from the LMRP policies.

Simplifying Cost Reporting

Issue:

The cost report for hospitals is many times larger under the current prospective payment system (PPS) than it was when hospitals were paid under cost-based reimbursement. Because services were moved incrementally to prospective systems, the cost report form and attached documentation grew to 3 and a half inches thick, the instruction is a separate volume, and there is a manual interpreting

the instructions. Thus, the cost report imposes a substantial burden on hospitals due, in part, to the amount of data collected for the sole purpose of filing the cost report. However, since many facilities are no longer paid under cost-based reimbursement, the importance of cost reporting has diminished.

Similarly, nursing home and home health cost reports are the same length under the PPS as under cost-based reimbursement. Moreover, intermediaries are reportedly still auditing cost reports when there is no possible impact on provider or program payment.

Proposals:

- For hospitals, HCFA should create a Technical Expert Panel (TEP) to develop a new cost report for FY 2003. The review should be directed at determining what data can be eliminated or simplified, given the current reimbursement methodologies. All stakeholders including HCFA, OIG, fiscal intermediaries, providers, and data users should be involved in the review process.
- For providers paid under cost-based reimbursement for only a few services or items, HCFA should not make any changes to the cost reporting manuals, unless it results in a reduction in administrative expense for providers or is directed towards improper payment problems.
- HCFA should not expend resources to audit the cost reports of facilities, where audit changes would not directly affect reimbursement.
- Electronically submitted cost reports from software that has been approved by HCFA should not be rejected because of errors in the electronic edits and affect the deadline for timely submissions. Instead, there should be alternative processes to resolve issues.
- For free-standing skilled nursing facilities, HCFA and the providers should evaluate the feasibility through a TEP of reducing the cost report to include only the financial data that shows assets, liabilities and owners equity, known as the trial balance, balance information and a few key Medicare statistics

such as the patient census and bad debt. Data available by other sources, for example, Medicare days by resource utilization group (RUG) should not be part of the cost report, without a compelling reason to include such data.

- For home health agencies, HCFA and the interested stakeholders should reevaluate through a Technical Expert Panel the length and complexity of the form and consistency of information provided in home health cost reporting.

The Expansion of Emergency Medical Treatment and Active Labor Act

Issue:

Congressional intent in enacting EMTALA was to protect indigent patients seeking emergency medical care in a hospital emergency department (ED) from being denied care or inappropriately transferred. It was assumed that patients could not determine their own need for treatment, thus, outpatients are only told of their financial obligations after they have received care.

However, the definitions underlying EMTALA have been expanded by HCFA: "Comes to the emergency department" in the statute has been interpreted as an individual arriving anywhere on the hospital premises and applying to hospitals without emergency departments.

Proposal:

- HCFA should reexamine how EMTALA applies to individuals presenting to non-emergency care sites on the hospital's main campus, reviewing the role of non-emergency staff.
- The expansion of EMTALA to non-hospital property beyond the main campus should be revised to a standard of close proximity. Moreover, emergency personnel would not be expected to leave the premises unless an emergency situation was observed or brought to their attention.

Advanced Beneficiary Notice for Home Health Services

Issue:

The Medicare benefit for home health services is limited to individuals who are home-bound, need a skilled service and do not need round the clock care. The Medicaid program however has a broader benefit and patients do not have to be home-bound or need skilled services. Some state Medicaid programs require home health agencies to submit a “demand” bill to Medicare when the patient is clearly not eligible under the Medicare benefit before Medicaid can be billed. This triggers a request for accelerated payment (RAP), which has to be repaid when the service is rejected. In addition, agencies have to give the ABN to the patient during the home health episode when they are decreasing or terminating services due to a change in the patient’s condition.

Proposal:

- HCFA should develop a demand bill process that is faster and does not trigger a RAP until the decision to pay is made. State Medicaid agencies should not require agencies to inappropriately submit a demand bill for patients that do not meet the coverage requirement under the “homebound” definition.
- HCFA should reevaluate the frequency that home health providers must give ABNs.

Ambulance Billing

Currently, ambulance billing is under a transition from an old capped charge system to a fee schedule. The carriers had wide discretion on coding and billing. The process and coding for demand bills, which permits companies to get rejections from HCFA in order to bill other parties, has not been consistently available from all carriers. The development of the fee schedule should require a consistent coding system. One suggested system is to use a new set of condition codes.

Proposal:

- HCFA should develop a consistent nationwide process and coding for demand bills for ambulance services.
- HCFA should report back to Congress by June 15 their evaluation of

condition codes, diagnosis codes and other methods for use in billing for ambulance services.

Medicare Secondary Payor (MSP)

Issue:

Hospitals must fill out a MSP form for every inpatient or outpatient. The hospital questions the patient in a face to face encounter about their insurance coverage, work status, and retirement date. Recently, HCFA has moved to require that hospital-based laboratories collect the same data. Moreover, HCFA is examining whether other providers should also be required to collect the data.

Proposals:

- HCFA should simplify Medicare secondary payor reporting to eliminate collection of known data (other than needed identifiers) and minimize the burdens on providers while maximizing HCFA's ability to comply with the law.
- Providers that do not have face to face contact with the patients should not be required to collect the MSP data.

Hospital Contracting in the Provider-Based Regulation

Issue:

Under the law, hospitals can provide services directly or under arrangement. For example, clinical laboratory companies may provide all the non-urgent lab services for a hospital. Or, a rehabilitation management company may provide management services and personnel for a rehabilitation unit.

In the provider-based section of the hospital outpatient prospective payment rule, HCFA states that an on-campus inpatient or outpatient service operated by a management company cannot be considered to be under the licensure and conditions of participation of the hospital. This intrudes on the ability of providers to contract for services in the most economical way.

