The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Dr. Price:

Thank you for your letter regarding the potential impact of our regulation, CMS-6036-F, “Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards” on existing consignment closet arrangements. The Centers for Medicare & Medicaid Services greatly appreciates your bringing these concerns to our attention.

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 new regulation, 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.

I appreciate your interest in these important issues as we work towards our mutual goal of strengthening the Medicare program. Should you have questions or wish to discuss our policy, please do not hesitate to contact me. Should members of your staff have questions, they may contact our Office of Legislation.

Sincerely,

Donald M. Berwick, M.D.
December 2, 2010

Dear Dr. Berwick:

As an orthopaedic surgeon with over two decades of practice experience, I have a personal and strong interest in government policies impacting patient access to care. Consequently, I am writing you in an effort to obtain written clarity about a sweeping new regulation impacting home medical equipment suppliers, physicians, and the patients they serve.

On August 27, 2010, CMS published in the Federal Register a final rule establishing additional standards that suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must meet in order to receive reimbursement from the Medicare program. Many of the standards are new and substantive in nature, and it has come to my attention that there has been significant confusion by many physicians about the impact of these changes on so-called “consignment closets.”

For example, there is a question as to whether the new rule prohibits a DMEPOS supplier from sharing a practice location with another Medicare supplier. I have been encouraged in recent weeks by discussions between CMS officials and Congressional staff that these new regulations would not impact so-called consignment closets. However, the language contained within the rule is at best unclear, and unless clarified in writing could lead some physicians and suppliers to suspend their current practice of utilizing these closets. During my days in practice, the use of consignment closets were most beneficial to my patients. If these become prohibitive, either by cost or regulatory nuisance, many Medicare patients will not be able to receive the vital care necessary in the most cost effective, efficient, and safe manner. Requiring patients to take a doctor's prescription for a particular device, leave the office without the medically necessary product, and seek a vendor, exposes patients to unreasonable burden and increased risk. Essentially, we would have a situation where Medicare patients are receiving a significantly lower and more burdensome level of care from patients receiving care through a private insurer.

We should not unnecessarily create obstacles to timely beneficiary access to medically necessary products. A rule that is generating this level of inquiry, and that leaves so many questions...
unanswered, demands that CMS provide written clarification and direction for physicians, patients and suppliers. Thank you for your prompt consideration and I look forward to your clarifying response.

Yours truly,

Tom Price, M.D.
Member of Congress
Mr. Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Ave. SW  
Hubert Humphrey Building Room  
Washington, DC 20024

Dear Acting Administrator Weems:

We are writing today to ask that the Centers for Medicare and Medicaid Services (CMS) delay the final rule capping Medicare reimbursements to home oxygen suppliers at 36 months, which is due to go into effect on January 1, 2009.

As you know, previous to the Deficit Reduction Act of 2005, oxygen equipment was rented to patients through Medicare on a continuous rental basis. However, a provision in the Deficit Reduction Act limited monthly rental payments to oxygen suppliers to 36 months of continuous use. After 36 months, the title of the equipment would be transferred to the patient.

This raised many concerns, since the administration of oxygen is sensitive, and the maintenance and repair of the equipment is complex. Patients may not be able to afford to have their equipment serviced or have their supplier come help them with the equipment, which could compromise their health and safety. It would also presumably increase the number of emergency room visits as a result of improper or inadequate equipment upkeep.

In an effort to avoid these potential problems, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) included a repeal of this provision, leaving ownership with the oxygen supplier. Congress instructed CMS to establish adequate payments for continued care of these patients after the 36-month period. However, when CMS published the final rule it continued to cap the number of months that an oxygen supplier would receive monthly rental reimbursements at 36 months, requiring suppliers to shoulder the burden of maintaining and repairing equipment for the remainder of the reasonable life of the equipment. The rule establishes inadequate maintenance and service payments equal to only two 30 minute visits annually at a payment rate of approximately $30 per visit. In addition, the rule requires the original oxygen provider to continue to provide oxygen therapy for those patients who move out of the original oxygen provider’s service area for the rest of the reasonable life of the equipment.

This rule does not take into account unscheduled or emergency repairs or the replacement of supplies associated with the oxygen use. This will result in a decreased level of care for oxygen patients, and will potentially greatly increase the incidence of emergency room visits. After the 9.5% Medicare reimbursement cuts for home oxygen suppliers goes into effect on January 1,
2009, a one-day hospital stay will cost more than it would cost to continue to provide home oxygen service for two years.

Home oxygen suppliers are more than just equipment suppliers; they are also caregivers. They show patients how to use their equipment, answer patients’ questions, make repairs and adjustments, and ensure that patients are receiving the correct amount of oxygen. Many suppliers provide 24/7 unscheduled, emergency care, and in rural areas drive significant distances to make sure that their patients receive the care they need. Without reimbursements for these visits, suppliers may not be able to afford to continue their current level of care, and the quality of care for many of these oxygen patients is going to decrease.

Thank you for your consideration of our request to delay this rule. If you have any questions, please contact Erin Doty in Congressman Shuler’s office at erin.doty@mail.house.gov (225-6401) or Emily Henehan in Congressman Tom Price’s office at emily.henehan@mail.house.gov (225-4501).

Sincerely,

Mae White
The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding a December 11, 2015 National Supplier Clearinghouse (NSC) announcement pertaining to Medicare policy on consignment closets. You expressed concern that the announcement, which was issued to clarify the Centers for Medicare & Medicaid Services' (CMS) policy on consignment closet arrangements, barred common arrangements through which orthotics specialists help physicians and hospitals furnish the most appropriate braces and other orthotics to their Medicare patients, and that this would impede patient access to medically necessary items.

After receiving many questions and comments from the supplier community regarding the clarification, on January 26, 2016, CMS instructed the NSC to remove the clarification from its website. The NSC did so on January 29, 2016, and the policy is no longer in effect. No claim payments should be impacted as a result of the policy clarification and subsequent removal. CMS is reevaluating this matter and will issue further guidance as needed.

Thank you again for taking the time to write me on this important issue. I look forward to working with you as we continue safeguarding Medicare beneficiaries' access to high-quality durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS), while also combatting and reducing fraud, waste, and abuse associated with DMEPOS.

Sincerely,

Andrew M. Slavitt
Acting Administrator
February 8th, 2016

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Mr. Slavitt:

I am writing in response to a December 11, 2015 National Supplier Clearinghouse (NSC) announcement pertaining to Medicare policy on “consignment closets.” This policy change is another example of CMS’ failure to recognize the reality faced by patients and their physicians and thereby disrupt patient care.

Consignment closet arrangements have long been used by physician offices and hospitals in outpatient settings as a convenient way to ensure that their patients can expeditiously receive needed durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) without the physician or hospital having to enroll as Medicare suppliers. For instance, a patient who seeks treatment from a physician for a foot fracture can receive the appropriate walking boot on the spot from an orthotics specialist working on behalf of an accredited orthotics supplier, without the injured beneficiary needing to travel to find a Medicare-participating supplier and without the physician having to go through the rigorous and expensive process of becoming a Medicare DMEPOS supplier.

According to the new NSC announcement, CMS has recently released clarification of the rules for the use of consignment closets. Although no new CMS policy is actually cited and we are unable to identify any such recent release, the NSC states that in order for a DMEPOS supplier to bill for items furnished through a consignment closet arrangement, “the DMEPOS supplier cannot be present or perform any functions at the medical provider/supplier facility.” This significant change bars common arrangements through which orthotics specialists help physicians and hospitals furnish the most appropriate braces and other orthotics to their Medicare patients. If this policy stands, it will impede patient access to medically necessary items.
It is very alarming that this CMS/NSC policy appears to have been issued without any public notice or comment opportunity, despite the significant impact this policy would have on suppliers and providers. It also appears to be effective immediately, which creates immediate access issues for patients and disrupts physician practices.

Given the fact that there has been no appropriate notice to the medical community about potential changes to the consignment closet policy, I insist that CMS instruct the NSC to retract its new guidance. Instead, any changes by CMS to consignment closet policy should always be made through the regular notice and comment rulemaking process.

This new policy change will continue to put patients at risk with each passing day. I look forward to your prompt response with a resolution for this critically important issue.

Sincerely,

Tom Price, M.D.
Member of Congress
The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding the proposed Local Coverage Determination (LCD) on Biomarkers in Cardiovascular Risk Assessment (DL36358) that is currently under review by multiple Medicare Administrative Contractors (MACs). The Centers for Medicare & Medicaid Services (CMS) greatly appreciates you bringing your concerns to our attention.

As you may be aware, CMS does not develop or implement LCDs. Rather, the MACs are authorized to develop LCDs in the absence of national policy or as long as those LCDs do not conflict with a national policy. MACs publish LCDs to provide guidance within their jurisdictions to assist providers in submitting proper claims for payment.

We do require, however, when developing LCDs, that the MACs follow the LCD development process established by CMS, including opportunities for public comment and input from the local medical community, as described in Chapter 13 of the CMS Medicare Program Integrity Manual, which is available at:

As part of that process, the MACs consider all comments received on a proposed LCD prior to developing and posting a final LCD. We have confirmed that your comments were received by the MACs involved in the development of this proposed policy for their consideration.

Thank you again for sharing your concerns and for your commitment to assuring access to innovative and value-based approaches to care for the Medicare population.

Sincerely,

Andrew M. Slavitt
Acting Administrator
February 8th, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Acting Administrator Slavitt,

I am writing to express concern about the Local Coverage Determination (LCD) ModDX: Biomarkers in Cardiovascular Risk Assessment (DL36358), which is currently under review in numerous Medicare Administrative Contractor (MAC) jurisdictions. This policy would discontinue coverage for most cardiovascular risk assessment diagnostics. If finalized, this policy will deny physicians and Medicare beneficiaries access to life-saving cardiovascular risk assessment tools and raise costs for the Medicare program.

Often called the “silent killer,” cardiovascular disease is our nation’s leading cause of death. According to data from Johns Hopkins, 84 million people in the United States suffer from some form of cardiovascular disease, causing approximately 2,200 deaths a day, or one death every 40 seconds. One out of three deaths in the United States is the result of cardiovascular disease, and the direct and indirect costs of cardiovascular disease and stroke are about $315 billion annually—a number that is increasing each year.¹

Complicating the issue, the traditional indicators of cardiovascular disease risk, like the 50 year-old lipid panel, are now known to detect such risk in only a subset of patients. In fact, the majority of people who suffer heart attacks and stroke have “normal” lipid panel values. Fortunately, researchers and clinicians have developed additional diagnostic tests to much more accurately identify cardiovascular risk. For example, peer-reviewed research has demonstrated that the presence of atherogenic plaque is an indicator of cardiovascular disease.²,³ For the

Medicare population with atherosclerosis, the correct diagnosis of an individual patient’s disease etiology is essential for treatment directed towards the underlying disorder. Clinicians who have access to these diagnostic tools can develop a personalized healthcare plan for their patients, including modifications to diet, exercise, and medication.

Clinically-appropriate, physician-ordered testing for cardiovascular risk can also lead to lower costs for taxpayers. These tests typically cost between $15 - $45 dollars, much less than the cost of acute and post-acute care for patients who have a cardiac episode. Of note, an April 2015 study in the Journal of Medical Economics estimated that biomarker testing among a subgroup of health plan members 35 years old and older significantly reduced cardiac events, yielding a cost savings of $187 million over 5 years for a patient population of one million members, or $3.13 per member per month, excluding test costs. The potential savings to the Medicare program, which has 54 million beneficiaries, would amount to more than $10 billion over 5 years.

To make health care for our seniors accessible and affordable, we must identify and foster innovative, value-based approaches to disease prevention and management. To the contrary, implementation of the proposed LCD would preclude Medicare beneficiaries in your jurisdiction from accessing this type of diagnostic testing. I urge, therefore, that the proposed LCD DL36358 be retracted, and that the MACs engage with clinicians and researchers to better understand their perspectives on these life-saving tests and develop a clinically-appropriate policy.

Sincerely,

Tom Price, M.D.

CC: Arthur Lurvey, MD, FACP, FACE, Medical Director, Noridian Healthcare Solutions, LLC.

Harry Feliciano, MD, MPH, Medical Director, Palmetto GBA

Earl Berman MD, FACP, Medical Director, CGS Administrators, LLC


4 M.S. Penn et al., The Economic Impact of Implementing a Multiple Inflammatory Biomarker-based Approach to Identify, Treat, and Reduce Cardiovascular Risk, JOURNAL OF MEDICAL ECONOMICS (April 1, 2015), http://www.ncbi.nlm.nih.gov/pubmed/25763924.

The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter expressing concern with the National Correct Coding Initiative edits (NCCI) that result in denial of payment for Current Procedure Terminology (CPT) code 29823, arthroscopic shoulder debridement, extensive, when furnished in conjunction with several other arthroscopic shoulder procedures, such as CPT code 29827, arthroscopic rotator cuff repair or CPT code 29824, arthroscopic distal claviculectomy including distal articular surface. The Centers for Medicare & Medicaid Services (CMS) appreciates your interest on this issue.

Since you wrote, CMS officials, including medical officers, met again with representatives of American Academy of Orthopaedic Surgeons (AAOS) to discuss these edits. Following that meeting we informed the AAOS that we would be deleting the NCCI procedure-to-procedure edits for the code pairs 29824/29823, 29827/29823 and 29828/29823. These deletions will be effective in the July 1, 2016 version of NCCI. We have informed the AAOS of this decision.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries and assuring access to cancer care for our citizens. I will also provide this response to Senator John Barrasso.

Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable John Barrasso, M.D.
United States Senate
Washington, DC 20510

Dear Senator Barrasso:

Thank you for your letter expressing concern with the National Correct Coding Initiative edits (NCCI) that result in denial of payment for Current Procedure Terminology (CPT) code 29823, arthroscopic shoulder debridement, extensive, when furnished in conjunction with several other arthroscopic shoulder procedures, such as CPT code 29827, arthroscopic rotator cuff repair or CPT code 29824, arthroscopic distal clavicleculectomy including distal articular surface. The Centers for Medicare & Medicaid Services (CMS) appreciates your interest on this issue.

Since you wrote, CMS officials, including medical officers, met again with representatives of American Academy of Orthopaedic Surgeons (AAOS) to discuss these edits. Following that meeting we informed the AAOS that we would be deleting the NCCI procedure-to-procedure edits for the code pairs 29824/29823, 29827/29823 and 29828/29823. These deletions will be effective in the July 1, 2016 version of NCCI. We have informed the AAOS of this decision.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries and assuring access to cancer care for our citizens. I will also provide this response to Representative Tom Price.

Sincerely,

Andrew M. Slavitt
Acting Administrator
February 25, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Acting Administrator Slavitt,

CMS relies on Correct Coding Initiative (CCI) software to issue and deny payments. Since 2013, edits made to CCI have bundled several codes together for shoulder surgery and have resulted in denied payment when these procedures are performed together. Specifically, these edits have denied CPT code 29823, Arthroscopic Shoulder Debridement, extensive, with several other arthroscopic shoulder procedures such as CPT code 29827, Arthroscopic Rotator Cuff Repair, or CPT code 29824, Arthroscopic distal claviclectomy. These are distinctly separate procedures.

This issue is of extreme importance to the American Association of Orthopaedic Surgeons (AAOS), the American Orthopaedic Society for Sports Medicine (AOSSM), the Arthroscopy Association of North America (AANA), and the American Shoulder and Elbow Surgeons (ASES). The societies have written multiple letters to CMS and the third party that owns and implements the CCI software (called the National Correct Coding Initiative-NCCI) and held multiple conference calls and face-to-face meetings with CMS and NCCI, including a meeting at CMS headquarters in May 2015 with Marc Hartstein, Director of the Hospital and Ambulatory Policy Group, and other CMS officials. After the May 2015 meeting, several documents were submitted to CMS indicating the CCI edits the societies felt were erroneous along with materials describing anatomically why these edits were incorrect. CMS stated they would take the request under review to change their edits and the policy manual for January 1, 2016. These edits and policy manual were released recently and did not result in any correction to the policy or edits in question.

Earlier this year, the AAOS submitted a request to meet with you, personally, about this issue. However, we recently received news that the request was denied, and they were offered an opportunity to meet with the Deputy Director of the Center for Medicare. The AAOS has already discussed this issue with other members of the CMS and it is important that this issue be fully understood. Therefore, we are asking you to reconsider their request and would like to encourage you, personally, to orchestrate a meeting to discuss the shoulder coding issue.

Sincerely,

Tom Price, M.D.

John Barrasso, M.D.
The Honorable Tom Price  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding the Calendar Year (CY) 2017 Advance Notice and Draft Call Letter for Medicare Advantage. I appreciate your observations and concerns and agree that Medicare Advantage (MA) is a critical part of the Medicare program.

As you are aware, the Centers for Medicare & Medicaid Services (CMS) released the CY 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter on April 4, 2016. The finalized policies seek to provide stable payments to plans and make improvements to the program for plans that provide high quality care to the most vulnerable beneficiaries.

Your comments on CMS’s proposed revision to the Medicare Employer Retiree Plan payment and bidding model were appreciated. CMS received many comments on this proposal, which we carefully evaluated and considered as we finalized policy for the 2017 plan year. The policy, which is supported by Medicare Payment Advisory Commission analysis, is intended to provide Medicare Employer Retiree Plans with a fair benchmark, reflective of comparable local MA trends and prices. Under this new policy, MA Organizations offering Medicare Employer Retiree Plan will need to compete for employers to contract with them for these offerings on access, quality, customer service, and wrap-around benefits. While each plan and beneficiary experience is distinct, payment under the new approach will allow Medicare Employer Retiree Plan to continue the offering of basic and supplemental benefits.

The finalized methodology for calculating Medicare Employer Retiree Plan county payments includes two important modifications based on the feedback we received:

- First, in the Advance Notice, CMS proposed to calculate the bid-to-benchmark ratios for 2017 using non-Medicare Employer Retiree Plan bids and benchmarks for 2017. However, to address timing concerns raised by commenters, CMS has calculated bid-to-benchmarks ratios for 2017 using 2016 bids and benchmarks. This revised approach will allow CMS to provide employers and insurers with information on payment rates in the Rate Announcement in April each year, rather than waiting until August.

- Second, to provide employers and plans more time to adapt to this payment change, CMS is providing a two-year transition to the new Medicare Employer Retiree Plans county payment rate methodology.
Page 2 – The Honorable Tom Price

Thank you again for taking the time to share your views. I look forward to working with you to maintain a strong MA program so that our nation’s Medicare beneficiaries can continue to have a wide range of quality plan choices.

Sincerely,

Andrew M. Slavitt
Acting Administrator
March 11, 2016

Dear Acting Administrator Slavitt:

The Centers for Medicare & Medicaid Services (CMS) 2017 Advance Notice proposed a cut of nearly 3% to Medicare Advantage (MA) Retiree Coverage. This cut will negatively impact over a quarter of all MA beneficiaries in Georgia. That amounts to over 132,000 seniors in Georgia and 3.3 million nationwide. The state of Georgia is ranked ninth in the country for the most MA beneficiaries who will be directly impacted by this severe cut.

The value of MA Retiree Coverage is significant for seniors that depend on this effective and comprehensive care in retirement. MA Retiree Coverage offers seniors high quality coordinated care and access to disease management. We have significant concerns that the proposed cuts to MA Retiree Coverage will result in the disruption of care for Georgia seniors by increasing beneficiary premiums and out-of-pocket costs, diminishing benefit packages, and generating narrower provider networks. In fact, a recent study released on March 2nd, 2016, from Milliman, Inc. found that this proposed 3% cut will result in a devaluation of MA Retiree Coverage plans by $19 to $22 per senior, per month on average.

Please eliminate this cut to MA Retiree Coverage from the 2017 Final Rate Notice so that retirees in Georgia and around the country will continue to have access to affordable and high quality health care coverage.

Yours Truly,

Tom Price, M.D.
The Honorable Tom Price  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS's policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
The CMS has administered a transparent public process in both the design and operation of the program. The work performed in researching, analyzing, and designing the Medicare competitive bidding program for DMEPOS has been carried out over the past 30 years by Medicare program experts within CMS, contracts with health economists, and consultation from experts in design theory. At each and every phase of the research, design and development of Medicare's competitive bidding program, the work has been performed in consultation with the DMEPOS manufacturers, suppliers, and beneficiaries so that the expertise and advice of stakeholders is included in the process of developing the program.

In addition, CMS has conducted dozens of briefings for congressional staff over the course of the program's design and implementation, and has also participated in several congressional hearings related to the program. Specific program data such as the number of contracts offered, single payment amounts, the percentage of contracts awarded to small suppliers, lists of contract suppliers, and the percentage of contracts accepted versus rejected are made available to the public as soon as possible. We have made available information about this new program through notice and comment rulemaking, public advisory committee meetings, educational and outreach programs, ongoing communication through listserv messages and open door forums, toll-free helplines for suppliers and beneficiaries, a Supplier Locator Tool for beneficiaries and referral agents, and the following three comprehensive websites:

- [www.dmecompetitivebid.com](http://www.dmecompetitivebid.com) (for bidders and contract suppliers)
- [www.medicare.gov](http://www.medicare.gov) (for beneficiaries)

Regarding your specific requests, I have enclosed information from our public website detailing the required tax and financial documents, and related financial accounting ratios that form the basis of the financial standards. We do not make public the specific thresholds in order to protect the integrity of the program. In addition, I have provided a public fact sheet which explains how area demand and supplier capacity are determined.

Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The competitive bidding law and regulations specify that the Centers for Medicare & Medicaid Services (CMS) may not award a competitive bidding program contract to a supplier unless that supplier meets applicable financial standards. Applying financial standards to suppliers is needed to assess the expected quality of suppliers, estimate the total potential capacity of selected suppliers, and ensure that selected suppliers are able to continue to serve market demand for the duration of their contracts.

The Request for Bids (RFB) Instructions specifies the financial information used to evaluate suppliers' financial health. CMS uses the required tax and financial documents to calculate standard accounting ratios for each bidder.

The following financial ratios will be used for the DMEPOS Competitive Bidding Program Round 2 and national mail-order competitions:

- **Return on Sales** = Net Income (Loss)/Annual Net Sales
- **Current Ratio** = Current Assets/Current Liabilities
- **Sales to Inventory** = Annual Net Sales/Inventory
- **Collection Period** = (Accounts Receivable/Annual Net Sales) x 360
- **Working Capital** = Current Assets – Current Liabilities
- **Accounts Payable to Sales** = Accounts Payable/Annual Net Sales
- **Debt to Equity** = Total Liabilities/Net Worth
- **Current Liabilities to Net Worth** = Current Liabilities/Net Worth
- **Quality of Earnings** = Cash Flow from Operations/(Net Income + Depreciation + Amortization)
- **Operating Cash Flow to Sales** = Cash Flow from Operations/(Revenue – Adjustment to Revenue)

These ratios and the credit report and score are used to determine bidder compliance with financial standards.

(You will need Adobe Acrobat Reader to view or print items on this page.)
Facts about the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program - Round 2 and National Mail Order Competitions

Review of Supplier Capacity and Expansion Plans

The Medicare DMEPOS Competitive Bidding Program bid evaluation process is designed to result in a sufficient number of contract suppliers to ensure that beneficiaries throughout the competitive bidding area (CBA) have ready access to quality products and services at reasonable prices during the entire contract period. This fact sheet describes how the Centers for Medicare & Medicaid Services (CMS) conducts its review of supplier capacity and expansion plans during the bid evaluation process.

Suppliers that bid in the DMEPOS Competitive Bidding Program must provide Form B in DBidS (the online bidding system) their estimated capacity for each item being bid. To determine estimated capacity, each supplier:

1. Calculates the number of units per Healthcare Common Procedure Coding System (HCPCS) code or payment class that it currently provides on a yearly basis in the CBA, and
2. Adds any additional units it is capable of providing throughout the entire CBA annually, beginning with the first year of the contract period.

CMS expects suppliers to be capable of sustaining this level of capacity throughout the entire contract period. Suppliers must be prepared to do so beginning on day one of the contract period. Suppliers that are new to a CBA, new to a product category, or otherwise plan to expand their capacity beyond their current levels must submit an expansion plan in Form B in DBidS. All bidders must also submit the required hardcopy financial documents specified in the Request for Bids (RFB).

The estimated capacity and financial documents are considered by CMS as part of the bid evaluation process. CMS begins the bid evaluation process by verifying bidder eligibility. All bids are checked for compliance with enrollment standards, licensure requirements, financial standards, quality standards, accreditation requirements, and other program requirements. Please note that CMS evaluates compliance with financial standards by first calculating standard accounting ratios for each bidder using the financial statements and tax extract submitted during bidding. An aggregate or total score is determined using the financial ratios and the credit score. The supplier's total financial score is then evaluated against a threshold score to determine if the supplier meets the minimum requirements to continue in the evaluation. Only suppliers that submit qualified bids are eligible for contracts.

An important step in the bid evaluation process is determining projected beneficiary demand. In the bid evaluation process, the sum of the projected capacity of eligible suppliers is compared to the projected demand. The DMEPOS Competitive Bidding Program demand calculation methodology takes into account not only the actual historic beneficiary utilization, but also considers expected changes in the number of beneficiaries enrolled and the expected growth in beneficiary services. CMS compared the projected demand calculated for the initial Round 1 to actual 2008 utilization and found that this methodology produced demand estimates well in excess of the actual utilization. This method of projecting demand helps to ensure further that a sufficient number of qualified contract suppliers is available to meet actual demand for items and services.

After calculating the projected demand, CMS sums the cumulative capacity of qualified suppliers bidding for a product category for a CBA and determines how many of these suppliers are needed to meet beneficiary demand throughout the contract period. CMS evaluates and adjusts supplier capacity as follows:

continued pg. 2
For Round 2, if a supplier submits an estimated capacity that is greater than 20 percent of projected beneficiary demand in the CBA, CMS will lower that supplier’s capacity to 20 percent of beneficiary demand. This lowering of a supplier’s projected capacity does not limit the number of items a supplier could furnish if awarded a contract. This adjustment does not apply to the national mail-order competition.

To evaluate the capacity of a supplier that plans to expand its capacity (i.e., total estimated capacity exceeds historic claims in the CBA or product category), CMS looks at the expansion plan as well as the hardcopy financial documents to determine the ability of that supplier to furnish its estimated capacity. CMS compares each qualified bidder’s total financial score (this is the same score used to determine whether a bidder meets the minimum financial requirements to participate in the program) to an expansion threshold score. If a supplier is new to an area, new to a product category, or submits estimated capacity that represents substantial growth over current levels, CMS may conduct a more detailed evaluation of that supplier’s expansion plan to verify the supplier’s ability to provide items and services in the CBA on day one of the contract period. If a bidder’s financial health and expansion plan do not support the supplier’s estimated capacity, CMS will adjust the capacity to the supplier’s historic level. Adjustments to the supplier’s estimated capacity have no effect on whether or not a supplier is awarded a contract.
Bidding Suppliers
Financial Measures

The competitive bidding law and regulations specify that the Centers for Medicare & Medicaid Services (CMS) may not award a competitive bidding program contract to a supplier unless that supplier meets applicable financial standards. Applying financial standards to suppliers is needed to assess the expected quality of suppliers, estimate the total potential capacity of selected suppliers, and ensure that selected suppliers are able to continue to serve market demand for the duration of their contracts.

The Request for Bids (RFB) Instructions specifies the financial information used to evaluate suppliers' financial health. CMS uses the required tax and financial documents to calculate standard accounting ratios for each bidder.

The following financial ratios will be used for the DMEPOS Competitive Bidding Program Round 2 and national mail-order competitions:

- **Return on Sales** = Net Income (Loss)/Annual Net Sales
- **Current Ratio** = Current Assets/Current Liabilities
- **Sales to Inventory** = Annual Net Sales/Inventory
- **Collection Period** = (Accounts Receivable/Annual Net Sales) x 360
- **Working Capital** = Current Assets - Current Liabilities
- **Accounts Payable to Sales** = Accounts Payable/Annual Net Sales
- **Debt to Equity** = Total Liabilities/Net Worth
- **Current Liabilities to Net Worth** = Current Liabilities/Net Worth
- **Quality of Earnings** = Cash Flow from Operations/(Net Income + Depreciation + Amortization)
- **Operating Cash Flow to Sales** = Cash Flow from Operations/(Revenue – Adjustment to Revenue)

These ratios and the credit report and score are used to determine bidder compliance with financial standards.

(You will need Adobe Acrobat Reader to view or print items on this page.)

Last updated on 11/30/2011
The Honorable Glenn Thompson  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Thompson:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
The CMS has administered a transparent public process in both the design and operation of the program. The work performed in researching, analyzing, and designing the Medicare competitive bidding program for DMEPOS has been carried out over the past 30 years by Medicare program experts within CMS, contracts with health economists, and consultation from experts in design theory. At each and every phase of the research, design and development of Medicare’s competitive bidding program, the work has been performed in consultation with the DMEPOS manufacturers, suppliers, and beneficiaries so that the expertise and advice of stakeholders is included in the process of developing the program.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Paul Ryan  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Ryan:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
May 1, 2013

The Honorable Michael Fitzpatrick
U.S. House of Representatives
Washington, DC 20515

Dear Representative Fitzpatrick:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Todd Rokita  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Rokita:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Bruce Braley  
U.S. House of Representatives  
Washington, DC  20515  

Dear Representative Braley:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Tim Ryan  
U.S. House of Representatives  
Washington, DC  20515  

Dear Representative Ryan:  

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Sincerely,

[Signature]

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Michael Coffman  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Coffman:

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Sincerely,

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Acting Administrator

Enclosures
The Honorable Michael G. Grimm  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Grimm:

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable David P. Roe  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Roe:  

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable David Joyce  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Joyce:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Marsha Blackburn  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Blackburn:

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner  
Acting Administrator

Enclosures
The Honorable Bill Posey  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Posey:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Mike Rogers  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Rogers:

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Hanna:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Page 2 – The Honorable Richard Hanna

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Meehan:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Alan Nunnelee  
U.S. House of Representatives  
Washington, DC  20515  

Dear Representative Nunnelee:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable David B. McKinley  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative McKinley:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable C.W. Bill Young  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Young:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Wilson:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Michael Michaud
U.S. House of Representatives
Washington, DC 20515

Dear Representative Michaud:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Dennis Ross  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Ross:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable John Barrow  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Barrow:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Frank Wolf  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Wolf:

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Sincerely,

Marilyn Tavenner
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Enclosures
The Honorable Tim Murphy  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Murphy:

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Brett Guthrie  
U.S. House of Representatives  
Washington, DC  20515  

Dear Representative Guthrie:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Trey Gowdy  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Gowdy:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Vern Buchanan  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Buchanan:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Lynn Westmoreland  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Westmoreland:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Ed Whitfield  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Whitfield:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Jo Bonner  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Bonner:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Christopher Smith
U.S. House of Representatives
Washington, DC 20515

Dear Representative Smith:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Robert Wittman  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Wittman:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Bill Johnson  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Johnson:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS's policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable James Renacci  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Renacci:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Gus Bilirakis  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Bilirakis:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Doug Lamborn  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Lamborn:

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Sincerely,

Marilyn Tavenner
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Enclosures
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Sincerely,

Marilyn Tavenner  
Acting Administrator

Enclosures
The Honorable C.A. Dutch Ruppersberger  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Ruppersberger:

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Sincerely,

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Acting Administrator

Enclosures
The Honorable Erik Paulsen  
U.S. House of Representatives  
Washington, DC 20515

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Enclosures
The Honorable Jim Jordan  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Jordan:

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Enclosures
The Honorable Peter King  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative King:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
The CMS has administered a transparent public process in both the design and operation of the program. The work performed in researching, analyzing, and designing the Medicare competitive bidding program for DMEPOS has been carried out over the past 30 years by Medicare program experts within CMS, contracts with health economists, and consultation from experts in design theory. At each and every phase of the research, design and development of Medicare’s competitive bidding program, the work has been performed in consultation with the DMEPOS manufacturers, suppliers, and beneficiaries so that the expertise and advice of stakeholders is included in the process of developing the program.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Bob Gibbs  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Gibbs:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner  
Acting Administrator

Enclosures
The Honorable Tim Griffin  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Griffin:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Steve Chabot
U.S. House of Representatives
Washington, DC 20515

Dear Representative Chabot:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Tom Marino  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Marino:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Adam Kinzinger  
U.S. House of Representatives  
Washington, DC  20515  

Dear Representative Kinzinger:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Christopher Gibson  
U.S. House of Representatives  
Washington, DC 20515

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Sincerely,

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Enclosures
The Honorable Leonard Lance  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Lance:

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Sincerely,

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Enclosures
The Honorable Charles Boustany
U.S. House of Representatives
Washington, DC 20515

Dear Representative Boustany:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Blaine Luetkemeyer  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Luetkemeyer:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Mick Mulvaney  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Mulvaney:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Walter Jones  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Jones:

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Gregg Harper  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Harper:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Markwayne Mullin  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Mullin:

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Sincerely,

Marilyn Tavenner
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Enclosures
The Honorable James Lankford  
U.S. House of Representatives  
Washington, DC 20515

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Sincerely,

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Enclosures
The Honorable Spencer Bachus  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Bachus:

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Sincerely,

[Marilyn Tavenner]
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Enclosures
The Honorable Steve Cohen  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Cohen:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Tom Reed  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Reed:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Renee Ellmers  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Ellmers:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Mark Amodei  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Amodei:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Robert Hurt  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Hurt:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Mike Kelly  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Kelly:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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The Honorable Tim Walberg  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Walberg:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Keith Rothfus  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Rothfus:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator
The Honorable Michael Turner  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Turner:

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Andy Barr  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Barr:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
The CMS has administered a transparent public process in both the design and operation of the program. The work performed in researching, analyzing, and designing the Medicare competitive bidding program for DMEPOS has been carried out over the past 30 years by Medicare program experts within CMS, contracts with health economists, and consultation from experts in design theory. At each and every phase of the research, design and development of Medicare's competitive bidding program, the work has been performed in consultation with the DMEPOS manufacturers, suppliers, and beneficiaries so that the expertise and advice of stakeholders is included in the process of developing the program.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Collin Peterson  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Peterson:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Richard Nugent  
U.S. House of Representatives  
Washington, DC  20515  

Dear Representative Nugent:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Robert Latta  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Latta:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Trent Franks  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Franks:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Ralph Hall  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Hall:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Rick Crawford  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Crawford:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Bob Goodlatte  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Goodlatte:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Todd Young  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Young:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS's policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Scott DesJarlais  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative DesJarlais:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Lynn Jenkins  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Jenkins:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable John Kline
U.S. House of Representatives
Washington, DC 20515

Dear Representative Kline:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Billy Long  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Long:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Stivers:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Shelley Moore Capito  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Capito:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Lou Barletta  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Barletta:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Austin Scott  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Scott:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
The CMS has administered a transparent public process in both the design and operation of the program. The work performed in researching, analyzing, and designing the Medicare competitive bidding program for DMEPOS has been carried out over the past 30 years by Medicare program experts within CMS, contracts with health economists, and consultation from experts in design theory. At each and every phase of the research, design and development of Medicare’s competitive bidding program, the work has been performed in consultation with the DMEPOS manufacturers, suppliers, and beneficiaries so that the expertise and advice of stakeholders is included in the process of developing the program.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Rob Woodall  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Woodall:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Robert Pittinger  
U.S. House of Representatives  
Washington, DC  20515

Dear Representative Pittinger:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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stakeholders is included in the process of developing the program.

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strengthening the Medicare program for all beneficiaries. I will also provide this response to the
co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Diane Black  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Black:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Paul Broun  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Broun:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Schock:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner

Acting Administrator

Enclosures
The Honorable Larry Buschon  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Buschon:  

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Rodney Davis  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Davis:  

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Steve Scalise  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Scalise:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

The CMS successfully implemented Round One of the program on January 1, 2011, in nine metropolitan areas after making a number of improvements, including new requirements from Congress, and after working closely with stakeholders. The CMS Actuary projects that the program will save $25.8 billion for Medicare over 10 years, and save another $17.2 billion for beneficiaries through lower coinsurance and premiums. The program has already saved in excess of $200 million in each of its first two years of operation with no disruption in access or negative health consequences for beneficiaries based on our active surveillance and monitoring program. In addition, CMS has received only a handful of complaints from beneficiaries about the program. CMS has shared the monitoring data with the public on the CMS website and briefed staff and members of various Congressional committees. CMS has now awarded contracts to experienced national and local suppliers across the country and is scheduled to move forward on July 1 of this year to implement the program in 91 additional areas, as the law requires.

While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Griffith:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Kristi Noem  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Noem:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Randy Forbes  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Forbes:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and taxpayers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Peter Roskam  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Roskam:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Niki Tsongas  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Tsongas:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Hank C. Johnson, Jr.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Johnson:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Smith:

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Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
Dear Representative Ros-Lehtinen:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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While we understand that manufacturers and suppliers are not in favor of lower Medicare prices, I can assure you that CMS’s policy and process results in appropriate payment amounts. These payment amounts are based on the bids of qualified suppliers that meet strict quality and accreditation standards, financial standards, Medicare supplier standards, and state licensing requirements. Each bid is screened to ensure that it is a bona fide bid and those that fail are excluded. In both Round One and Round Two of the program, suppliers overwhelmingly accepted contract offers (92 percent) at the payment amounts set through the competition. Given recent reports by the Government Accountability Office and the Office of Inspector General documenting the excessive payment amounts in the current DMEPOS fee schedule, we would expect to see much lower payment amounts under the competitive bidding program.
The CMS has administered a transparent public process in both the design and operation of the program. The work performed in researching, analyzing, and designing the Medicare competitive bidding program for DMEPOS has been carried out over the past 30 years by Medicare program experts within CMS, contracts with health economists, and consultation from experts in design theory. At each and every phase of the research, design and development of Medicare’s competitive bidding program, the work has been performed in consultation with the DMEPOS manufacturers, suppliers, and beneficiaries so that the expertise and advice of stakeholders is included in the process of developing the program.

In addition, CMS has conducted dozens of briefings for congressional staff over the course of the program’s design and implementation, and has also participated in several congressional hearings related to the program. Specific program data such as the number of contracts offered, single payment amounts, the percentage of contracts awarded to small suppliers, lists of contract suppliers, and the percentage of contracts accepted versus rejected are made available to the public as soon as possible. We have made available information about this new program through notice and comment rulemaking, public advisory committee meetings, educational and outreach programs, ongoing communication through listserv messages and open door forums, toll-free helplines for suppliers and beneficiaries, a Supplier Locator Tool for beneficiaries and referral agents, and the following three comprehensive websites:

- www.dmecompetitivebid.com (for bidders and contract suppliers)
- www.cms.gov/DMEPOSCompetitiveBid/ (for non-contract suppliers and referral agents)
- www.medicare.gov (for beneficiaries)

Regarding your specific requests, I have enclosed information from our public website detailing the required tax and financial documents, and related financial accounting ratios that form the basis of the financial standards. We do not make public the specific thresholds in order to protect the integrity of the program. In addition, I have provided a public fact sheet which explains how area demand and supplier capacity are determined.

Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Virginia Foxx  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Foxx:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
The Honorable Rick A. Crawford  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Crawford:

Thank you for your letter regarding the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that this new program has already been effective in reducing beneficiary out-of-pocket costs, providing significant savings to Medicare and tax payers, reducing over-utilization and fraud, and ensuring beneficiary access to high quality items and services. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing your concerns to our attention.

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Thank you again for your letter regarding the DMEPOS competitive bidding program. I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator

Enclosures
March 15, 2013

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Tavenner:

We are writing to express our concern regarding the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding program and the recently announced Round 2 bid prices for durable medical equipment.

As you know, Medicare published payment rates for durable medical equipment subject to Round 2 of the Competitive Bidding program. Based on Medicare’s calculations, reimbursement rates will be reduced by 45% below the current Medicare fee schedule and 72% below the fee schedule for diabetic supplies as of July 1, 2013. Furthermore, the national mail order program for diabetic supplies will impact every diabetic Medicare beneficiary in the United States.

Congress, in the Medicare Modernization Act of 2003, designed the Competitive Bidding program with the intention of reducing Medicare and beneficiary expenditures through competition while ensuring that beneficiaries continue to have access to quality items. However, the current CMS-designed program is neither competitive nor does it protect beneficiary access to high quality medical supplies. In fact, many patients will likely have to find a new supplier, often in another state.

There are numerous flaws in the Competitive Bidding program that prevent it from ensuring quality and access for Medicare beneficiaries. As just one example, the program does not ensure that bidders are qualified to provide the products in the bid markets.

Furthermore, the lack of transparency surrounding the Competitive Bidding program from the Centers for Medicare and Medicaid Services is a source of major concern for patients, providers, and Congress alike. Therefore, we respectfully request the following information:

- The financial standards used to determine if a provider is qualified to bid.
- How patient demand in given metropolitan statistical areas is determined.
- Details about how provider capacity to meet patient demand is determined.
• Whether CMS would consider a delay in implementation of Round 2.

We continue to hear the concerns surrounding the DMEPOS Competitive Bidding program from patients and providers in our districts. American businesses all across this country as well as the aging and vulnerable Medicare population they serve are potentially at-risk due to the way in which CMS is implementing this program. We look forward to your timely response to these concerns.