Proposal:

- HCFA should reexamine management contracts as a criteria for determining the provider-based status of on-campus services and departments.

The Medicare Summary Notice (MSN)**Issue:**

The Medicare Summary Notice (formerly called the Explanation of Medicare Benefits or EOMB) gives the beneficiary information on its potential liabilities for copayments, deductibles, and any uncovered services. The information should be clear precise and meaningful.

However, because it includes charges, the information on the MSN is confusing to beneficiaries. Under the Prospective Payment System (PPS) for hospital outpatient services, charges are not used to determine either the program payment or the copayment for beneficiary services. However, the MSN lists the hospital charges, the deductible and copayments but not the amount the government pays to the hospital. When the hospital's charges are less than the copayment, beneficiaries are left with the inaccurate appearance that the government is paying nothing.

Proposal:

- HCFA should simplify and clarify the MSN during the next cycle of system revisions (by October 1, 01.)

Medigap Premium Safe Harbor

Dialysis facilities were permitted for many years to subsidize the Medigap premiums of their patients, because it was believed that the greater good for beneficiaries was more important than the potential for an anti-kickback violation. In 1998, Congress required that a Safe Harbor be established that would permit dialysis facilities to subsidize the Medigap premiums of their patients. In response to the bill, the Office of the Inspector General (OIG) published a draft safe harbor that would limit it to independent free-standing centers that were not part of chains or hospital-based -- a small number of the total facilities. The intent of Congress was to aid in coverage for this sick population and it was not the intent of Congress to limit the safe harbor to only certain facilities.

Proposal:

- The Inspector General should broaden a proposed safe harbor to allow **all** dialysis facilities to subsidize the Medigap premiums for indigent ESRD patients.

Improving Access to New Technology

Technology used for diagnosing and treating outpatients is rapidly changing. But the availability of those services is hampered by the long waiting process for outpatient (HCFA Common Procedure Coding System or HCPCs) codes that describe the technology or service. Moreover, the process for incorporating new laboratory tests and limitations on coverage through the Local Medical Review Policies are inconsistent across different carriers.

Proposal:

- HCFA should develop a public process for adopting new HCPC codes, including consideration of a quarterly addition of new HCPC codes.
- HCFA should establish an open and timely coverage process for new laboratory tests. Consistent with the intent of the BBA, the LMRPs should be more national in scope and supported by a process that allows for comments from clinicians outside of government.

3. Medicare+Choice**Improving Oversight of Medicare+Choice****Issue:**

Medicare+Choice plans have expressed frustration with the regulatory process, from new and conflicting rules and operational policy letters both from HCFA and across regions. In addition, new rules with which plans have to comply have grown. The new HCFA monitoring guide used to evaluate plans during biennial site visits includes 261 items for review; before BBA, there were 139 requirements, according to HCFA.

In a June 2000 letter to Medicare+Choice organizations, the HCFA administrator pledged to better coordinate HCFA's functions related to the program and to take steps to lessen the regulatory burdens placed on M+C plans. HCFA subsequently created a new "Medicare Managed Care Group," with a new "Director of Medicare Managed Care" position under the Center for Health Plans and Providers.

However, a number of important functions remain outside the Medicare Managed Care Group, including encounter data reporting, appeals and grievances oversight and data reporting, enrollment and disenrollment administration and oversight. Without one central point of control for all M+C regulatory and administrative activity, HCFA's actions continue to be uncoordinated and sometimes conflicting.

Proposal:

- Regulatory authority for Medicare+Choice should be consolidated into a single office of Managed Care. The office should be located in the Washington, D.C. area instead of Baltimore.
- Current law requires plans to provide information on advance directives to all enrollees. Current HCFA rules also require plans to track decisions made by patients about whether they have an advance directive, to notify the enrollee's primary care provider (PCP) of the advance directive and if it changes or is cancelled. Since such decisions are primarily private matters between patients and physicians, the current requirement for plans to track advanced directives should be discontinued.
- Allow on-line enrollment application for beneficiaries with appropriate protection for beneficiary privacy.

Risk-Adjustment Mechanism for Medicare+Choice

Issue:

Risk adjustment of payments to Medicare+Choice organizations is needed to pay them fairly for the people they enroll. Paying fairly means adjusting the payments plans receive to take into account the relative health of individual enrollees. Risk adjustment is intended to put plans on an equal footing so they can compete on the

basis of the benefits and services they offer.

The Balanced Budget Act of 1997 directed HCFA to replace the existing system of risk adjustment – which relied solely on demographic factors and a 5 percent reduction in payments to average fee-for-service beneficiaries – with one that took enrollees’ health status into account. HCFA began phasing in payments based on the new model, which measures enrollees’ health status using diagnoses from inpatient hospitalizations, in 2000. Although the new model improves on the demographic system in terms of predicting the costliness of plans’ enrollees, it could be improved.

Proposal:

- HHS should continue to develop a risk adjuster that better reflects the cost of providing care to beneficiaries and is based on the most accurate data possible.

Plan Information – Improving the Decision Making Process

Issue:

Marketing materials are used to educate beneficiaries about their options related to Medicare+Choice plans in their area. All plan information sent to Medicare beneficiaries and enrollees of particular plans must be approved by HCFA and HCFA’s regional offices. This has led to conflicting materials being sent to beneficiaries. It has also caused frustration with health plans.

Proposal:

- A consistent process should be developed with improved turn around times. HHS should allow uniform marketing package related to standard benefits to be used nationally.
- Once marketing materials are approved, they should be valid for the entire plan contract (annual). Subsequent changes in plan benefits should be sent as a separate

- HHS should examine standard form letters for different categories of beneficiary notices.
- HHS should re-evaluate the review process for beneficiary documents – especially the 45 day rule – to determine where the process can be streamlined.