Yours truly,

[Signature]

Rep. Tom Price

[Signature]

Rep. Glenn Thompson

[Signature]

Rep. Todd Rokita

[Signature]

Rep. Paul Ryan

[Signature]

Rep. Bruce Braley

[Signature]

Rep. Michael Fitzpatrick

[Signature]

Rep. Tim Ryan
Rep. Michael Coffman

Rep. Mike Rogers (AL)

Rep. Michael Grimm

Rep. Richard Hanna

Rep. David P. Roe

Rep. Patrick Meehan

Rep. David Joyce

Rep. Alan Nunnelee

Rep. Marsha Blackburn

Rep. David B. McKinley

Rep. Bill Posey

Rep. C.W. Bill Young
Rep. Joe Wilson

Rep. Michael Michaud

Rep. Dennis Ross

Rep. John Barrow

Rep. Frank Wolf

Rep. Tim Murphy

Rep. Vern Buchanan

Rep. Lyon Westmoreland

Rep. Brett Guthrie

Rep. Trey Gowdy

Rep. Vern Buchanan

Rep. Lynn Westmoreland

Rep. Ed Whitfield

Rep. Jo Bonner
Rep. Christopher Smith
Rep. Doug Lamborn
Rep. Robert Wittman
Rep. Patrick Tiberi
Rep. Bill Johnson
Rep. C.A. Dutch Ruppersberger
Rep. James Renacci
Rep. Erik Paulsen
Rep. Gus Bilirakis
Rep. Jim Jordan
Rep. Gregg Harper

Rep. Renee Ellmers

Rep. Markwayne Mullin

Rep. Mark Amodi

Rep. James Lankford

Rep. Robert Hurt

Rep. Spencer Bachus

Rep. Mark Amodi

Rep. Steve Cohen

Rep. Mike Kelly

Rep. Tim Walberg

Rep. Keith Rothfus

Rep. Tom Reed
Rep. Michael Turner
Rep. Ralph Hall
Rep. Andy Barr
Rep. Rick Crawford
Rep. Collin Peterson
Rep. Bob Goodlatte
Rep. Richard Nugent
Rep. Todd Young
Rep. Robert Latta
Rep. Scott DesJarlais
Rep. Trent Franks
Rep. Lynn Jenkins
Rep. John Kline

Rep. Rob Woodall

Rep. Billy Long

Rep. Robert Pittenger

Rep. Steve Stivers

Rep. Diane Black

Rep. Shelley Moore Capito

Rep. Paul Broun

Rep. Lou Barletta

Rep. Aaron Schock

Rep. Austin Scott

Rep. Larry Buschon
The Honorable Tom Price, MD  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Price:

Thank you for sharing your thoughts regarding our proposed Part B Drug Payment Model. The Centers for Medicare & Medicaid Services (CMS) appreciates you bringing these views to our attention.

As you note, CMS has issued a proposed rule describing a new Part B Drug Payment Model that would test a two-phase model whether alternative drug payment designs may improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care. This proposal is part of the Administration’s broader strategy to encourage better care, smarter spending, and healthier people by paying for what works, unlocking health data, and finding new ways to coordinate and integrate care to improve quality. More specifically, this proposed rule is designed to test different physician and patient incentives to do two things: drive the prescribing of the most effective drugs and test new payment approaches that reward positive patient outcomes.

The comment period for the proposed rule closed on May 9, 2016. We have included your comments as part of the public record. We will carefully consider the public comments on this proposal that we received during the public comment period in developing a final rule.

We appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will provide a copy of this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt  
Acting Administrator
The Honorable Andy Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Acting Administrator Slavitt:

We write to express our deep concerns regarding the Centers for Medicare & Medicaid Services (CMS) “Part B Drug Payment Model” proposed rule, published in the Federal Register on March 11, 2016. CMS’s proposed Medicare drug experiment would unnecessarily disrupt care for the sickest seniors who depend on Medicare, including those with cancer, macular degeneration, rheumatoid arthritis, neurological disorders, rare diseases and primary immunodeficiency diseases. Given these concerns outlined here, we ask that CMS withdraw this proposed rule that could endanger access to care for America’s most vulnerable seniors.

CMS’s proposed Medicare experiment would impose cuts in Phase I that will severely harm patient access to needed drugs. Under CMS’s Medicare drug experiment, numerous physicians would face acquisition costs that exceed the Medicare payment amount for certain drugs. This policy will make it harder for patients to receive the drugs they need and especially hurt seniors who depend on doctors in smaller practices or those who live in rural areas.

The scope of the proposed experiment on drugs for seniors is also deeply troubling. CMS proposes forcing nearly 75% of the country to participate in the Medicare drug experiment. The impact on patients will be sweeping and affect seniors across the country.

CMS’s proposed Medicare drug experiment would also lead physicians to refer patients to a hospital outpatient department (HOPD). Driving more care to an often less convenient, more costly setting makes it more challenging for beneficiaries to access needed care and increases overall Medicare costs. This will lead to further consolidation and less choice for seniors.

The policies in the proposed Part B model were developed with no input from outside experts and those with real-world experience. CMS should have consulted with affected stakeholders considering the proposal’s broad scope and risk for beneficiaries.
We are concerned that the proposed model will hinder physician efforts to participate in delivery and payment reforms, including the Oncology Care Model (OCM) and the various alternative payment models (APMs) incentivized by the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). OCM practices have voluntarily engaged to make changes aimed at bringing more value through a model that CMS established in close consultation with stakeholders. Layering cuts on top of sweeping systematic changes will hurt efforts at payment reform in Medicare.

We are also concerned that the proposal fails to state how CMS will assess the impact on the quality of care beneficiaries receive. The proposal states an expectation that the model will reduce Part B drug spending while maintaining the quality of care beneficiaries receive, yet it does not provide the specifics of how access and quality will be assessed throughout the duration of the model or in the evaluation phase. Understanding the quality metrics used to determine whether there are acute problems or what constitutes the ultimate success of the model is critically important. Yet CMS failed to address this in their proposed rule.

This experiment affects all our constituents, Democrat or Republican, and we believe that Congress, whose responsibility is to the electorate, is best tasked with making these decisions, not an unaccountable entity. Every American should have their voices heard rather than be silenced by Washington politics.

Given the numerous concerns regarding this rule and the impact it will have on Medicare seniors’ access to lifesaving drugs, we again urge CMS to withdraw this proposed regulation.

Sincerely,

TOM PRICE, M.D.  
John Shimkus  
Charles Boustany, Jr., M.D.

Kevin Brady  
Fred Upton  
Steve Scalise

U.S. House of Representatives  
U.S. House of Representatives  
U.S. House of Representatives
The Honorable Tom Price, M.D.
The Honorable John Shimkus
The Honorable Charles Boustany Jr., M.D.
The Honorable Kevin Brady
The Honorable Fred Upton
The Honorable Steve Scalise
The Honorable Mac Thornberry
The Honorable Candice Miller
The Honorable Steve Chabot
The Honorable Bill Shuster
The Honorable Charles W. Dent
The Honorable Michael T. McCaul
The Honorable Luke Messer
The Honorable Patrick McHenry
The Honorable Cathy McMorris-Rodgers
The Honorable Lamar Smith
The Honorable John Kline
The Honorable Jeb Hensarling
The Honorable Robert W. Bishop
The Honorable Harold Rogers
The Honorable Pete Sessions
The Honorable Michael Conaway
The Honorable Bob Goodlatte
The Honorable Edward R. Royce
The Honorable Jason Chaffetz
The Honorable Jeff Miller
The Honorable Robert Dold
The Honorable Larry Bucshon, M.D.
The Honorable Michael C. Burgess, M.D.
The Honorable Randy Hultgren
The Honorable Michael G. Fitzpatrick
The Honorable Brett Guthrie
The Honorable Tom Cole
The Honorable Rodney Davis
The Honorable Tom Reed
The Honorable Tim Walberg
The Honorable David W. Jolly
The Honorable Frank Lucas
The Honorable Doug Lamborn
The Honorable Bob Latta
The Honorable Robert J. Wittman
The Honorable Stephen Fincher
The Honorable Kristi Noem
The Honorable Daniel M. Donovan, Jr.
The Honorable Richard Nugent
The Honorable F. James Sensenbrenner, Jr.
The Honorable Darren LaHood
The Honorable Christopher H. Smith
The Honorable Tom Graves
The Honorable Jeff Denham
The Honorable Mike Coffman
The Honorable Cynthia M. Lummis
The Honorable Virginia Foxx
The Honorable Walter B. Jones
The Honorable Frank A. LoBiondo
The Honorable Stevan Pearce
The Honorable Ted Poe
The Honorable Blaine Luetkemeyer
The Honorable John L. Mica
The Honorable Tom McClintock
The Honorable Collin C. Peterson
The Honorable Mick Mulvaney
The Honorable Duncan Hunter
The Honorable John R. Carter
The Honorable Michael Simpson
The Honorable David A. Trott
The Honorable Austin Scott
The Honorable Trent Franks
The Honorable John Culberson
The Honorable Patrick Meehan
The Honorable Rod Blum
The Honorable Ryan A. Costello
The Honorable Barbara Comstock
The Honorable Gregg Harper
The Honorable George Holding
The Honorable Mimi Walters
The Honorable Mike Rogers
The Honorable Paul A. Gosar, D.D.S.
The Honorable Scott DesJarlais, M.D.
The Honorable Brad Ashford
The Honorable Tom Marino
The Honorable Doug LaMalfa
The Honorable Scott Tipton
The Honorable Ann Wagner
The Honorable Erik Paulsen
The Honorable Joseph R. Pitts
The Honorable Bradley Byrne
The Honorable Bruce Westerman
The Honorable David Rouzer
The Honorable Rick Allen
The Honorable David P. Roe, M.D.
The Honorable Mike Pompeo
The Honorable Bob Gibbs
The Honorable Robert Pittenger
The Honorable David Young
The Honorable Earl L. "Buddy" Carter
The Honorable Robert B. Aderholt
The Honorable Steve Russell
The Honorable James B. Renacci
The Honorable Richard Hudson
The Honorable Dan Benishek, M.D.
The Honorable John R. Moolenaar
The Honorable Mike Bishop
The Honorable Chris Stewart
The Honorable Dennis A. Ross
The Honorable Lou Barletta
The Honorable Ron DeSantis
The Honorable David B. McKinley
The Honorable Martha Roby
The Honorable Jackie Walorski
The Honorable Glenn "GT" Thompson
The Honorable Jim Bridenstine
The Honorable Mia Love
The Honorable Crescent Hardy
The Honorable Ralph L. Abraham Jr., M.D.
The Honorable Mark E. Amodei
The Honorable Charles J. Fleischmann
The Honorable Brian Babin, D.D.S.
The Honorable Frank C. Guinta
The Honorable Evan Jenkins
The Honorable Mario Diaz-Balart
The Honorable Glenn Grothman
The Honorable Tom Rice
The Honorable Kevin Yoder
The Honorable Scott E. Rigell
The Honorable Joe Heck, D.O.
The Honorable Tom Emmer
The Honorable Dave Brat
The Honorable John Ratcliffe
The Honorable Garret Graves
The Honorable Barry Loudermilk
The Honorable Thomas Massie
The Honorable Jason Smith
The Honorable Andy Barr
The Honorable Bill Flores
The Honorable Steve Womack
The Honorable Kevin Cramer
The Honorable Diane Black
The Honorable Devin Nunes
The Honorable French Hill
The Honorable Morgan H. Griffith
The Honorable David G. Valadao
The Honorable Adam Kinzinger
The Honorable Patrick J. Tiberi
The Honorable Mike Bost
The Honorable Markwayne Mullin
The Honorable Carlos Curbelo
The Honorable Chris Collins
The Honorable Susan Brooks
The Honorable Steve Knight
The Honorable Keith Rothfus
The Honorable Renee Ellmers
The Honorable Bill Huizenga
The Honorable David B. Reichert
The Honorable David P. Joyce
The Honorable Steve Stivers
The Honorable Todd Young
The Honorable Doug Collins
The Honorable Daniel Webster
The Honorable Scott Perry
The Honorable Michael R. Turner
The Honorable Joe Wilson
The Honorable Randy J. Forbes
The Honorable Steve King
The Honorable Ander Crenshaw
The Honorable Mike Kelly
The Honorable Billy Long
The Honorable Lynn Jenkins
The Honorable Bill Johnson
The Honorable Jeff Fortenberry
The Honorable Andy Harris, M.D.
The Honorable Lee Zeldin
The Honorable Todd Rotika
The Honorable Eric A. Crawford
The Honorable Jody Hice
The Honorable Dan Newhouse
The Honorable Ken Buck
The Honorable Peter T. King
The Honorable Steven Palazzo
The Honorable Krysten Sinema
The Honorable Ted S. Yoho
The Honorable Mark Walker
The Honorable Jeff Duncan
The Honorable Jim Jordan
The Honorable Bill Posey
The Honorable Elise Stefanik
The Honorable Randy Weber
The Honorable Will Hurd
The Honorable Bruce Poliquin
The Honorable Robert Hurt
The Honorable David Schweikert
The Honorable Ryan Zinke
The Honorable Trent Kelly
The Honorable Chris Gibson
The Honorable Paul Cook
The Honorable Richard L. Hanna
The Honorable Curt Clawson
The Honorable C.A. Dutch Ruppersberger
The Honorable Gary Palmer
The Honorable Mo Brooks
The Honorable Tom MacArthur
The Honorable Raúl Labrador
The Honorable Tom Price, M.D.
House of Representatives
Washington, DC 20515

Dear Dr. Price:

Thank you for your letter regarding the transitional pass-through payment policy under Medicare’s hospital outpatient prospective payment system (OPPS). The Centers for Medicare & Medicaid Services (CMS) greatly appreciates you bringing your concerns to our attention.

You express concern that CMS has not approved a device for pass-through payment in nearly 3 years. We share your goal that truly innovative devices that bring improved clinical outcomes to Medicare beneficiaries should be encouraged. Therefore, CMS carefully evaluates each pass-through application for a new device category to ensure that it meets all applicable pass-through criteria. These evaluations are completed by a panel of CMS physicians who are trained in various specialties.

Since 2003, CMS has approved 10 devices under this process for pass-through payment. Each application has been reviewed according to the same standards by our clinical panel, and our evaluation process has not changed since we last approved a device for pass-through payment in 2007. Concerning the pass-through application for the bioactive polymer composite for vertebral augmentation, please be aware that although we did not approve the initial application, we are currently reconsidering the application at the request of the applicant. As with all evaluations, we will give this device careful and deliberate consideration. We previously met with the applicant, and recently met with them again to discuss their reconsideration request.

I appreciate your interest in these important issues as we work towards our mutual goal of strengthening the Medicare program. I will also provide this response to the cosigner of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator and Chief Operating Officer
The Honorable John Barrasso, M.D.
United States Senate
Washington, DC 20515

Dear Dr. Barrasso:

Thank you for your letter regarding the transitional pass-through payment policy under Medicare’s hospital outpatient prospective payment system (OPPS). The Centers for Medicare & Medicaid Services (CMS) greatly appreciates you bringing your concerns to our attention.

You express concern that CMS has not approved a device for pass-through payment in nearly 3 years. We share your goal that truly innovative devices that bring improved clinical outcomes to Medicare beneficiaries should be encouraged. Therefore, CMS carefully evaluates each pass-through application for a new device category to ensure that it meets all applicable pass-through criteria. These evaluations are completed by a panel of CMS physicians who are trained in various specialties.

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Sincerely,

Marilyn Tavenner
Acting Administrator and Chief Operating Officer
April 30, 2010

Ms. Marilyn Tavenner
Principal Deputy Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave SW, Room 314G
Hubert Humphrey Building
Washington, D.C. 20201

Dear Principal Deputy Administrator Tavenner:

As orthopedic surgeons with a combined total of over 50 years practice experience, we have a strong interest in government policies impacting patient access to new, innovative medical devices and treatment therapies. That is why we write to express our concerns about the Centers for Medicare and Medicaid Services (CMS) transitional device “pass-through” policy.

In August 2000, the CMS implemented a new prospective payment system for hospital outpatient services (HOPPS). Congress subsequently passed the Balanced Budget Refinement Act (BBRA) mandating changes to the new HOPPS system. The BBRA approved temporary, additional Medicare payments or “transitional pass-through payments” for certain innovative medical devices, drugs, and biologics. Congress intended these items be available to Medicare patients – even if prices for the new and innovative items exceeded Medicare’s regularly set HOPPS payment amounts.

In November 2001, CMS issued final regulatory guidance outlining the transitional pass-through payment eligibility criteria. This regulation required, among other things, that new devices and technologies “offer substantial clinical improvement in the treatment of Medicare beneficiaries”. We support this requirement as a way to incentivize manufacturers to develop cutting-edge therapies and devices. Medicare patients deserve access to new, life-saving, and even life-altering medical technologies. To accomplish both goals, we believe the federal government simply must provide adequate and predictable reimbursement to manufacturers and participating providers – acknowledging the substantial financial investment required to research, develop, and bring to market these novel products.

It has come to our attention; however, that recent CMS application of the pass-through payment policy may not specifically follow Congressional intent. CMS has not approved any transitional pass-through payment applications in nearly three years. For example, the Food and Drug Administration (FDA) recently approved a novel, bioactive polymer composite for vertebral augmentation. The FDA cleared the product based on a clinical trial comprised of 256 patients showing: 1) statistically significant improvements in pain and function; 2) reductions in subsequent adjacent level fractures; 3) reductions in subsequent vertebral augmentation procedures; and 4) reductions in re-hospitalizations for spinal fracture.

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It is our understanding that the denial of the vertebral augmentation pass-through payment application has the potential to negatively affect patients. This is not an isolated example as CMS has failed to approve pass-through payments in nearly three years. We respectfully request CMS work to improve this area so that together we can make the process more transparent and predictable. The pass-through payment application process should not be so onerous that it stifles medical innovation — ultimately restricting Medicare patient access to new devices, therapies, and drugs.

We believe uninterrupted patient care, improved patient outcomes, and avoiding increased patient spending are strong justifications for CMS to reconsider the new vertebral augmentation composite application and reassess its pass-through payment application process.

Yours Truly,

Tom Price, M.D.
Member of Congress

John Barrasso, M.D.
United States Senator

cc: Mr. Jonathan Blum
Deputy Administrator for Medicare

Ms. Liz Richter
Deputy Director of the Center for Medicare Management

Ms. Amy Bassano
Director of the Hospital and Ambulatory Policy Group

Mr. Christine Smith-Ritter
Acting Director of the Division of Outpatient Care
December 11, 2008

Mr. Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Ave. SW  
Hubert Humphrey Building Room  
Washington, DC 20224

Dear Acting Administrator Weems:

We are writing today to ask that the Centers for Medicare and Medicaid Services (CMS) delay the final rule capping Medicare reimbursemens to home oxygen suppliers at 36 months, which is due to go into effect on January 1, 2009.

As you know, previous to the Deficit Reduction Act of 2005, oxygen equipment was rented to patients through Medicare on a continuous rental basis. However, a provision in the Deficit Reduction Act limited monthly rental payments to oxygen suppliers to 36 months of continuous use. After 36 months, the title of the equipment would be transferred to the patient.

This raised many concerns, since the administration of oxygen is sensitive, and the maintenance and repair of the equipment is complex. Patients may not be able to afford to have their equipment serviced or have their supplier come help them with the equipment, which could compromise their health and safety. It would also presumably increase the number of emergency room visits as a result of improper or inadequate equipment upkeep.

In an effort to avoid these potential problems, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) included a repeal of this provision, leaving ownership with the oxygen supplier. Congress instructed CMS to establish adequate payments for continued care of these patients after the 36-month period. However, when CMS published the final rule it continued to cap the number of months that an oxygen supplier would receive monthly rental reimbursements at 36 months, requiring suppliers to shoulder the burden of maintaining and repairing equipment for the remainder of the reasonable life of the equipment. The rule establishes inadequate maintenance and service payments equal to only two 30 minute visits annually at a payment rate of approximately $30 per visit. In addition, the rule requires the original oxygen provider to continue to provide oxygen therapy for those patients who move out of the original oxygen provider’s service area for the rest of the reasonable life of the equipment.

This rule does not take into account unscheduled or emergency repairs or the replacement of supplies associated with the oxygen use. This will result in a decreased level of care for oxygen patients, and will potentially greatly increase the incidence of emergency room visits. After the 9.5% Medicare reimbursement cuts for home oxygen suppliers goes into effect on January 1,
2009, a one-day hospital stay will cost more than it would cost to continue to provide home oxygen service for two years.

Home oxygen suppliers are more than just equipment suppliers, they are also caregivers. They show patients how to use their equipment, answer patients’ questions, make repairs and adjustments, and ensure that patients are receiving the correct amount of oxygen. Many suppliers provide 24/7 unscheduled, emergency care, and in rural areas drive significant distances to make sure that their patients receive the care they need. Without reimbursements for these visits, suppliers may not be able to afford to continue their current level of care, and the quality of care for many of these oxygen patients is going to decrease.

Thank you for your consideration of our request to delay this rule. If you have any questions, please contact Erin Doty in Congressman Shuler’s office at erin.doty@mail.house.gov (225-6401) or Emily Henehan in Congressman Tom Price’s office at emily.henehan@mail.house.gov (225-4501).

Sincerely,

Mae White
The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding Medicare coding and payment for Vertos Medical’s minimally invasive treatment for lumbar spinal stenosis. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

Vertos Medical’s mild® procedure currently may be covered and paid at local Medicare contractor discretion using a category III Current Procedural Terminology (CPT) code. Category III CPT codes are used temporarily to describe emerging technologies. The CPT Editorial Panel may create a permanent category I CPT code when it retires a category III code. CMS often receives requests to create Healthcare Common Procedure Codes (HCPCS) for items or services. However, our longstanding practice has been to create codes only when there is a statutory or regulatory program need for which a CPT code is unavailable, or the CPT code is incompatible with Medicare statute or regulations. At this time, there is no statutory or regulatory provision that would necessitate creation of a HCPCS code for Vertos Medical’s mild® procedure. We suggest that Vertos Medical continue to work with the CPT Editorial Panel to create a category I CPT code.

Your letter indicates that relative values for surgical approaches to treat lumbar spinal stenosis have not been updated for 15 years. CMS has been engaged in a vigorous effort over the past several years to identify potentially misvalued codes and, when codes are found to be misvalued, to revise the payment accordingly. We thank you for bringing this family of codes to our attention and we will consider making these services part of the misvalued code initiative.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signer of your letter.

Sincerely,

Marilyn Tavenner
Acting Administrator
The Honorable Bill Cassidy, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Cassidy:

Thank you for your letter regarding Medicare coding and payment for Vertos Medical’s minimally invasive treatment for lumbar spinal stenosis. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

Vertos Medical’s mild® procedure currently may be covered and paid at local Medicare contractor discretion using a category III Current Procedural Terminology (CPT) code. Category III CPT codes are used temporarily to describe emerging technologies. The CPT Editorial Panel may create a permanent category I CPT code when it retires a category III code. CMS often receives requests to create Healthcare Common Procedure Codes (HCPCS) for items or services. However, our longstanding practice has been to create codes only when there is a statutory or regulatory program need for which a CPT code is unavailable, or the CPT code is incompatible with Medicare statute or regulations. At this time, there is no statutory or regulatory provision that would necessitate creation of a HCPCS code for Vertos Medical’s mild® procedure. We suggest that Vertos Medical continue to work with the CPT Editorial Panel to create a category I CPT code.

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Sincerely,

Marilyn Tavenner
Acting Administrator
June 20, 2012

Marilyn Tavenner
Acting Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Room 314G
Washington, DC 20201

Dear Administrator Tavenner:

We are writing to you concerning a Medicare coverage and access issue that has recently come to my attention regarding the availability of a minimally invasive, cost effective treatment option for Medicare beneficiaries who suffer from spinal conditions such as lumbar spinal stenosis (LSS).

We understand that Vertos Medical, a device company, has developed a safe and efficacious technique to treat Medicare beneficiaries and other patients with LSS by using the minimally invasive lumbar decompression procedure or mild®. We have spoken with providers unaffiliated with Vertos who treat LSS and they have confirmed that this is a significant therapy that we need to advance. However, due to a number of technical coding and payment policy hurdles, many beneficiaries do not have access to the technology and may be forced to undergo a more invasive and expensive treatment option, which requires hospitalization.

In order to resolve the coding and local coverage issues with this technology, Vertos Medical, at the suggestion of CMS, pursued the American Medical Association’s (AMA) Current Procedural Terminology (CPT) coding process. However, the professional group representatives responsible for the spinal care specialty within the AMA’s CPT Editorial Panel have made no change to the CPT coding for this technology. Although the Health Insurance Portability and Accountability Act of 1996 (HIPAA) legislatively mandates the use of the AMA’s CPT codes for coding and billing, it also requires the use of the CMS’ Healthcare Common Procedure Coding System (HCPCS). CMS has the authority to develop procedure codes within the HCPCS manual to serve the needs of the Medicare program and its beneficiaries when the AMA CPT coding process is inadequate.
Ensuring that Medicare participating providers and beneficiaries have access to choose amongst all available technologies allows for physicians and patients to determine the best appropriate treatment plan for them. We are concerned about the lack of access that beneficiaries would have to all available and appropriate treatment options for LSS, including those that are most cost effective for the Medicare program at a time when the solvency of the program is of such significant concern to all Americans. We request that CMS exercise its authority to utilize the HCPCS coding process in this case, or explain the reason for inaction in this area. Thank you for your attention to this matter.

Sincerely,

Tom Price, M.D.
Member of Congress

Bill Cassidy, M.D.
Member of Congress

Cc: Jonathan Blum
The Honorable Thomas Price, MD  
U.S. House of Representatives  
Washington, DC 20515  

Dear Dr. Price:

Thank you for your letter regarding the New Technology request for CardioMEMS™ HF (Heart Failure) System in the Hospital Inpatient Prospective Payment System and Long Term Care Hospital Prospective Payment System (IPPS/LTCH) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

The IPPS/LTCH proposed rule went on display on April 30, with a 60-day comment period that ended on June 30. We appreciate your interest in seeing CardioMEMS™ HF System approved for a new technology add-on payment and will consider all comments received during the comment period before making a final policy decision and publishing the final rule. CMS will include its ultimate determination in the final regulation, along with a summary of the comments and our responses. We typically publish the IPPS/LTCH final rule on or about August 1 each year.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. Please do not hesitate to contact me with any further thoughts or concerns.

Sincerely,

Marilyn Tavenner
The Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Tavenner:

The proposed Inpatient Prospective Payment System (IPPS) rule for 2015 includes an invitation for comments on several New Technology DRG Add-On Payment applications. I am writing to bring to your attention a new device to monitor pulmonary artery pressure produced by CardioMEMS, an Atlanta-based company.

Heart failure is one of the most prevalent and costly chronic medical conditions, affecting more than one in seven Medicare beneficiaries. Remote monitoring technologies offer the potential to improve management of chronic conditions, enabling providers to offer better-quality care at a lower cost. The CardioMEMS HF system includes a miniaturized sensor that measures pulmonary artery pressure and wirelessly transmits this data to a secure website that is accessed by the patient’s clinical care team. It also generates automatic alerts to the patient’s physician if pressure readings fall outside a preset range. In this way, the CardioMEMS technology may allow physicians to initiate more timely interventions and prevent hospitalizations. In fact, data from an FDA clinical trial demonstrated an approximately one-third reduction in heart failure-related hospitalizations for patients with pulmonary artery pressure monitoring.

We respectfully request that you give full consideration to the CardioMEMS new technology application to ensure appropriate access for Medicare beneficiaries.

Sincerely,

Thomas Price, MD  
Member of Congress
The Honorable Tom Price  
U.S. House of Representatives  
Washington, DC  20515  

Dear Dr. Price:

Thank you for your letter concerning the Centers for Medicare & Medicaid Services' (CMS') Medicare Recovery Audit program and the backlog of claims at the Department of Health and Human Services' (HHS') Office of Medicare Hearings and Appeals (OMHA). We share your concern about delayed hearings for providers (as well as suppliers) who have appealed Qualified Independent Contractor (QIC) reconsiderations of Medicare claims denials to OMHA. We assure you that HHS has taken significant actions to address this challenge.

Congress established the Medicare Fee-for-Service (FFS) Recovery Audit program in 2009 to help ensure Medicare payments are being appropriately made. It is one of a number of tools CMS has to reduce improper payments and prevent fraud. In total, CMS manually reviews less than 0.3 percent of claims each year through programs such as the Recovery Audit program. Since full implementation in FY 2010 through the third quarter of FY 2014, the Recovery Audit program has recovered $8.8 billion in improper payments. CMS uses the results of audits performed by the Recovery Auditors to identify potential vulnerabilities and take appropriate corrective actions to prevent future improper payments. As CMS has enhanced its efforts to prevent or recoup improper payments, however, provider and supplier appeals of payment denials have also increased.

We are always looking for ways to reduce the burden on providers, and we have received feedback on the Recovery Audit program from many stakeholders, including physicians and medical specialty societies. In response to this feedback, CMS has made a series of improvements to the program. Providers will have more time to engage with Recovery Auditors with a new 30-day discussion period that we anticipate will help resolve technical disputes. Recovery Auditors will receive their contingency fee only after the second level of appeal is exhausted. A more detailed description of these program improvements is enclosed. CMS is confident that these changes with the next Recovery Audit Program contract awards will result in a more effective and efficient program, including improved accuracy, decreased provider burden, and more transparency. Our goal is to balance our responsibilities to ensure all beneficiaries maintain access to care while providers and suppliers are paid promptly, and to ensure all Medicare claims are paid accurately, with a fair, impartial, and timely administrative review process for appellants.

It is important to note that CMS’s Recovery Auditors apply the same Medicare policies and regulations as other Medicare contractors. These regulations and other policies, such as local coverage determinations, are open to public comments. We would encourage stakeholders to
participate in these feedback processes. Further, all review topics for potential audits are approved by CMS before the Recovery Auditors begin widespread review. For some reviews, this occurs through a CMS New Issue Review Board that is comprised of CMS policy and coverage staff and clinicians. This ensures that the appropriate CMS personnel both are aware of and approve of what the Recovery Auditors are reviewing and that they have the correct interpretation of the policies used in their audit methodologies. For other types of reviews, CMS uses the expertise of the MACs to review potential review topics and make recommendations to CMS regarding approval. This ensures that the contractor that implemented the policy is aware of the audit and that the Recovery Auditors are correctly interpreting the policies in their region. These discussions sometimes reveal that certain guidelines may be outdated or no longer clinically appropriate. This leads to changes in updating certain coverage or billing guidelines to align with more current practice.

The CMS has implemented measures designed to reduce the backlog of provider appeals and to reduce the number of appeals that reach the third level of appeal at OMHA (the Administrative Law Judge (ALJ) level). On August 29, 2014, CMS announced a new effort to address the current backlog of appeals, available for those appeals where the claim was denied due to incorrect inpatient status with dates of admission before October 1, 2013. Incorrect inpatient status denials occur when the physician admits a Medicare beneficiary as inpatient while the medical record supports the provision of care in a hospital outpatient or other non-hospital based setting. For these cases, CMS is offering an administrative agreement to hospitals willing to withdraw pending appeals in exchange for partial payment (68 percent) of eligible inpatient claims. The deadline for hospitals to submit settlement requests to CMS is October 31, 2014. More information is available at: http://go.cms.gov/InpatientHospitalReview. CMS also plans to expand a prior authorization demonstration for Power Mobility Devices (PMD), which helps ensure proper payment while reducing PMD claim denials and appeals.

The OMHA has also taken steps to operate more efficiently in the face of increased provider appeals. Despite relatively stable funding levels over the years, OMHA's ALJs were previously able to handle a steadily growing workload by increasing productivity and using resources more efficiently. Indeed, OMHA judges have doubled their productivity rate over the last three years. To reduce the current backlog, OMHA recently announced that it is offering two new options for appellants to resolve their pending claim appeals. The first facilitates resolution of large numbers of claims based upon resolution of a statistically valid sample. The second uses alternative dispute resolution techniques during a facilitated settlement conference. More information can be found at: http://www.hhs.gov/omha/. OMHA has also increased its adjudicatory capacity by adding 10 new ALJs at the beginning of August. Six of these new ALJs reported to a new OMHA field office in Kansas City, Missouri. This is the first new field office since OMHA opened its doors in July 2005. It marks a significant step in the future expansion of the agency in order to meet increasing demands.

We appreciate your comments about the implementation of the Medicare inpatient admission policy or the "two-midnight rule." After the two midnight rule became effective, CMS initiated a probe and education process on a sample of claims per hospital to ensure that hospitals understand and fully comply with the policy. We also prohibited post-payment patient status
reviews for claims with dates of admission beginning on or after October 1, 2013. The
Protecting Access to Medicare Act of 2014 requires CMS to continue the probe and education
process and prohibits the Recovery Auditors from conducting post-payment patient status
reviews of inpatient claims with dates of admission through March 31, 2015.

In the FY 2015 Inpatient Prospective Payment System (IPPS) proposed rule, we solicited public
comments on the general concept of an alternative payment methodology for short-inpatient
stays under the Medicare program and specifically how such a methodology might be designed
(79 FR 28169). In the recently-released FY 2015 IPPS final rule (79 FR 49853), we noted the
many comments submitted on the issue. We will take these comments into account in any
potential future rulemaking. Although there was no consensus among the commenters, we look
forward to continuing to actively work with hospitals and stakeholders to address the complex
question of how to further improve payment policy for short inpatient hospital stays. We also
continue to discuss and address these issues with the hospital community as concerns are raised.

We appreciate your interest in these important issues as we work towards our mutual goals of
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thoughts or concerns. We will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
Nancy J. Griswold

Enclosure
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Recovery Audit Program Improvements

The CMS is pleased to announce a number of changes to the Recovery Audit program in response to industry feedback. The CMS is confident that these changes will result in a more effective and efficient program, including improved accuracy, less provider burden, and more program transparency. These changes will be effective with the next Recovery Audit program contract awards.

- **More time for providers to engage with the Recovery Auditors.** Recovery Auditors will be required to wait 30 days (to allow for a discussion period) before sending the claim to the MAC for adjustment. Today, in some cases, providers must delay filing an appeal in order to initiate a discussion period with the RAC.

- **Improved customer service.** Recovery Auditors will be required to confirm receipt of a discussion request within three days.

- **More time before Recovery Auditors receive contingency fee if there is an appeal.** Recovery Auditors will be required to wait until the 2nd level appeal is exhausted before the CMS will pay them any contingency fee.

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- **Number of additional document requested during Recovery Auditors review proportional to denial rates.** CMS will require Recovery Auditors to adjust the ADR limits in accordance with a provider’s denial rate. Providers with low denial rates will have lower ADR limits while providers with high denial rates will have higher ADR limits.

- **Central point of contact for complaints/concerns about claim reviews.** CMS has established a Provider Relations Coordinator who can be reached at:
  - RAC@cms.hhs.gov for Recovery Auditor review process concerns/suggestions
  - MedicareMedicalReview@cms.hhs.gov or other contractor review process concerns/suggestions
The Honorable Charles Boustany, Jr.
U.S. House of Representatives
Washington, DC 20515

Dear Dr. Boustany:

Thank you for your letter concerning the Centers for Medicare & Medicaid Services' (CMS') Medicare Recovery Audit program and the backlog of claims at the Department of Health and Human Services' (HHS') Office of Medicare Hearings and Appeals (OMHA). We share your concern about delayed hearings for providers (as well as suppliers) who have appealed Qualified Independent Contractor (QIC) reconsiderations of Medicare claims denials to OMHA. We assure you that HHS has taken significant actions to address this challenge.

Congress established the Medicare Fee-for-Service (FFS) Recovery Audit program in 2009 to help ensure Medicare payments are being appropriately made. It is one of a number of tools CMS has to reduce improper payments and prevent fraud. In total, CMS manually reviews less than 0.3 percent of claims each year through programs such as the Recovery Audit program. Since full implementation in FY 2010 through the third quarter of FY 2014, the Recovery Audit program has recovered $8.8 billion in improper payments. CMS uses the results of audits performed by the Recovery Auditors to identify potential vulnerabilities and take appropriate corrective actions to prevent future improper payments. As CMS has enhanced its efforts to prevent or recoup improper payments, however, provider and supplier appeals of payment denials have also increased.

We are always looking for ways to reduce the burden on providers, and we have received feedback on the Recovery Audit program from many stakeholders, including physicians and medical specialty societies. In response to this feedback, CMS has made a series of improvements to the program. Providers will have more time to engage with Recovery Auditors with a new 30-day discussion period that we anticipate will help resolve technical disputes. Recovery Auditors will receive their contingency fee only after the second level of appeal is exhausted. A more detailed description of these program improvements is enclosed. CMS is confident that these changes with the next Recovery Audit Program contract awards will result in a more effective and efficient program, including improved accuracy, decreased provider burden, and more transparency. Our goal is to balance our responsibilities to ensure all beneficiaries maintain access to care while providers and suppliers are paid promptly, and to ensure all Medicare claims are paid accurately, with a fair, impartial, and timely administrative review process for appellants.

It is important to note that CMS's Recovery Auditors apply the same Medicare policies and regulations as other Medicare contractors. These regulations and other policies, such as local coverage determinations, are open to public comments. We would encourage stakeholders to...
participate in these feedback processes. Further, all review topics for potential audits are approved by CMS before the Recovery Auditors begin widespread review. For some reviews, this occurs through a CMS New Issue Review Board that is comprised of CMS policy and coverage staff and clinicians. This ensures that the appropriate CMS personnel both are aware of and approve of what the Recovery Auditors are reviewing and that they have the correct interpretation of the policies used in their audit methodologies. For other types of reviews, CMS uses the expertise of the MACs to review potential review topics and make recommendations to CMS regarding approval. This ensures that the contractor that implemented the policy is aware of the audit and that the Recovery Auditors are correctly interpreting the policies in their region. These discussions sometimes reveal that certain guidelines may be outdated or no longer clinically appropriate. This leads to changes in updating certain coverage or billing guidelines to align with more current practice.

The CMS has implemented measures designed to reduce the backlog of provider appeals and to reduce the number of appeals that reach the third level of appeal at OMHA (the Administrative Law Judge (ALJ) level). On August 29, 2014, CMS announced a new effort to address the current backlog of appeals, available for those appeals where the claim was denied due to incorrect inpatient status with dates of admission before October 1, 2013. Incorrect inpatient status denials occur when the physician admits a Medicare beneficiary as inpatient while the medical record supports the provision of care in a hospital outpatient or other non-hospital based setting. For these cases, CMS is offering an administrative agreement to hospitals willing to withdraw pending appeals in exchange for partial payment (68 percent) of eligible inpatient claims. The deadline for hospitals to submit settlement requests to CMS is October 31, 2014. More information is available at: http://go.cms.gov/InpatientHospitalReview. CMS also plans to expand a prior authorization demonstration for Power Mobility Devices (PMD), which helps ensure proper payment while reducing PMD claim denials and appeals.

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We appreciate your interest in these important issues as we work towards our mutual goals of strengthening the Medicare program for beneficiaries, ensuring timely, appropriate payments to providers of services and suppliers, and providing a fair, impartial, and timely administrative review process for appellants. Please do not hesitate to contact us if you have any further thoughts or concerns. We will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner

Nancy J. Griswold

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The Honorable Vern Buchanan  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Buchanan:

Thank you for your letter concerning the Centers for Medicare & Medicaid Services' (CMS') Medicare Recovery Audit program and the backlog of claims at the Department of Health and Human Services' (HHS') Office of Medicare Hearings and Appeals (OMHA). We share your concern about delayed hearings for providers (as well as suppliers) who have appealed Qualified Independent Contractor (QIC) reconsiderations of Medicare claims denials to OMHA. We assure you that HHS has taken significant actions to address this challenge.

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The CMS has implemented measures designed to reduce the backlog of provider appeals and to reduce the number of appeals that reach the third level of appeal at OMHA (the Administrative Law Judge (ALJ) level). On August 29, 2014, CMS announced a new effort to address the current backlog of appeals, available for those appeals where the claim was denied due to incorrect inpatient status with dates of admission before October 1, 2013. Incorrect inpatient status denials occur when the physician admits a Medicare beneficiary as inpatient while the medical record supports the provision of care in a hospital outpatient or other non-hospital based setting. For these cases, CMS is offering an administrative agreement to hospitals willing to withdraw pending appeals in exchange for partial payment (68 percent) of eligible inpatient claims. The deadline for hospitals to submit settlement requests to CMS is October 31, 2014. More information is available at: http://go.cms.gov/InpatientHospitalReview. CMS also plans to expand a prior authorization demonstration for Power Mobility Devices (PMD), which helps ensure proper payment while reducing PMD claim denials and appeals.

The OMHA has also taken steps to operate more efficiently in the face of increased provider appeals. Despite relatively stable funding levels over the years, OMHA's ALJs were previously able to handle a steadily growing workload by increasing productivity and using resources more efficiently. Indeed, OMHA judges have doubled their productivity rate over the last three years. To reduce the current backlog, OMHA recently announced that it is offering two new options for appellants to resolve their pending claim appeals. The first facilitates resolution of large numbers of claims based upon resolution of a statistically valid sample. The second uses alternative dispute resolution techniques during a facilitated settlement conference. More information can be found at: http://www.hhs.gov/ornha/. OMHA has also increased its adjudicatory capacity by adding 10 new ALJs at the beginning of August. Six of these new ALJs reported to a new OMHA field office in Kansas City, Missouri. This is the first new field office since OMHA opened its doors in July 2005. It marks a significant step in the future expansion of the agency in order to meet increasing demands.

We appreciate your comments about the implementation of the Medicare inpatient admission policy or the "two-midnight rule." After the two midnight rule became effective, CMS initiated a probe and education process on a sample of claims per hospital to ensure that hospitals understand and fully comply with the policy. We also prohibited post-payment patient status
reviews for claims with dates of admission beginning on or after October 1, 2013. The Protecting Access to Medicare Act of 2014 requires CMS to continue the probe and education process and prohibits the Recovery Auditors from conducting post-payment patient status reviews of inpatient claims with dates of admission through March 31, 2015.

In the FY 2015 Inpatient Prospective Payment System (IPPS) proposed rule, we solicited public comments on the general concept of an alternative payment methodology for short-inpatient stays under the Medicare program and specifically how such a methodology might be designed (79 FR 28169). In the recently-released FY 2015 IPPS final rule (79 FR 49853), we noted the many comments submitted on the issue. We will take these comments into account in any potential future rulemaking. Although there was no consensus among the commenters, we look forward to continuing to actively work with hospitals and stakeholders to address the complex question of how to further improve payment policy for short inpatient hospital stays. We also continue to discuss and address these issues with the hospital community as concerns are raised.

We appreciate your interest in these important issues as we work towards our mutual goals of strengthening the Medicare program for beneficiaries, ensuring timely, appropriate payments to providers of services and suppliers, and providing a fair, impartial, and timely administrative review process for appellants. Please do not hesitate to contact us if you have any further thoughts or concerns. We will also provide this response to the co-signers of your letter.

Sincerely,

[Signature]

Marilyn Tavenner

[Signature]

Nancy J. Griswold

Enclosure
Recovery Audit Program Improvements

The CMS is pleased to announce a number of changes to the Recovery Audit program in response to industry feedback. The CMS is confident that these changes will result in a more effective and efficient program, including improved accuracy, less provider burden, and more program transparency. These changes will be effective with the next Recovery Audit program contract awards.

- **More time for providers to engage with the Recovery Auditors.** Recovery Auditors will be required to wait 30 days (to allow for a discussion period) before sending the claim to the MAC for adjustment. Today, in some cases, providers must delay filing an appeal in order to initiate a discussion period with the RAC.

- **Improved customer service.** Recovery Auditors will be required to confirm receipt of a discussion request within three days.

- **More time before Recovery Auditors receive contingency fee if there is an appeal.** Recovery Auditors will be required to wait until the 2nd level appeal is exhausted before the CMS will pay them any contingency fee.

- **More claim diversity across a facility (e.g., inpatient, outpatient).** CMS is establishing revised additional document request (ADR) limits, so that they can be diversified across claim types.

- **Number of additional document requested during Recovery Auditors review proportional to denial rates.** CMS will require Recovery Auditors to adjust the ADR limits in accordance with a provider’s denial rate. Providers with low denial rates will have lower ADR limits while providers with high denial rates will have higher ADR limits.

- **Central point of contact for complaints/concerns about claim reviews.** CMS has established a Provider Relations Coordinator who can be reached at:
  - RAC@cms.hhs.gov for Recovery Auditor review process concerns/suggestions
  - MedicareMedicalReview@cms.hhs.gov or other contractor review process concerns/suggestions
August 5, 2014

The Honorable Marilyn Tavenner
Administrator
Center for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Tavenner:

We write today to express our concern regarding the Center for Medicare and Medicaid Service’s management and oversight of the Recovery Audit Contractor (RAC) program, as well as the current backlog of appeals at the Administrative Law Judge (ALJ) level. While we appreciate the administration’s efforts to ensure the appropriate use of taxpayer dollars and prevent improper payments within the Medicare and Medicaid programs, we are concerned that the RAC program has had unintended consequences for both providers and patients.

The RAC program, first authorized as a demonstration program and expanded nationally in 2010, is responsible for reviewing, auditing, and identifying improper payments to Medicare providers. There are five distinct levels of appeals afforded to providers in the Medicare program. Between 2011 and 2013, the number of appeals at the ALJ, or the third level of appeals, increased from 92,000 to 460,000 claims—a growth of 500%. At the beginning of 2014, the Office of Medicare Hearings & Appeals (OMHA) suspended the assignment of new appeals at the ALJ level in reaction to this exponential growth in appeals. The average processing time of an appeal at the ALJ level for fiscal year 2014 is now 387 days, far greater than the 90-day time frame outlined in statute.1 While we appreciate that CMS has recognized there is a problem and is actively working to reform both the audit program and the appeals process, we urge the administration to keep the following in mind as it advances this effort.

When RACs began to audit hospitals in 2009, CMS recognized a problem in the determination between inpatient and outpatient status. It took CMS four years, however, to offer clarification in the form of the two-midnight rule. Sadly, this has only exacerbated the problem. Variation in interpretation of inpatient admission standards is caused by CMS’s failure to ensure that the RAC audit guidelines are made public or are specifically approved by CMS as accurate interpretations of Medicare policy and adherence to accepted medical practice before these guidelines are utilized in any audit. The two-midnight rule failed to clarify the determination for inpatient admissions and raises just as many risks for excessive audits as before. In order to ameliorate

confusion over short inpatient stays, we encourage CMS to consider site-neutral payments as a solution to this problem.

We also urge CMS to increase the level of transparency in the audit process for hospitals and RACs. Any and all criteria used by RACs to make medically complex judgments should be made public so that consensus can be achieved as to whether the RAC review guideline correctly interprets Medicare policy. The expansive growth in appeals coupled by the overturn rate of 72% of inpatient hospital short stays at the ALJ level seems representative of confusion, rather than improper payments. 2 By bringing greater clarity to the program at the outset of the audit process, fewer unnecessary audits will be performed, reducing pressure on the appeals system to adjudicate disagreements over policy interpretations and reducing the undue and unintended burden on healthcare providers seeking to achieve compliance.

We ask that CMS consult stakeholders, physicians, and the medical specialty societies in developing further guidelines or criteria under which medically complex judgments must be made to evaluate claims. Ensuring expert input into the guidelines or “review methodologies” that RACs use would improve the quality of the RAC audits and reduce unnecessary audits. CMS should place immediate priority on review guidelines for certain types of short-term inpatient stays where such expert consensus is sorely needed, such as those associated with cardiac procedures which, according to CMS’s 2012 RAC report to Congress, have received the most audit focus from RACs. 3

We encourage CMS to bring greater fairness to the program, both within the audit program and the appeals process. For example, the administration has halted any new appeals at the ALJ level, the first level appeals open to providers outside of the Medicare program, and yet CMS has not restricted the RACs ability to continue to audit and recover payments. We hear from our constituent stakeholders numerous examples of overly technical application of the rules that are easily overturned on appeal (missing physician signatures that can be easily located in the medical record) and of RACs reaching inconsistent decisions on two similar inpatient claims. We encourage CMS to ensure that there is some mechanism to resolve technical disputes and provide consistency in decision making, without adding to the overburdened appeals system.

Finally, it is imperative to remain thoughtful of the unintended consequence these and other programs have on Medicare beneficiaries. We hear from district stakeholders that the cost of compliance takes away resources that could otherwise be utilized for patient care. Most providers have had significant experience with Medicare and Medicaid audits, and RAC audits are unique in diverting significant amounts of manpower and operational resources away from patient care in order to respond to record requests and

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pursue appeals of improper denials. As with all integrity programs in Medicare, we understand that there are limited resources and CMS must constantly review how to apply those resources effectively. We ask CMS to encourage RACs to audit those Medicare programs with historically higher error rates reflecting improper payments, instead of those programs with the greatest potential monetary reward.  

We thank you for your consideration of our request and remain committed to working with you to improve this program.

Sincerely,

Tom Price, MD (GA-06)  
Member of Congress

Charles Boustany, Jr., MD (LA-03)  
Member of Congress

Vern Buchanan (FL-16)  
Member of Congress

CC: Judge Nancy Griswold, Office of Medicare Hearings & Appeals

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The Honorable Tom Price, MD  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Price:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

After reviewing and considering nearly 400 comments from the public on the proposed rule for the CJR Model, we issued the final rule on November 16, 2016. The CJR Model includes several revised policies in the final rule that are designed to afford hospitals and their partners in care delivery adequate time to prepare for success under the model prior to the start date. The final policies are listed and described below.

- **Delayed Start Date:** In order to allow participant hospitals more time to prepare for success under the model, the first performance period for the model will begin on April 1, 2016, instead of the proposed January 1, 2016 performance period start date.

- **Financial Protections:** In response to comments from the public, we have finalized additional policies to phase in financial responsibility for hospitals participating in the CJR Model. Hospitals will have no repayment responsibility in Performance Year (PY) 1, and repayment responsibility will be phased in gradually over the course of PYs 2 and 3. The final rule also includes stop-loss protections limiting the amount of financial responsibility for all participant hospitals, with additional financial protection for certain types of participant hospitals, such as rural hospitals or sole community hospitals. The stop-loss protections in the final rule also follow a more gradual implementation timeline than those in the proposed rule, with a stop-loss limit of 5 percent in PY 2, 10 percent in PY Year 3, and 20 percent in PYs 4 and 5.

- **Data Sharing:** The CJR Model will provide all participant hospitals with the opportunity to request robust data to aid them in identifying opportunities for care redesign and savings and to identify appropriate clinical partners. Such data will provide
participants in the model with the information necessary to identify opportunities for care redesign and evaluate their current care patterns.

- **Utilizing Existing Payment Processes:** The usual Medicare Fee-or-Service claims submission processes will continue throughout the model. In other words, providers and suppliers furnishing services during the episode of care will submit a claim to Medicare and receive payment as they normally would.

- **Accounting for Complex Patients:** The CJR Model has been designed to include appropriate safeguards for complex patients, including a payment method that protects hospitals from the risk of high payment episodes. In addition, in response to commenters’ requests to modify our payment structure to account for more complex patients, we finalized a risk stratification method that will set different prices for beneficiaries undergoing lower joint replacement procedures due to hip fracture.

We have also finalized the following proposals to protect beneficiaries: additional monitoring of claims data from participant hospitals to ensure that hospitals continue to provide all necessary services; and continued protection of patient data under the Health Insurance Portability and Accountability Act of 1996 (and other applicable privacy laws; and patient notification by providers and suppliers. Further, beneficiaries retain their freedom of choice to choose services and providers, and all existing safeguards to protect beneficiaries and patients will remain in place. If a beneficiary believes that his or her care has been adversely affected, he or she can call 1-800-MEDICARE or contact his or her state’s Quality Improvement Organization. If concerns are identified, the Centers for Medicare & Medicaid Services can initiate audits and corrective action under existing authority.

Participating hospitals meeting certain criteria, such as rural hospitals, Medicare-dependent hospitals, and sole community hospitals, will be afforded additional financial protections for the duration of the model. We will implement a stop-loss limit of 3 percent of episode payments for these categories of hospitals in PY 2 and a stop-loss limit of 5 percent of episode payments for PYs 3 through 5.

Under existing bundled payment models, in which providers across the continuum of care share accountability for the clinical management and total cost of an episode of care, the capacity to share information electronically across disparate provider systems can be important for delivering efficient, safe, high-quality care. With respect to the utilization of electronic health records (EHRs) by participant hospitals and their clinical partners in the CJR Model, we received comments from the public on an EHR usage measure in the proposed rule. We appreciate the insights and concerns expressed around utilizing a measure of health information technology tied to participation in EHR incentive programs. We will consider these comments as we assess any future measures for the CJR model.

Finally, we note that while participant hospitals will be the episode initiators under this model and the entities financially responsible, the model will allow participant hospitals to enter into
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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Phil Roe M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Roe:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration's commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Charles Boustany M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Boustany:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
Dear Representative DesJarlais:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Joseph Heck, D.O.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Heck:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt  
Acting Administrator
The Honorable Paul Gosar DDS
U.S. House of Representatives
Washington, DC 20515

Dear Representative Gosar:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration's commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Andy Harris M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Harris:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Andrew M. Slavitt
Acting Administrator
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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Brad Wenstrup DPM  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Wenstrup:

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Sincerely,

[Signature]
Andrew M. Slavitt
Acting Administrator
The Honorable Ruben Hinojosa  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Hinojosa:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Devin Nunes  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Nunes:

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
Dear Representative Young:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Jim Renacci  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Renacci:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Jason Smith  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Smith:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Vern Buchanan  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Buchanan:  

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Sincerely,

Andrew M. Slavitt
Acting Administrator
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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Mark Meadows  
U.S. House of Representatives  
Washington, DC 20515

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
Dear Representative Blackburn:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Kurt Schrader  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Schrader:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Ann Wagner  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Wagner:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Earl "Buddy" Carter  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Carter:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Austin Scott  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Scott:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Pete Olson  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Olson:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration's commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

[Signature]

Andrew M. Slavitt
Acting Administrator
The Honorable Lynn Westmoreland  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Westmoreland:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Rick Allen  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Allen:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Steve Chabot  
U.S. House of Representatives  
Washington, DC 20515

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Page 3 - The Honorable Steve Chabot

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Louie Gohmert  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Gohmert:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
Dear Representative Thornberry:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable John Mica  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Mica:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Mike Coffman  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Coffman:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
Dear Representative Rice:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Dina Titus  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Titus:

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable John Duncan  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Duncan:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration's commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

[Signature]

Andrew M. Slavitt
Acting Administrator
The Honorable Gary Palmer  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Palmer:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Jackie Walorski  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Walorski:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Daniel Webster  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Webster:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
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Acting Administrator
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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Bill Posey  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Posey:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Mike Kelly  
U.S. House of Representatives  
Washington, DC 20515

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Bruce Westerman
U.S. House of Representatives
Washington, DC 20515

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Renee Ellmers  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Ellmers:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration's commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Jody Hice
U.S. House of Representatives
Washington, DC 20515

Dear Representative Hice:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration's commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Gus Bilirakis  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Bilirakis:

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Acting Administrator
Dear Representative Hensarling:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Bob Goodlatte
U.S. House of Representatives
Washington, DC 20515

Dear Representative Goodlatte:

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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Pat Tiberi  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Tiberi:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Andrew M. Slavitt
Acting Administrator
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Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Lou Barletta
U.S. House of Representatives
Washington, DC 20515

Dear Representative Barletta:

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Sincerely,

[Signature]

Andrew M. Slavitt
Acting Administrator
The Honorable Larry Bucshon M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Bucshon:

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Andrew M. Slavitt
Acting Administrator
The Honorable David Scott
U.S. House of Representatives
Washington, DC 20515

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- **Utilizing Existing Payment Processes:** The usual Medicare Fee-or-Service claims submission processes will continue throughout the model. In other words, providers and suppliers furnishing services during the episode of care will submit a claim to Medicare and receive payment as they normally would.

- **Accounting for Complex Patients:** The CJR Model has been designed to include appropriate safeguards for complex patients, including a payment method that protects hospitals from the risk of high payment episodes. In addition, in response to commenters’ requests to modify our payment structure to account for more complex patients, we finalized a risk stratification method that will set different prices for beneficiaries undergoing lower joint replacement procedures due to hip fracture.

We have also finalized the following proposals to protect beneficiaries: additional monitoring of claims data from participant hospitals to ensure that hospitals continue to provide all necessary services; and continued protection of patient data under the Health Insurance Portability and Accountability Act of 1996 (and other applicable privacy laws; and patient notification by providers and suppliers. Further, beneficiaries retain their freedom of choice to choose services and providers, and all existing safeguards to protect beneficiaries and patients will remain in place. If a beneficiary believes that his or her care has been adversely affected, he or she can call 1-800-MEDICARE or contact his or her state’s Quality Improvement Organization. If concerns are identified, the Centers for Medicare & Medicaid Services can initiate audits and corrective action under existing authority.

Participating hospitals meeting certain criteria, such as rural hospitals, Medicare-dependent hospitals, and sole community hospitals, will be afforded additional financial protections for the duration of the model. We will implement a stop-loss limit of 3 percent of episode payments for these categories of hospitals in PY 2 and a stop-loss limit of 5 percent of episode payments for PYs 3 through 5.

Under existing bundled payment models, in which providers across the continuum of care share accountability for the clinical management and total cost of an episode of care, the capacity to share information electronically across disparate provider systems can be important for delivering efficient, safe, high-quality care. With respect to the utilization of electronic health records (EHRs) by participant hospitals and their clinical partners in the CJR Model, we received comments from the public on an EHR usage measure in the proposed rule. We appreciate the insights and concerns expressed around utilizing a measure of health information technology tied to participation in EHR incentive programs. We will consider these comments as we assess any future measures for the CJR model.

Finally, we note that while participant hospitals will be the episode initiators under this model and the entities financially responsible, the model will allow participant hospitals to enter into
financial arrangements with collaborating providers and suppliers who are engaged in care redesign with the hospital and who furnish services to the beneficiary during an episode. Under these arrangements, a participant hospital may share payments received from Medicare as a result of reduced episode spending and hospital internal cost savings with collaborating providers and suppliers, subject to parameters outlined in the rule. Our experience with other episode payment models has demonstrated that many providers view these arrangements to be useful mechanisms in better aligning financial incentives between different provider types. That said, we believe it is necessary to have a limit on the maximum amount a collaborating provider or supplier could earn through these arrangements to ensure that distributions are not made for purposes other than improving the quality and value of care to beneficiaries. In addition to sharing savings, participant hospitals may also share financial accountability for increased episode spending with collaborating providers and suppliers. Finally, participant hospitals may provide beneficiaries with certain incentives to advance the clinical goals of their care, under certain conditions.

Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

[Signature]

Andrew M. Slavitt
Acting Administrator
The Honorable Lynn Jenkins  
U.S. House of Representatives  
Washington, DC 20515  

Dear Representative Jenkins:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

After reviewing and considering nearly 400 comments from the public on the proposed rule for the CJR Model, we issued the final rule on November 16, 2016. The CJR Model includes several revised policies in the final rule that are designed to afford hospitals and their partners in care delivery adequate time to prepare for success under the model prior to the start date. The final policies are listed and described below.

- **Delayed Start Date:** In order to allow participant hospitals more time to prepare for success under the model, the first performance period for the model will begin on April 1, 2016, instead of the proposed January 1, 2016 performance period start date.

- **Financial Protections:** In response to comments from the public, we have finalized additional policies to phase in financial responsibility for hospitals participating in the CJR Model. Hospitals will have no repayment responsibility in Performance Year (PY) 1, and repayment responsibility will be phased in gradually over the course of PYs 2 and 3. The final rule also includes stop-loss protections limiting the amount of financial responsibility for all participant hospitals, with additional financial protection for certain types of participant hospitals, such as rural hospitals or sole community hospitals. The stop-loss protections in the final rule also follow a more gradual implementation timeline than those in the proposed rule, with a stop-loss limit of 5 percent in PY 2, 10 percent in PY Year 3, and 20 percent in PYs 4 and 5.

- **Data Sharing:** The CJR Model will provide all participant hospitals with the opportunity to request robust data to aid them in identifying opportunities for care redesign and savings and to identify appropriate clinical partners. Such data will provide
participants in the model with the information necessary to identify opportunities for care redesign and evaluate their current care patterns.

- **Utilizing Existing Payment Processes:** The usual Medicare Fee-or-Service claims submission processes will continue throughout the model. In other words, providers and suppliers furnishing services during the episode of care will submit a claim to Medicare and receive payment as they normally would.

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We have also finalized the following proposals to protect beneficiaries: additional monitoring of claims data from participant hospitals to ensure that hospitals continue to provide all necessary services; and continued protection of patient data under the Health Insurance Portability and Accountability Act of 1996 (and other applicable privacy laws; and patient notification by providers and suppliers. Further, beneficiaries retain their freedom of choice to choose services and providers, and all existing safeguards to protect beneficiaries and patients will remain in place. If a beneficiary believes that his or her care has been adversely affected, he or she can call 1-800-MEDICARE or contact his or her state’s Quality Improvement Organization. If concerns are identified, the Centers for Medicare & Medicaid Services can initiate audits and corrective action under existing authority.

Participating hospitals meeting certain criteria, such as rural hospitals, Medicare-dependent hospitals, and sole community hospitals, will be afforded additional financial protections for the duration of the model. We will implement a stop-loss limit of 3 percent of episode payments for these categories of hospitals in PY 2 and a stop-loss limit of 5 percent of episode payments for PYs 3 through 5.

Under existing bundled payment models, in which providers across the continuum of care share accountability for the clinical management and total cost of an episode of care, the capacity to share information electronically across disparate provider systems can be important for delivering efficient, safe, high-quality care. With respect to the utilization of electronic health records (EHRs) by participant hospitals and their clinical partners in the CJR Model, we received comments from the public on an EHR usage measure in the proposed rule. We appreciate the insights and concerns expressed around utilizing a measure of health information technology tied to participation in EHR incentive programs. We will consider these comments as we assess any future measures for the CJR model.

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
The Honorable Terri Sewell  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Sewell:

Thank you for your interest in and feedback on the Comprehensive Care for Joint Replacement (CJR) Model. This payment, quality, and care improvement initiative takes a major step forward in the Administration’s commitment to transform our health system to deliver better quality care and spend our health care dollars in a smarter way. The model will hold hospitals accountable for the costs and quality of care furnished to Medicare beneficiaries for hip and knee replacements from surgery through recovery.

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Thank you for your feedback on the CJR Model. We look forward to continuing to partner with you to achieve better care, smarter spending, and healthier people. We look forward to engaging further on this important initiative. I will also provide this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator
September 21, 2015

Mr. Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Patrick Conway, M.D., MSc  
Deputy Administrator, Innovation & Quality  
Chief Medical Officer  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Mr. Slavitt and Dr. Conway:

CMS recently proposed the Comprehensive Care for Joint Replacement Model (CCJR), a new episode-based payment model for lower extremity joint replacement (LEJR) that would apply to 75 Metropolitan Statistical Areas (MSA’s) for five years. The CCJR proposed payment model represents a significant change for beneficiaries and providers because it constitutes the first mandatory Medicare episode payment model promulgated under CMS’ CMMI authority. Other CMS proposed models, including the Bundled Payments for Care Improvement (BPCI) on which the CCJR model was based, have all been voluntary. Given this substantial change for Medicare beneficiaries and providers, we raise certain questions and ask that you delay the implementation of the CCJR payment model for at least one year.

HHS has a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016 and 90 percent by 2018 through programs such as Hospital Value Based Purchasing. To be sure, increasing value by means of improved outcomes and reduced cost is a goal that we all share. As a result, the questions below relate not to the goal itself but, rather, how the Centers for Medicare and Medicaid Services (CMS) seeks to achieve it.

1. We recognize the uniquely positive influence that patient choice has in achieving quality, responsiveness, effectiveness, and efficiency of healthcare services. Systems that foster patient choice have proven to work, whereas those that supplant patient choice with centralized control have often led to shortages, rationing, and poor outcomes. If it ultimately places post-acute care (PAC) funding with hospital control, the CCJR model would likely create a strong incentive for hospitals to acquire post-acute care facilities and orthopedic surgery practices, or preclude independent practices from performing surgeries at the hospital. There is a considerable body of evidence suggesting that healthcare market consolidation can have deleterious effects on patients, providers, and taxpayers. It also appears likely that hospitals would be compelled to

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1 Between 1998 and 2012, there were 1,113 mergers and acquisitions involving a total of 2,277 hospitals. Mergers have nearly doubled in recent years. There were 95 hospital mergers in 2014, 98 in 2013, and 95 in 2012. Compare that with
restrict the provision of additional services by Medicare beneficiaries’ physicians in order to mitigate the risk that hospitals will face under the CCJR program. What safeguards are incorporated into the proposed CCJR model, and are under consideration in any possible future iteration, that would guard against hospital-driven vertical integration or other forms of market consolidation that could lead to higher costs? Consequently, what protections are incorporated into the proposed CCJR model to maintain a patient’s freedom to choose their provider, course of treatment, and medical services?

2. We are concerned that patients requiring higher-cost complex surgeries (such as hip fractures and ankle replacement procedures) or who suffer from multiple chronic conditions may find it more difficult to find hospitals willing to serve them, since the greater risk of complications or the higher level of post-acute care associated with their condition would be logically viewed by hospitals as increasing their risk under the proposed CCJR model. Additionally, since the CCJR model excludes “non-elective” joint replacement surgeries (many of which involve complex hip fractures) from its quality framework, but otherwise maintains such cases for “target price” and episode expenditure purposes, this could potentially place too much emphasis on the cost of these vulnerable patients’ post-acute care without adequate consideration of their outcomes and the quality of care they receive. What safeguards are incorporated into the proposed CCJR model to ensure that patients with complex surgeries or chronic conditions would have access to the full spectrum of hospitals, physicians, and post-acute care providers under CCJR that they are able to access today?

3. Small and rural hospitals are a crucial resource for numerous communities. The risk placed on hospitals by CCJR, as well as the oversight and administrative responsibilities that hospitals would have to bear for 90 days post-discharge may be so burdensome that small and rural hospitals may have little option other than to be subsumed into larger systems or refrain from offering lower extremity joint replacement surgeries. What safeguards are incorporated into the proposed CCJR program to address the specific needs and circumstances of small and rural hospitals?

4. This CCJR model requires sophisticated coordination of care that will demand additional providers within the post-acute setting to collaborate with hospitals to define and monitor a patient’s care plan. The CCJR proposed rule indicates that forcing post-acute care providers to invest in Electronic Health Records (EHRs) will accomplish the needed coordination, as hospitals that rely on post-acute care providers without EHRs may not be eligible for reconciliation payments in the future. How would this mandatory approach within the CCJR model prevent forced relationships between providers based on the meaningful use of EHRs, rather than allowing these choices to be based on who provides the best quality of care, keeps patients the safest, and does the best job of coordinating with the hospital and other providers?

5. The total amount of gainsharing payments for a calendar year paid to an individual physician, nonphysician practitioner, or physician group practice who is a CCJR collaborator cannot exceed a cap equal to 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital’s CCJR beneficiaries during a CCJR episode by that physician, nonphysician practitioner, or members of the physician group practice. Why are you limiting gainsharing payments to providers who will be responsible for much of the care-redesign required in this model? Additionally, why are post-acute care providers not meaningfully included in the CCJR bundle to ensure quality care is provided over the entire continuum of care?

In light of the January 1, 2016 effective date proposed by the Agency, we request your response to these questions no later than October 1, 2015. The CMS proposal represents a significant change to our healthcare delivery system which could have a negative impact on patient choice, access and quality. Given the fact that the proposed rule will not be finalized until almost the year’s end, it will give physicians, hospitals and post-acute providers little or no time to prepare for this abrupt shift in payment for these high-volume procedures and the changes in care delivery that they will require. As a result, we ask that you seriously reconsider the CCJR payment model. At a minimum, we ask that you delay the implementation of the CCJR payment model for at least one year.

Yours truly,

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2 CMS assumes that hospitals will enter sharing arrangements with post-acute care providers. See pg. 41297 of the CMS proposed CCJR rule.
Steve Chabot
Louie Gohmert
Mac Thornberry
John Mica
Mike Coffman
Tom Rice
Dina Titus

John Duncan
Gary Palmer
Jackie Walorski
Daniel Webster
Ryan Costello
Ileana Ros-Lehtinen
Bill Posey
The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20015

Dear Representative Price:

Thank you for your letter regarding the Center for Medicare and Medicaid Innovation (Innovation Center) and its authority to test innovative payment and service delivery models. We share your goal of moving to higher quality, more value-based care for our nation's seniors.

The Innovation Center's mission is to test innovative payment and service delivery models designed to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. To be successful in this mission, the Innovation Center must remain nimble and flexible, capable of not only developing new models, but also of improving upon models quickly based on feedback from beneficiaries, doctors and other clinicians, and other stakeholders. Several ideas for Innovation Center models have come directly from physicians and other clinicians, and the clinicians in Innovation Center models help shape and refine the models through feedback.

The Innovation Center is essential to the implementation of the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) legislation. To move towards paying for value, MACRA directs the Secretary of the Department of Health and Human Services (HHS) to establish a new approach to payment called the Quality Payment Program. The Quality Payment Program allows eligible clinicians participating in Advanced Alternative Payment Models (Advanced APMs) at certain threshold levels to receive an incentive payment, and the Innovation Center is creating as many opportunities for eligible clinicians to participate in Advanced APMs as possible.

The Innovation Center has launched over 35 payment and service delivery models, and the vast majority of the Innovation Center models are voluntary. But, there are certain promising potential models that are difficult or impossible to test on a voluntary basis. For example, some potential models are unlikely to have a positive impact on quality and cost unless they are applied uniformly and equitably to eligible providers or suppliers in a geographic area, and in some potential models requiring participation is necessary to control for potential bias in evaluation results. In these circumstances, we propose the model design and propose requiring participation through notice and comment rulemaking, and we consider public comments carefully before each rule is finalized. Only the Comprehensive Care for Joint Replacement (CJR) Model, the Home Health Value-Based Purchasing Model, and the recently finalized models in the Advancing Care Coordination through Episode Payment Models Final Rule require participation by all eligible providers or suppliers in a given geographic area. The remaining model tests have voluntary participation.
Preserving beneficiary rights and beneficiary freedom of choice are bedrock considerations in the design and implementation of all Innovation Center models. Under all current Innovation Center models, beneficiaries retain access to all covered Medicare, Medicaid, and CHIP services. Beneficiaries also retain access to claims and appeals processes under the Innovation Center’s existing models. In some cases, models include certain increased beneficiary protections. We also implement robust monitoring plans for each model test to protect beneficiaries by detecting any potential issues.

In addition, no Innovation Center model dictates the practice of medicine. Physicians and other clinicians are encouraged to innovate and improve care as part of Innovation Center models. We engage extensively with stakeholders, and we take such feedback into consideration before model designs are finalized. This engagement continues after models have launched, as we regularly refine approaches in response to stakeholder feedback. As an example, in response to stakeholder input and feedback, the Innovation Center included a 3-day Skilled Nursing Facility Rule Waiver in the Pioneer Accountable Care Organization (ACO) Model and incorporated that improvement in the Next Generation ACO Model.

All Innovation Center models are designed to further our mission to preserve or enhance quality of care while reducing expenditures. For instance, in the CJR Model, payment is tied to quality using a composite score assigned each year based on the participant hospital’s performance and improvement on rates of complications associated with joint replacement, along with patient-reported satisfaction. Participant hospitals that voluntarily submit performance data on patient-reported outcomes receive additional points for their composite quality score, which can result in higher payment. Linking payment to quality of care in this way is typical, both in Innovation Center models and in Medicare programs such as the Shared Savings Program. We believe it is essential to simultaneously pursue both reduced spending and improved quality, consistent with our authorizing statute. Results from some Innovation Center models, such as the Pioneer ACO Model, have shown the Innovation Center’s success in generating savings while improving the quality of care.

We appreciate your interest in the Innovation Center’s design and testing of models and their role in moving toward the goal of strengthening the Medicare, Medicaid, and CHIP programs for all beneficiaries. We look forward to further engaging with you and your colleagues, physicians, patients, states, and other stakeholders to shape the future of the Innovation Center. I will provide a copy of this response to the co-signers of your letter.

Sincerely,

Andrew M. Slavitt
Acting Administrator

The Honorable Charles W. Boustany, Jr., M.D.
U.S. House of Representatives
Washington, DC 20015

Dear Representative Boustany, Jr.:

Thank you for your letter regarding the Center for Medicare and Medicaid Innovation (Innovation Center) and its authority to test innovative payment and service delivery models. We share your goal of moving to higher quality, more value-based care for our nation’s seniors.

The Innovation Center’s mission is to test innovative payment and service delivery models designed to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) beneficiaries. To be successful in this mission, the Innovation Center must remain nimble and flexible, capable of not only developing new models, but also of improving upon models quickly based on feedback from beneficiaries, doctors and other clinicians, and other stakeholders. Several ideas for Innovation Center models have come directly from physicians and other clinicians, and the clinicians in Innovation Center models help shape and refine the models through feedback.

The Innovation Center is essential to the implementation of the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) legislation. To move towards paying for value, MACRA directs the Secretary of the Department of Health and Human Services (HHS) to establish a new approach to payment called the Quality Payment Program. The Quality Payment Program allows eligible clinicians participating in Advanced Alternative Payment Models (Advanced APMs) at certain threshold levels to receive an incentive payment, and the Innovation Center is creating as many opportunities for eligible clinicians to participate in Advanced APMs as possible.

The Innovation Center has launched over 35 payment and service delivery models, and the vast majority of the Innovation Center models are voluntary. But, there are certain promising potential models that are difficult or impossible to test on a voluntary basis. For example, some potential models are unlikely to have a positive impact on quality and cost unless they are applied uniformly and equitably to eligible providers or suppliers in a geographic area, and in some potential models requiring participation is necessary to control for potential bias in evaluation results. In these circumstances, we propose the model design and propose requiring participation through notice and comment rulemaking, and we consider public comments carefully before each rule is finalized. Only the Comprehensive Care for Joint Replacement (CJR) Model, the Home Health Value-Based Purchasing Model, and the recently finalized models in the Advancing Care Coordination through Episode Payment Models Final Rule require participation by all eligible providers or suppliers in a given geographic area. The remaining model tests have voluntary participation.
September 29, 2016

Mr. Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Patrick Conway, M.D., MSc  
Deputy Administrator, Innovation & Quality  
Chief Medical Officer  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Mr. Slavitt and Dr. Conway,

The Center for Medicare and Medicaid Innovation (CMMI) is charged with testing and evaluating voluntary healthcare payment and service delivery models with the intent of increasing quality and efficiency while reducing program expenditures under Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). However, as evidenced by three recently proposed mandatory models, CMMI has exceeded its authority, failed to engage stakeholders, and has upset the balance of power between the legislative and executive branches. What makes these proposals even more disconcerting is their potentially negative effects on patients, especially our vulnerable seniors. Policies that have the potential to create access issues for beneficiaries, further provider consolidation, and reduce provider participation in Medicare can drastically deteriorate quality of care our seniors rely on. This would be a step backwards in our unified effort to move to higher quality, more value-based care for our nation’s seniors. We ask that you cease all current and future planned mandatory initiatives under the CMMI.

Until recently, the tests and models developed by CMMI were implemented, as intended, on a voluntary, limited-scale basis where no state, healthcare provider, or health insurer had any obligation to participate. However, on November 24th, 2015, the Centers for Medicare and Medicaid Services (CMS) published a final rule requiring at least 800 hospitals in 67 geographical areas selected by CMS to participate in a new bundled payment model for hip and knee replacements, the Comprehensive Care Joint Replacement (CJR) Model. Furthermore, on March 8th, 2016, CMS released a proposed rule that requires thousands of providers across the country to comply with a new drug payment model under Part B of Medicare. The proposed Part B Drug Payment Model is a clear example of the CMMI’s overstep of authority, given the mandatory participation required of thousands of providers and millions of patients with serious conditions and rare diseases on a

1 Social Security Act Sec. 1115A(a).
2 CMS bases its authority for the Part B Proposal on Section 1115A, which can be viewed as an unconstitutional delegation of legislative power. Article I, Section 1 of the Constitution prohibits Congress from delegating its legislative powers to other bodies, including executive agencies like CMS. See Whitman v. Am. Trucking Assn’s, 531 U.S. 457, 472 (2001).
3 80 Federal Register 73274, November 24, 2015.
4 81 Federal Register 13230, March 11, 2016.
5 The Demonstration Program would change reimbursement practices for 75 percent of the country.

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near-nationwide scale. Most recently, on July 25th, 2016, CMS announced the Cardiac Bundled Payment Model (Cardiac Models) that forces one quarter of all metropolitan areas across the nation into bundled payments for certain severe cardiac conditions and expands the controversial CJR Model to include more hip services. In contravention of the statute, these CMMI models were developed absent input from impacted stakeholders and fail to include safeguards to protect the delicate balance of quality, cost, and access to care for beneficiaries. These mandatory models overhaul major payment systems, commandeer clinical decision-making, and dramatically alter the delivery of care.

By focusing solely on cost-savings without adequate regard to the detrimental effects that the CJR Model, Part B Drug Payment Model, and Cardiac Models may potentially have, CMS at best has heeded only part of its statutory duty—"reduc[ing] program expenditures"—at the expense of its other duties—"preserving or enhancing the quality of care." However, a 2015 blog post by the Congressional Budget Office would suggest that CMMI’s demonstrations do not in fact reduce costs, stating that they have "not yet yielded noticeable savings." In addition to failing to cut costs, mandating participation in large scale demonstrations could have the opposite effect of "preserving or enhancing the quality of care." We are aware that some models tested under demonstration programs fail to produce quality improvements and anticipated cost savings. This is why the statute authorized the Secretary to "test innovative payment and service delivery models"—not mandate them for all providers in designated geographical areas. CMMI’s mandatory models “experiment” with thousands of patient lives without prior testing on a smaller scale or even a basic indication that they will actually achieve improved quality or, at the very least, maintain present quality.

CMMI has failed to meet its statutory requirements for implementing models, including starting with a limited, “Phase I” test, engaging stakeholders in model development, and describing the “defined population” and “deficits in care” the model seeks to address. As a result, Medicare providers and their patients are blindly being forced into high-risk government-dictated reforms with unknown impacts. Any true medical experiment requires patient consent. However, patients residing in an affected geographical area will have no choice about their participation.

As elected Representatives of our constituents and patients who will be directly impacted by these CMMI models or “experiments,” we are limited in our rightful ability to act on behalf of our constituencies to alter, delay or upend these mandatory demonstration programs. CMS’ Part B proposal, for example, would rewrite Medicare Part B payment law in 75 percent of the country without going through the Constitutional procedures where legislation is debated and approved in

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7 42 U.S.C. § 1315a(a).
8 Estimating the Budgetary Effects of Legislation Involving the Center for Medicare and Medicaid Innovation, Congressional Budget Office
9 CB0 reiterated the contents of the blogpost in testimony before the House Budget Committee on September 7th, 2016. (Mark P. Hadley, CBO’s Estimates of the Budgetary Effects of the Center for Medicare & Medicaid Innovation, testimony before the Committee on the Budget, U.S. House of Representatives, 7 September 2016)
10 As Justice Scalia cautioned, “Chevron allows agencies to choose among competing reasonable interpretations of a statute; it does not license interpretive gerrymanders under which an agency keeps parts of statutory context it likes while throwing away parts it does not.” Michigan v. EPA, 576 U.S. ___ (2015), slip op. 9 (citing Chevron v. NRDC, 467 U.S. 837 (1984)).
12 Social Security Act Sec. 1115A(b)(2)(A).
both chambers of Congress, and subsequently signed by the President. These most basic tenets of our government, intended by our Founding Fathers to preserve and maintain balance of power, have clearly been neglected. CMMI interprets their authority to “test” innovative models on a limited basis as a means to substantially alter both the delivery and reimbursement of care without any input or approval from Congress and the constituents we represent.

Accordingly, we insist CMMI stop experimenting with Americans’ health, and cease all current and future planned mandatory initiatives within the CMMI. Additionally, we ask that you commit to ensuring future CMMI models fully comply with current law, including: limiting the size and scope of CMMI demonstrations so they represent true tests rather than wholesale changes to statute; seeking Congressional approval if expansion of test models require changes to the underlying statute; and establishing an open, transparent process that supports clear and consistent communication with physicians, patients and other relevant stakeholders in the development of new CMMI models.

We look forward to your response detailing next steps as to how the agency plans to ensure that the CMMI will cease current mandatory initiatives and refrain from pursuing any future initiatives that exceed CMMI’s scope of authority.

Sincerely,

Tom Price, M.D.  
Member of Congress

Charles W. Boustany, Jr., M.D.  
Member of Congress

Erik Paulsen  
Member of Congress
Harold Rogers  
Member of Congress

Mike G. Fitzpatrick  
Member of Congress

Jim Jordan  
Member of Congress

Jordan   
Member of Congress

Joe Wilson  
Member of Congress

Mike Simpson  
Member of Congress

Mike G. Fitzpatrick  
Member of Congress

Mike Kelly  
Member of Congress

Greg Walden  
Member of Congress

Louie Gohmert  
Member of Congress

Steve Scalise  
Member of Congress

Harold Rogers  
Member of Congress

Kristi Noem  
Member of Congress

John Kline  
Member of Congress

F. James Sensenbrenner, Jr.  
Member of Congress

Darin LaHood  
Member of Congress
Glenn "GT" Thompson  
Member of Congress

Robert B. Aderholt  
Member of Congress

Chris Stewart  
Member of Congress

Ryan A. Costello  
Member of Congress

Glenn Grothman  
Member of Congress

Dan Benishek, M.D.  
Member of Congress

Randy Forbes  
Member of Congress

Joe Heck, D.O.  
Member of Congress

Doug LaMalfa  
Member of Congress

Ralph Abraham, M.D.  
Member of Congress

Richard Hudson  
Member of Congress

Ted S. Yoho  
Member of Congress

Walter B. Jones  
Member of Congress

Mark Sanford  
Member of Congress
George Holding
Member of Congress

Devin Nunes
Member of Congress

Chris Collins
Member of Congress

Adam Kinzinger
Member of Congress

Brad Wenstrup, D.P.M.
Member of Congress

Susan W. Brooks
Member of Congress

Andy Harris, M.D.
Member of Congress

Rick Allen
Member of Congress

Bill Flores
Member of Congress

Patrick Tiberi
Member of Congress

French Hill
Member of Congress

Andy Barr
Member of Congress

Lynn Jenkins
Member of Congress

Renee Ellmers
Member of Congress
Robert Pittenger  
Member of Congress

Bradley Byrne  
Member of Congress

John Moolenaar  
Member of Congress

Gary Palmer  
Member of Congress

Bruce Westerman  
Member of Congress

Robert J. Dold  
Member of Congress

Rod Blum  
Member of Congress

Bradley Byrne  
Member of Congress

Blanchard  
Member of Congress

Lou Barletta  
Member of Congress

Rex Ryan  
Member of Congress

Chuck Fleischmann  
Member of Congress

Mimi Walters  
Member of Congress

Gregg Harper  
Member of Congress

Brian Babin, D.D.S.  
Member of Congress
Mike Rogers
Member of Congress

Jim Renacci
Member of Congress

Jackie Walorski
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Ann Wagner
Member of Congress

David P. Roe, M.D.
Member of Congress

Evan Jenkins
Member of Congress

Frank Guinta
Member of Congress

Ken Buck
Member of Congress

David Rouzer
Member of Congress

Patrick Meehan
Member of Congress

Mike Pompeo
Member of Congress

Martha Roby
Member of Congress

Paul Gosar, D.D.S.
Member of Congress
Ron DeSantis  
Member of Congress

Elise Stefanik  
Member of Congress

Steve Stivers  
Member of Congress

H. Morgan Griffith  
Member of Congress

Diane Black  
Member of Congress

Thomas J. Rooney  
Member of Congress

Edward R. Royce  
Member of Congress

Mark Walker  
Member of Congress

David G. Valadao  
Member of Congress

Mark Meadows  
Member of Congress

David Joyce  
Member of Congress

Lee M. Zeldin  
Member of Congress

Bob Goodlatte  
Member of Congress

Virginia Foxx  
Member of Congress
Randy Neugebauer
Member of Congress

Mike Bost
Member of Congress

Jody Hice
Member of Congress

Rodney Davis
Member of Congress

Scott Garrett
Member of Congress

Patrick McHenry
Member of Congress

Austin Scott
Member of Congress

Carlos Curbelo
Member of Congress

Reid Ribble
Member of Congress

Dave Trott
Member of Congress

Pete Olson
Member of Congress

Bill Shuster
Member of Congress

John Culberson
Member of Congress

Tim Walberg
Member of Congress
Kevin Cramer  
Member of Congress

Dennis A. Ross  
Member of Congress

Scott DesJarlais, M.D.  
Member of Congress

Martha McSally  
Member of Congress

Jason Smith  
Member of Congress

John Katko  
Member of Congress

Sean Duffy  
Member of Congress

Tom Rice  
Member of Congress

Tom Marino  
Member of Congress

Todd Young  
Member of Congress

Markwayne Mullin  
Member of Congress

Steve Womack  
Member of Congress

Keith Rothfus  
Member of Congress

Mo Brooks  
Member of Congress
Mike Bishop
Member of Congress

David Young
Member of Congress

Bill Huizenga
Member of Congress

Bill Johnson
Member of Congress

Lynn A. Westmoreland
Member of Congress

Darrell Issa
Member of Congress

Blaine Luetkemeyer
Member of Congress

Crescent Hardy
Member of Congress

Warren Davidson
Member of Congress

Chris Gibson
Member of Congress

John Fleming, M.D.
Member of Congress

Steve King
Member of Congress

Ted Poe
Member of Congress

Randy Hultgren
Member of Congress
Jeff Duncan
Member of Congress

Rob Bishop
Member of Congress

Cathy McMorris Rodgers
Member of Congress

Mia Love
Member of Congress

Thomas Massie
Member of Congress

David B. McKinley
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Bill Posey
Member of Congress

Michael T. McCaul
Member of Congress

Kevin Yoder
Member of Congress

Barry Loudermilk
Member of Congress

Dave Brat
Member of Congress

Tom Emmer
Member of Congress

Paul Cook
Member of Congress
Ryan Zinke
Member of Congress

Scott Tipton
Member of Congress

Tom MacArthur
Member of Congress

Alex Mooney
Member of Congress

Doug Collins
Member of Congress

Dan Newhouse
Member of Congress

Rob Woodall
Member of Congress

Dave Reichert
Member of Congress
Dear Acting Administrator Slavitt and Director Donovan:

On April 27th, CMS released a proposed rule to implement the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. By repealing the Sustainable Growth Rate Formula, MACRA has the potential to transform the healthcare landscape and the delivery of care. However, if CMS implements the rule in a manner which is inconsistent with Congressional intent, MACRA has the potential to overcomplicate an already burdensome and complex quality reporting system and take more time away from patient care.¹

According to a Health Affairs study published in March of 2016, physician practices in four common specialties spend, on average, 785 hours per physician and more than $15.4 billion each year on quality measure reporting programs. Furthermore, the majority of time spent on quality reporting consists of “entering information into the medical record only for the purpose of reporting quality measures from external entities,” and nearly three-quarters of practices stated their group was being evaluated on quality measures that were not clinically relevant. Congress recognized that these programs may actually detract from quality care by driving providers’ time away from patients, and, as a result, replaced them with what is supposed to be a streamlined quality program, known as the Merit-based Incentive Payment System (MIPS).

Under MACRA, providers will use either MIPS or an advanced alternative payment model (APM). In an impact analysis within its proposed MACRA implementation rule, CMS projects that as few as 6% of physicians may participate in qualified APMs. While we believe there are ways to expand the APM option to more physicians, it is clear that the vast majority of physicians will be reporting under MIPS in 2017. Given the immediate focus on MIPS, we are particularly concerned about the complexity of MIPS, the timing of the performance period, and the significant impact of the MIPS program on small and rural practices, among other issues.

We urge you to carefully address a number of multi-layered, high-level concerns that will likely require multi-faceted solutions. Thus, we encourage the agency to take note of the technical issues being presented in the comment letters of the various providers, specialty physicians and medical industry stakeholders.

MACRA brings significant changes to physician workflows, yet most physicians remain entirely

¹ According to a survey released in July of 2016 by Deloitte, 74% of physicians already find quality reporting to be burdensome.
unaware of MACRA or its implications. Deloitte recently surveyed 600 primary care and specialty physicians regarding MACRA. Of those surveyed, 50% of physicians reported that they have never heard of MACRA, and an additional 32% said that they have heard of it but are unfamiliar with its requirements. Thus, 82% of physicians are unaware of how their reimbursement will be impacted by this new law. Following publication of the final rule and ahead of the start date, the agency must devote significant resources to educate practices about MACRA.

**MIPS is Too Complex**

As proposed, even the smallest physician group practices (10 or fewer eligible professionals) would need to expend finite resources on measuring and monitoring their performance on at least 22 measures, including a minimum of eight measures in the quality category, at least two measures in resource use, at least 11 measures in ACI, and at least one measure in the clinical practice improvement activity (CPIA) category. In order to be successful, MIPS must engage clinicians with a reporting system that is not overly burdensome, a scoring system that is simple and transparent, attainable thresholds, and a short enough quality/payment feedback loop to allow physicians to learn and make necessary changes to avoid further penalty.

More detailed feedback reports are needed to assist physicians in understanding their performance rating, including the specific cause for a penalty assessment, the reporting rate for each measure, the calculation methodology and any errors in received data. A transparent process with detailed reports will aid providers to more quickly rectify inaccuracies in their data, and enhance their ability to submit timely appeals before payment reductions are applied and performance ratings are made public. In the past, eligible professionals were left to decipher this rationale on their own, taking valuable time and resources away from patient care.

Within the same vein, an appeals process that is transparent and not administratively burdensome should be readily available to physicians throughout MIPS. An appeals process should have a reasonable time frame for providers to participate, especially given that MIPS will be new to all providers. An appeals process should also promptly address provider concerns with explicit timetables for review.

**Start and Length of Performance Reporting Are Unrealistic**

The proposed rule requires MIPS performance measurement to start on January 1, 2017, with the first MIPS payment adjustments being made in January 2019. Physicians and the organizations that represent them have expressed the widely-shared view that the timeline is unrealistic, prompting a recent announcement that CMS intends to give physicians considerable flexibility on when and how they meet MIPS participation requirements in 2017. We share the timeline concerns expressed by our physician colleagues and are encouraged that CMS appears to be taking a step in the right direction. We await further details to determine the extent to which this proposal and other provisions in the final rule alleviate potential problems raised by a 2017 start date. Specifically, we want to be sure that physicians have time to prepare with sufficient notice of program requirements in the final rule and a final list of qualified Advanced APMs.

We also ask CMS to adopt a 90-day reporting period, rather than the year-long period called for in the proposed rule, for the Advancing Care Information (ACI) category of MIPS to enable more small practices to succeed. Especially in the initial years of MIPS, a shorter reporting period is necessary.

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2 Larger practices would have two additional CPIA measures and one additional quality measure.
for all providers, but particularly smaller practices who have fewer resources to keep up with the changing regulatory environment. A shorter reporting period would ensure that more providers are able to successfully make the transition to MIPS, upgrade their EHR technology and meet the new Stage 3 measures by 2018.³

The Impact of the MIPS Program on Small and Rural Practices will Continue to Drive Consolidation

According to the aforementioned Deloitte study, 58% of physicians say MIPS would encourage them to be part of a larger organization to reduce individual increased financial risk and have access to supporting resources and capabilities. In fact, 80% of surveyed physicians believe MACRA will drive consolidation.

To help reduce administrative burden for small practices and allow for flexibility in quality reporting, CMS should lower its patient minimum reporting thresholds. CMS proposed that providers using a registry must report quality measures on 90% of their patients from all payers, and 80% of Medicare patients for those reporting by claims. This is a significant jump from what is currently 50% of Medicare patients. Such a high minimum threshold would be impossible for many physicians, particularly those in small practices, to meet. We recommend that CMS maintain the minimum threshold at a maximum of 50% of Medicare patients.

Additionally, the MACRA statute included the concept of virtual groups to help assist small practices; however, CMS proposes not to implement virtual groups until the 2018 performance period. The newly-announced participation flexibility policy in 2017 may make this delay more acceptable. However, we strongly urge CMS to act swiftly on forming these groups as soon as possible to ensure that this option is communicated to physicians early enough to provide them with sufficient time to organize and participate. Without this assistance, we believe small practices face even greater challenges when attempting to adapt to the MIPS program structure.

CMS should also broaden its MIPS exclusion for providers who treat a low volume of Medicare patients. To help mitigate adverse effects on small practices, CMS has proposed a low-volume threshold that would exempt physicians from MIPS if their practice has less than $10,000 in Medicare allowed charges and fewer than 100 unique Medicare patients per year. The proposed threshold, however, would help very few physicians and other clinicians. An AMA analysis of the 2014 “Medicare Provider Utilization and Payment Data: Physician and Other Supplier” file found that just 10% of physicians and 16% of all MIPS eligible clinicians would be exempt under the $10,000/100 beneficiary proposal, and that these clinicians account for less than one percent of total Medicare allowed charges for Physician Fee Schedule services. As one example, by increasing the threshold to $30,000 in Medicare allowed charges or fewer than 100 unique Medicare patients seen by the physician, CMS would provide a better safety net for small providers. This would exclude less than 30% of physicians while still subjecting more than 93% of allowed spending to MIPS. We recommend that the low-volume threshold be raised significantly in the final rule.

Resource Measures May Not Provide Accurate and Relevant Assessment of Physician Performance

³ CMS must minimize any unfair negative impact to small practices. In Table 64 of the proposed rule, CMS estimates that a disproportionate number of solo practitioners and small practices would fail the Merit-Based Incentive Program and would experience financial penalties as a result. CMS should modify its proposals to ensure an equal opportunity for all providers to succeed in the program.
Resource use measures that CMS has used in the value-based modifier were originally developed for use in hospitals and are neither accurate nor relevant for many physicians. Recognizing this, Congress made clear that this category under MIPS should be limited to 10% or less of the total MIPS score in the first year and 15% or less in 2020. MACRA also called for the development of new episode measures and physician-patient relationship codes that are intended to improve the reliability and relevance of scores in this category. Final versions of the physician-patient relationship codes are not due to take effect until 2018 and many of the episode measures that CMS has developed to date have not been adequately reviewed by physicians or tested for use in physician offices. We believe that CMS should make the resource use category optional for at least one year while the measures and related methodologies are refined.

We strongly urge CMS to make necessary changes in the final rule so that physicians may be provided with the tools necessary to succeed under this new payment regime. We look forward to continuing to work with CMS to ensure effective implementation of this rule.

Sincerely,

Tom Price, M.D.
Member of Congress

David P. Roe, M.D.
Member of Congress
Scott DesJarlais, M.D.
Member of Congress

Mike Simpson, D.M.D.
Member of Congress
Dear Representative Chaffetz:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

First, under the statute and conforming regulations, CMS is required to ensure that communications provided to Medicare beneficiaries are accurate and not confusing or misleading. Second, CMS is required to ensure that plans do not misuse beneficiary information for purposes inconsistent with restrictions they have agreed to in their contract on the use of such information. Third, CMS is required to ensure that Federal funds paid to contracting entities, including MA plans, are not used for impermissible purposes such as lobbying.

With regard to Humana, the communications in question had the potential to be confusing and/or misleading to beneficiaries. The specific mailing of concern included the following statement on the envelope, "Important information about your Medicare Advantage plan--open today!" The statement on the envelope purported to have current plan benefit information, it could be misleading to a beneficiary since the information inside the envelope instead discussed pending health reform legislation. Given that MA and Part D prescription drug plans were soon to begin mailing annual required notices to beneficiaries about specific changes to plan benefits or plan structures for the upcoming year, wholly unrelated to any possible future legislative changes, the timing and content of this messaging was particularly concerning to the Agency. Under section 1851(h)(1) of the Social Security Act (incorporated for Part D under section 1860D-l(b)(vi) plans are required to submit all materials defined as marketing to CMS for review and approval prior to sending them to their Medicare enrollees. The regulations define "marketing materials" to include "any information targeted to Medicare beneficiaries" that, among other things, provides information on plan benefits (42 CFR 422.2260; 423.2260). We are concerned that the particular mailing in question violated these regulations because it purported to provide MA enrollees with "information" about their "Medicare Advantage plan" that suggested that the mailing contained "official" information from the Medicare program about the enrollee's Medicare plan, when this was not the case.

The Agency had a second concern about misuse of beneficiary information given that Part C and Part D plans sign an attestation under which they agree to use Medicare beneficiary data
obtained by virtue of their contracts with CMS only for purposes of administering their plans. CMS is investigating whether plans inappropriately used beneficiary data subject to this limitation in their health care reform outreach efforts.

Finally, we are concerned that Federal funds not be used improperly for activities that are prohibited under the Department of Health and Human Services’ (HHS) appropriations acts. HHS’s appropriations acts very specifically provide that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. See Division F, Title V, Section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by Section 5, Omnibus Appropriations Act, 2009, Pub. L. 111-11, 123 Stat. 524,802 (March 11, 2009). Because administrative costs incurred by MA and Part D prescription drug plans are included in their “bids,” and these bids form the basis for Medicare payments, CMS needs to ensure that no Federal funds were used for the lobbying activities in question. I should note that under recent audits, it appears that in some cases lobbying costs may have been included as administrative costs in Medicare health and drug plan bids. CMS is therefore committed to ensuring that plans have not done so in this case, and that other contracted organizations contemplating lobbying activities also do not pay for these activities with Federal funds.

To be clear, HHS believes that contracted organizations that sponsor MA and prescription drug plans may communicate their views on pending legislation with no interference from CMS or others in the Department, assuming compliance with the provisions noted above. Indeed, such communication may be outside of HHS review if done by the corporate sponsors of these plans with no interaction (e.g., use of funds or protected beneficiary information) with Medicare. You also ask about mailings by the Association for the Advancement of Retired Persons (AARP), and specifically whether any enforcement actions were initiated by CMS regarding AARP mailings. The AARP is not a Medicare contractor and maintains its own membership records. The Medicare health and drug plans advertised by AARP are sponsored by United Health Group under contract with CMS, and therefore mailings by United Health Group are included in our overall investigation.

I appreciate your interest in our actions since we share a responsibility to Medicare beneficiaries and taxpayers to ensure fair and appropriate communication and information. To ensure that any compliance and enforcement actions are appropriately and consistently applied, CMS will continue its review to determine whether Medicare contractors that sponsor health and drug plans may have violated marketing guidelines and other provisions noted above. In addition, CMS prepared a ready reference for Medicare health and drug plan sponsors on outreach related activities providing summary guidance that compiles all the relevant statutes and guiding regulations in this area.

Sincerely,

Charlene Frizzera
Acting Administrator
Dear Representative Luetkemeyer:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency’s actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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The Agency had a second concern about misuse of beneficiary information given that Part C and Part D plans sign an attestation under which they agree to use Medicare beneficiary data...
obtained by virtue of their contracts with CMS only for purposes of administering their plans. CMS is investigating whether plans inappropriately used beneficiary data subject to this limitation in their health care reform outreach efforts.

Finally, we are concerned that Federal funds not be used improperly for activities that are prohibited under the Department of Health and Human Services' (HHS) appropriations acts. HHS's appropriations acts very specifically provide that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. See Division F, Title V, Section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by Section 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524,802 (March 11, 2009). Because administrative costs incurred by MA and Part D prescription drug plans are included in their "bids," and these bids form the basis for Medicare payments, CMS needs to ensure that no Federal funds were used for the lobbying activities in question. I should note that under recent audits, it appears that in some cases lobbying costs may have been included as administrative costs in Medicare health and drug plan bids. CMS is therefore committed to ensuring that plans have not done so in this case, and that other contracted organizations contemplating lobbying activities also do not pay for these activities with Federal funds.

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I appreciate your interest in our actions since we share a responsibility to Medicare beneficiaries and taxpayers to ensure fair and appropriate communication and information. To ensure that any compliance and enforcement actions are appropriately and consistently applied, CMS will continue its review to determine whether Medicare contractors that sponsor health and drug plans may have violated marketing guidelines and other provisions noted above. In addition, CMS prepared a ready reference for Medicare health and drug plan sponsors on outreach related activities providing summary guidance that compiles all the relevant statutes and guiding regulations in this area.

Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Dan Lungren  
House of Representatives  
Washington, DC 20515  

Dear Representative Lungren:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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Sincerely,

[Signature]
Charlene Frizzera
Acting Administrator
The Honorable John Sminkus  
House of Representatives  
Washington, DC 20515  

Dear Representative Sminkus:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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With regard to Humana, the communications in question had the potential to be confusing and/or misleading to beneficiaries. The specific mailing of concern included the following statement on the envelope. "Important information about your Medicare Advantage plan--open today!" The statement on the envelope purported to have current plan benefit information, it could be misleading to a beneficiary since the information inside the envelope instead discussed pending health reform legislation. Given that MA and Part D prescription drug plans were soon to begin mailing annual required notices to beneficiaries about specific changes to plan benefits or plan structures for the upcoming year, wholly unrelated to any possible future legislative changes, the timing and content of this messaging was particularly concerning to the Agency. Under section 1851(h)(1) of the Social Security Act (incorporated for Part D under section 1860D-(b)(vi) plans are required to submit all materials defined as marketing to CMS for review and approval prior to sending them to their Medicare enrollees. The regulations define "marketing materials" to include "any information targeted to Medicare beneficiaries" that, among other things, provides information on plan benefits (42 CFR 422.2260; 423.2260). We are concerned that the particular mailing in question violated these regulations because it purported to provide MA enrollees with "information" about their "Medicare Advantage plan" that suggested that the mailing contained "official" information from the Medicare program about the enrollee’s Medicare plan, when this was not the case.

The Agency had a second concern about misuse of beneficiary information given that Part C and Part D plans sign an attestation under which they agree to use Medicare beneficiary data
obtained by virtue of their contracts with CMS only for purposes of administering their plans. CMS is investigating whether plans inappropriately used beneficiary data subject to this limitation in their health care reform outreach efforts.

Finally, we are concerned that Federal funds not be used improperly for activities that are prohibited under the Department of Health and Human Services' (HHS) appropriations acts. HHS’s appropriations acts very specifically provide that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. See Division F, Title V, Section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by Section 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524,802 (March 11, 2009). Because administrative costs incurred by MA and Part D prescription drug plans are included in their "bids," and these bids form the basis for Medicare payments, CMS needs to ensure that no Federal funds were used for the lobbying activities in question. I should note that under recent audits, it appears that in some cases lobbying costs may have been included as administrative costs in Medicare health and drug plan bids. CMS is therefore committed to ensuring that plans have not done so in this case, and that other contracted organizations contemplating lobbying activities also do not pay for these activities with Federal funds.

To be clear, HHS believes that contracted organizations that sponsor MA and prescription drug plans may communicate their views on pending legislation with no interference from CMS or others in the Department, assuming compliance with the provisions noted above. Indeed, such communication may be outside of HHS review if done by the corporate sponsors of these plans with no interaction (e.g., use of funds or protected beneficiary information) with Medicare. You also ask about mailings by the Association for the Advancement of Retired Persons (AARP), and specifically whether any enforcement actions were initiated by CMS regarding AARP mailings. The AARP is not a Medicare contractor and maintains its own membership records. The Medicare health and drug plans advertised by AARP are sponsored by United Health Group under contract with CMS, and therefore mailings by United Health Group are included in our overall investigation.

I appreciate your interest in our actions since we share a responsibility to Medicare beneficiaries and taxpayers to ensure fair and appropriate communication and information. To ensure that any compliance and enforcement actions are appropriately and consistently applied, CMS will continue its review to determine whether Medicare contractors that sponsor health and drug plans may have violated marketing guidelines and other provisions noted above. In addition, CMS prepared a ready reference for Medicare health and drug plan sponsors on outreach related activities providing summary guidance that compiles all the relevant statutes and guiding regulations in this area.

Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Joe Pitts  
House of Representatives  
Washington, DC 20515

Dear Representative Pitts:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

First, under the statute and conforming regulations, CMS is required to ensure that communications provided to Medicare beneficiaries are accurate and not confusing or misleading. Second, CMS is required to ensure that plans do not misuse beneficiary information for purposes inconsistent with restrictions they have agreed to in their contract on the use of such information. Third, CMS is required to ensure that Federal funds paid to contracting entities, including MA plans, are not used for impermissible purposes such as lobbying.

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I appreciate your interest in our actions since we share a responsibility to Medicare beneficiaries and taxpayers to ensure fair and appropriate communication and information. To ensure that any compliance and enforcement actions are appropriately and consistently applied. CMS will continue its review to determine whether Medicare contractors that sponsor health and drug plans may have violated marketing guidelines and other provisions noted above. In addition. CMS prepared a ready reference for Medicare health and drug plan sponsors on outreach related activities providing summary guidance that compiles all the relevant statutes and guiding regulations in this area.

Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Roscoe Bartlett  
House of Representatives  
Washington, DC 20515  

Dear Representative Bartlett:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency’s actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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Sincerely,

Charlene Frizzera
Acting Administrator
Dear Representative Shock:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency’s actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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Sincerely,

Charlene Frizzera
Acting Administrator
Dear Representative Blackburn:

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Sincerely,

Charlene Frizzera
Acting Administrator
Dear Representative Jenkins:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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The Agency had a second concern about misuse of beneficiary information given that Part C and Part D plans sign an attestation under which they agree to use Medicare beneficiary data
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Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Jo Bonner  
House of Representatives  
Washington, DC 20515  

Dear Representative Bonner:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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The Agency had a second concern about misuse of beneficiary information given that Part C and Part D plans sign an attestation under which they agree to use Medicare beneficiary data
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Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable George Radanovich  
House of Representatives  
Washington, DC 20515  

Dear Representative Radanovich:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency’s actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

First, under the statute and conforming regulations, CMS is required to ensure that communications provided to Medicare beneficiaries are accurate and not confusing or misleading. Second, CMS is required to ensure that plans do not misuse beneficiary information for purposes inconsistent with restrictions they have agreed to in their contract on the use of such information. Third, CMS is required to ensure that Federal funds paid to contracting entities, including MA plans, are not used for impermissible purposes such as lobbying.

With regard to Humana, the communications in question had the potential to be confusing and/or misleading to beneficiaries. The specific mailing of concern included the following statement on the envelope, "Important information about your Medicare Advantage plan--open today!" The statement on the envelope purported to have current plan benefit information, it could be misleading to a beneficiary since the information inside the envelope instead discussed pending health reform legislation. Given that MA and Part D prescription drug plans were soon to begin mailing annual required notices to beneficiaries about specific changes to plan benefits or plan structures for the upcoming year, wholly unrelated to any possible future legislative changes, the timing and content of this messaging was particularly concerning to the Agency. Under section 1851(h)(1) of the Social Security Act (incorporated for Part D under section 1860D-l(b)(vi) plans are required to submit all materials defined as marketing to CMS for review and approval prior to sending them to their Medicare enrollees. The regulations define "marketing materials" to include "any information targeted to Medicare beneficiaries" that, among other things, provides information on plan benefits (42 CFR 422.2260; 423.2260). We are concerned that the particular mailing in question violated these regulations because it purported to provide MA enrollees with "information" about their "Medicare Advantage plan" that suggested that the mailing contained "official" information from the Medicare program about the enrollee's Medicare plan, when this was not the case.

The Agency had a second concern about misuse of beneficiary information given that Part C and Part D plans sign an attestation under which they agree to use Medicare beneficiary data...
obtained by virtue of their contracts with CMS only for purposes of administering their plans. CMS is investigating whether plans inappropriately used beneficiary data subject to this limitation in their health care reform outreach efforts.

Finally, we are concerned that Federal funds not be used improperly for activities that are prohibited under the Department of Health and Human Services’ (HHS) appropriations acts. HHS’s appropriations acts very specifically provide that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. See Division F, Title V, Section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by Section 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524,802 (March 11, 2009). Because administrative costs incurred by MA and Part D prescription drug plans are included in their "bids," and these bids form the basis for Medicare payments, CMS needs to ensure that no Federal funds were used for the lobbying activities in question. I should note that under recent audits, it appears that in some cases lobbying costs may have been included as administrative costs in Medicare health and drug plan bids. CMS is therefore committed to ensuring that plans have not done so in this case, and that other contracted organizations contemplating lobbying activities also do not pay for these activities with Federal funds.

To be clear, HHS believes that contracted organizations that sponsor MA and prescription drug plans may communicate their views on pending legislation with no interference from CMS or others in the Department, assuming compliance with the provisions noted above. Indeed, such communication may be outside of HHS review if done by the corporate sponsors of these plans with no interaction (e.g., use of funds or protected beneficiary information) with Medicare. You also ask about mailings by the Association for the Advancement of Retired Persons (AARP), and specifically whether any enforcement actions were initiated by CMS regarding AARP mailings. The AARP is not a Medicare contractor and maintains its own membership records. The Medicare health and drug plans advertised by AARP are sponsored by United Health Group under contract with CMS, and therefore mailings by United Health Group are included in our overall investigation.

I appreciate your interest in our actions since we share a responsibility to Medicare beneficiaries and taxpayers to ensure fair and appropriate communication and information. To ensure that any compliance and enforcement actions are appropriately and consistently applied, CMS will continue its review to determine whether Medicare contractors that sponsor health and drug plans may have violated marketing guidelines and other provisions noted above. In addition, CMS prepared a ready reference for Medicare health and drug plan sponsors on outreach related activities providing summary guidance that compiles all the relevant statutes and guiding regulations in this area.

Sincerely,

Charlene Frizzera
Acting Administrator
DEC 16 2009

The Honorable Paul Broun
House of Representatives
Washington, DC 20515

Dear Representative Broun:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

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Sincerely,

Charlene Frizzera
Acting Administrator
Dear Representative Souder:

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Sincerely,

Charlene Frizzera
Acting Administrator
DEC 1 6 2009

The Honorable Waller Herger
House of Representatives
Washington, DC 20515

Dear Representative Herger:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

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Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Louie Gohmert  
House of Representatives  
Washington, DC 20515  

Dear Representative Gohmert:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

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Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Mike Conaway  
House of Representatives  
Washington, DC 20515

Dear Representative Conaway:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

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Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Todd Akin  
House of Representatives  
Washington, DC 20515

Dear Representative Akin:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

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Charlene Frizzera
Acting Administrator
The Honorable Trent Franks
House of Representatives
Washington, DC 20515

Dear Representative Franks:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

First, under the statute and conforming regulations, CMS is required to ensure that communications provided to Medicare beneficiaries are accurate and not confusing or misleading. Second, CMS is required to ensure that plans do not misuse beneficiary information for purposes inconsistent with restrictions they have agreed to in their contract on the use of such information. Third, CMS is required to ensure that Federal funds paid to contracting entities, including MA plans, are not used for impermissible purposes such as lobbying.

With regard to Humana, the communications in question had the potential to be confusing and/or misleading to beneficiaries. The specific mailing of concern included the following statement on the envelope, "Important information about your Medicare Advantage plan--open today!" The statement on the envelope purported to have current plan benefit information, it could be misleading to a beneficiary since the information inside the envelope instead discussed pending health reform legislation. Given that MA and Part D prescription drug plans were soon to begin mailing annual required notices to beneficiaries about specific changes to plan benefits or plan structures for the upcoming year, wholly unrelated to any possible future legislative changes, the timing and content of this messaging was particularly concerning to the Agency. Under section 1851(h)(1) of the Social Security Act (incorporated for Part D under section 1860D-1(b)(vi) plans are required to submit all materials defined as marketing to CMS for review and approval prior to sending them to their Medicare enrollees. The regulations define "marketing materials" to include "any information targeted to Medicare beneficiaries" that, among other things, provides information on plan benefits (42 CFR 422.2260; 423.2260). We are concerned that the particular mailing in question violated these regulations because it purported to provide MA enrollees with "information" about their "Medicare Advantage plan" that suggested that the mailing contained "official" information from the Medicare program about the enrollee's Medicare plan, when this was not the case.

The Agency had a second concern about misuse of beneficiary information given that Part C and Part D plans sign an attestation under which they agree to use Medicare beneficiary data
obtained by virtue of their contracts with CMS only for purposes of administering their plans. CMS is investigating whether plans inappropriately used beneficiary data subject to this limitation in their health care reform outreach efforts.

Finally, we are concerned that Federal funds not be used improperly for activities that are prohibited under the Department of Health and Human Services’ (HHS) appropriations acts. HHS’s appropriations acts very specifically provide that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. See Division F, Title V, Section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by Section 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524,802 (March 11, 2009). Because administrative costs incurred by MA and Part D prescription drug plans are included in their "bids," and these bids form the basis for Medicare payments, CMS needs to ensure that no Federal funds were used for the lobbying activities in question. I should note that under recent audits, it appears that in some cases lobbying costs may have been included as administrative costs in Medicare health and drug plan bids. CMS is therefore committed to ensuring that plans have not done so in this case, and that other contracted organizations contemplating lobbying activities also do not pay for these activities with Federal funds.

To be clear, HHS believes that contracted organizations that sponsor MA and prescription drug plans may communicate their views on pending legislation with no interference from CMS or others in the Department, assuming compliance with the provisions noted above. Indeed, such communication may be outside of HHS review if done by the corporate sponsors of these plans with no interaction (e.g., use of funds or protected beneficiary information) with Medicare. You also ask about mailings by the Association for the Advancement of Retired Persons (AARP), and specifically whether any enforcement actions were initiated by CMS regarding AARP mailings. The AARP is not a Medicare contractor and maintains its own membership records. The Medicare health and drug plans advertised by AARP are sponsored by United Health Group under contract with CMS, and therefore mailings by United Health Group are included in our overall investigation.

I appreciate your interest in our actions since we share a responsibility to Medicare beneficiaries and taxpayers to ensure fair and appropriate communication and information. To ensure that any compliance and enforcement actions are appropriately and consistently applied, CMS will continue its review to determine whether Medicare contractors that sponsor health and drug plans may have violated marketing guidelines and other provisions noted above. In addition, CMS prepared a ready reference for Medicare health and drug plan sponsors on outreach related activities providing summary guidance that compiles all the relevant statutes and guiding regulations in this area.

Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Jack Kingston
House of Representatives
Washington, DC 20515

Dear Representative Kingston:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

First, under the statute and conforming regulations, CMS is required to ensure that communications provided to Medicare beneficiaries are accurate and not confusing or misleading. Second, CMS is required to ensure that plans do not misuse beneficiary information for purposes inconsistent with restrictions they have agreed to in their contract on the use of such information. Third, CMS is required to ensure that Federal funds paid to contracting entities, including MA plans, are not used for impermissible purposes such as lobbying.

With regard to Humana, the communications in question had the potential to be confusing and/or misleading to beneficiaries. The specific mailing of concern included the following statement on the envelope, "Important information about your Medicare Advantage plan—open today!" The statement on the envelope purported to have current plan benefit information, it could be misleading to a beneficiary since the information inside the envelope instead discussed pending health reform legislation. Given that MA and Part D prescription drug plans were soon to begin mailing annual required notices to beneficiaries about specific changes to plan benefits or plan structures for the upcoming year, wholly unrelated to any possible future legislative changes, the timing and content of this messaging was particularly concerning to the Agency. Under section 1851(h)(1) of the Social Security Act (incorporated for Part D under section 1860D-l(b)(vi) plans are required to submit all materials defined as marketing to CMS for review and approval prior to sending them to their Medicare enrollees. The regulations define "marketing materials" to include "any information targeted to Medicare beneficiaries" that, among other things, provides information on plan benefits (42 CFR 422.2260; 423.2260). We are concerned that the particular mailing in question violated these regulations because it purported to provide MA enrollees with "information" about their "Medicare Advantage plan" that suggested that the mailing contained "official" information from the Medicare program about the enrollee's Medicare plan, when this was not the case.

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obtained by virtue of their contracts with CMS only for purposes of administering their plans. CMS is investigating whether plans inappropriately used beneficiary data subject to this limitation in their health care reform outreach efforts.

Finally, we are concerned that Federal funds not be used improperly for activities that are prohibited under the Department of Health and Human Services' (HHS) appropriations acts. HHS's appropriations acts very specifically provide that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature. See Division F, Title V, Section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by Section 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524,802 (March 11, 2009). Because administrative costs incurred by MA and Part D prescription drug plans are included in their "bids," and these bids form the basis for Medicare payments, CMS needs to ensure that no Federal funds were used for the lobbying activities in question. I should note that under recent audits, it appears that in some cases lobbying costs may have been included as administrative costs in Medicare health and drug plan bids. CMS is therefore committed to ensuring that plans have not done so in this case, and that other contracted organizations contemplating lobbying activities also do not pay for these activities with Federal funds.

To be clear, HHS believes that contracted organizations that sponsor MA and prescription drug plans may communicate their views on pending legislation with no interference from CMS or others in the Department, assuming compliance with the provisions noted above. Indeed, such communication may be outside of HHS review if done by the corporate sponsors of these plans with no interaction (e.g., use of funds or protected beneficiary information) with Medicare. You also ask about mailings by the Association for the Advancement of Retired Persons (AARP), and specifically whether any enforcement actions were initiated by CMS regarding AARP mailings. The AARP is not a Medicare contractor and maintains its own membership records. The Medicare health and drug plans advertised by AARP are sponsored by United Health Group under contract with CMS, and therefore mailings by United Health Group are included in our overall investigation.

I appreciate your interest in our actions since we share a responsibility to Medicare beneficiaries and taxpayers to ensure fair and appropriate communication and information. To ensure that any compliance and enforcement actions are appropriately and consistently applied, CMS will continue its review to determine whether Medicare contractors that sponsor health and drug plans may have violated marketing guidelines and other provisions noted above. In addition, CMS prepared a ready reference for Medicare health and drug plan sponsors on outreach related activities providing summary guidance that compiles all the relevant statutes and guiding regulations in this area.

Sincerely,

Charlene Frizzera
Acting Administrator
The Honorable Cathy McMorris Rodger  
House of Representatives  
Washington, DC 20515

Dear Representative McMorris Rodger:

Thank you for your letter regarding steps taken by the Centers for Medicare & Medicaid Services (CMS) to address information disseminated by certain Medicare Advantage (MA) plans. We appreciate the opportunity to respond to this matter.

In particular, you question the motivation underlying the Agency's actions, including the investigation into Humana. This letter responds by summarizing the three overarching concerns that led CMS to take immediate action and also identifies several statutory and regulatory authorities supporting the action.

First, under the statute and conforming regulations, CMS is required to ensure that communications provided to Medicare beneficiaries are accurate and not confusing or misleading. Second, CMS is required to ensure that plans do not misuse beneficiary information for purposes inconsistent with restrictions they have agreed to in their contract on the use of such information. Third, CMS is required to ensure that Federal funds paid to contracting entities, including MA plans, are not used for impermissible purposes such as lobbying.

With regard to Humana, the communications in question had the potential to be confusing and/or misleading to beneficiaries. The specific mailing of concern included the following statement on the envelope, "Important information about your Medicare Advantage plan--open today!" The statement on the envelope purported to have current plan benefit information, it could be misleading to a beneficiary since the information inside the envelope instead discussed pending health reform legislation. Given that MA and Part D prescription drug plans were soon to begin mailing annual required notices to beneficiaries about specific changes to plan benefits or plan structures for the upcoming year, wholly unrelated to any possible future legislative changes, the timing and content of this messaging was particularly concerning to the Agency. Under section 1851(h)(1) of the Social Security Act (incorporated for Part D under section 1860D-1(b)(vi) plans are required to submit all materials defined as marketing to CMS for review and approval prior to sending them to their Medicare enrollees. The regulations define "marketing materials" to include "any information targeted to Medicare beneficiaries" that, among other things, provides information on plan benefits (42 CFR 422.2260; 423.2260). We are concerned that the particular mailing in question violated these regulations because it purported to provide MA enrollees with "information" about their "Medicare Advantage plan" that suggested that the mailing contained "official" information from the Medicare program about the enrollee's Medicare plan, when this was not the case.

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obtained by virtue of their contracts with CMS only for purposes of administering their plans. CMS is investigating whether plans inappropriately used beneficiary data subject to this limitation in their health care reform outreach efforts.

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Sincerely,

Charlene Frizzera
Acting Administrator
Fax Cover Sheet
Congressman Tom Price
6th District of Georgia
424 Cannon House Office Building
Washington, DC 20515
Phone: (202) 225-4501
Fax: (202) 225-4656

To: Acting Administrator Frizzera

From: Emily Henehan Murry

Comments: Letter to CMS regarding the recent gag order on Medicare Advantage plans and dealing with AARP

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Number of Pages including Cover Sheet: 5
Ms. Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Acting Administrator Frizzera:

We are writing to express our opposition to the recent gag order the Centers for Medicare and Medicaid Services (CMS) has placed on all Medicare Advantage plans relating to factual information about how pending health reform legislation may negatively affect their beneficiaries’ access and coverage. American seniors deserve to know how their coverage would be affected by the plans being promoted by the President and Congress.

CMS’s letter to Humana instituting the gag order stated “CMS is concerned that, among other things, this information is misleading and confusing to beneficiaries...” However, the information presented by Humana to beneficiaries is not misleading; in fact CBO affirmed that millions of seniors could lose benefits or have their premium costs go up, thus limiting access. Humana in its communications to beneficiaries wrote:

"Leading health reform proposals being considered in Washington, D.C., this summer include billions in Medicare Advantage funding cuts, as well as spending reductions to original Medicare and Medicaid. While these programs need to be made more efficient, if the proposed funding cut levels become law, millions of seniors and disabled individuals could lose many of the important benefits and services that make Medicare Advantage health plans so valuable."

We are concerned that CMS is misusing its regulatory powers to influence the debate, and we believe it is not their proper role to limit freedom of speech by silencing companies who have opposing views to the current administration.

Curiously, the lobbying activities of the AARP, which sponsors Medicare Advantage and Medigap plans, and has been vocally supportive of pending health reform legislation, appear to have been overlooked by CMS. AARP stated on its website that it is a “myth” that “health care reform will hurt Medicare,” while it is a “fact” that “none of the health care reform proposals being considered by Congress will cut Medicare benefits or increase your out-of-pocket costs.” We believe this to be inaccurate; however we trust seniors to be able to determine who is providing them with the most trustworthy information. If CMS were to apply the same standards, taking into account CBO’s analysis, AARP’s statement would surely qualify as “misleading and confusing.”
Therefore, we respectfully request that the CMS gag order be rescinded on any communication related to pending health legislation in Congress. Furthermore, we request that CMS release all communications between the Agency and AARP since the beginning of this calendar year.

We appreciate your attention to this issue and look forward to your prompt response.

Yours truly,

[Signatures]

[Signatures]
Please see below the names of the co-signers to the 9/30/09 MA letter.

Michele Bachmann
Rob Bishop
Doug Lamorphn
Lynn Westmoreland
Cynthia Lummis
Mike Pence
John Kline
Virginia Foxx
Henry F. Brown, Jr.
John Fleming
Dan Burton
Rodney Alexander
Pete Olson
John Abney Culberson
Erik Paulsen
Steve Scalise
Zach Wamp
Robert E. Latta
Jerry Moran
Brian Bilbray
Robert Aderholt
Gus M. Bilirakis
Bob Inglis
Joe Wilson
Paul Broun
Mark Souder
Tom Price
Wally Herger
Louie Gohmert
Mike Conaway
Todd Akin
Trent Franks
Jack Kingston
Cathy McMorris Rodgers
Jason Chaffetz
Blaine Luetkemeyer
Dan Lungren
John Shimkus
Joe Pitts
Roscoe Bartlett

Emily Henchman Murry
Professional Staff Member
Republican Study Committee (RSC)
Office of Rep. Tom Price, M.D., Chairman
424 Cannon Building
202-225-4501
The Honorable Tom Price, MD
U.S. House of Representatives
Washington, DC 20515

Dear Senator Price:

Thank you for your letter regarding our proposal to package “skin substitutes” as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

The CY 2014 OPPS proposed rule was issued on July 8, 2013, with a 60-day comment period that closed on September 6, 2013. We appreciate your concerns and are carefully considering the issues raised in this letter, in addition to other public comments we received on proposed changes during the comment period, before making a final policy decision and publishing the final rule. CMS will include its final policies in the CY 2014 OPPS final rule with comment period, along with a summary of the comments received on the proposed rule and our responses. We anticipate issuing a final rule in the near future.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Christina Smith Ritter, Ph.D.
Deputy Director
Hospital and Ambulatory Policy Group
Center for Medicare
The Honorable Phil Gingery, MD  
U.S. House of Representatives  
Washington, DC 20515

Dear Senator Gingery:

Thank you for your letter regarding our proposal to package “skin substitutes” as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Christina Smith Ritter, Ph.D.  
Deputy Director  
Hospital and Ambulatory Policy Group  
Center for Medicare
NOV 08 2013

The Honorable Phil Roe, MD  
U.S. House of Representatives  
Washington, DC 20515  

Dear Senator Roe:

Thank you for your letter regarding our proposal to package “skin substitutes” as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Christina Smith Ritter, Ph.D.  
Deputy Director  
Hospital and Ambulatory Policy Group  
Center for Medicare
Dear Senator Benishek:

Thank you for your letter regarding our proposal to package "skin substitutes" as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Christina Smith Ritter, Ph.D.
Deputy Director
Hospital and Ambulatory Policy Group
Center for Medicare
The Honorable Andy Harris, MD  
U.S. House of Representatives  
Washington, DC 20515

Dear Senator Harris:

Thank you for your letter regarding our proposal to package "skin substitutes" as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Christina Smith Ritter, Ph.D.
Deputy Director  
Hospital and Ambulatory Policy Group  
Center for Medicare
The Honorable Bill Cassidy, MD  
U.S. House of Representatives  
Washington, DC 20515

Dear Senator Cassidy:

Thank you for your letter regarding our proposal to package “skin substitutes” as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Christina Smith Ritter, Ph.D.  
Deputy Director  
Hospital and Ambulatory Policy Group  
Center for Medicare
The Honorable Renee Ellmers  
U.S. House of Representatives  
Washington, DC 20515

Dear Senator Ellmers:

Thank you for your letter regarding our proposal to package "skin substitutes" as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Christina Smith Ritter, Ph.D.  
Deputy Director  
Hospital and Ambulatory Policy Group  
Center for Medicare
The Honorable Tom Reed  
U.S. House of Representatives  
Washington, DC 20515

Dear Senator Reed:

Thank you for your letter regarding our proposal to package “skin substitutes” as a drug or biological that functions as a supply or device in a surgical procedure in the Calendar Year (CY) 2014 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

The CY 2014 OPPS proposed rule was issued on July 8, 2013, with a 60-day comment period that closed on September 6, 2013. We appreciate your concerns and are carefully considering the issues raised in this letter, in addition to other public comments we received on proposed changes during the comment period, before making a final policy decision and publishing the final rule. CMS will include its final policies in the CY 2014 OPPS final rule with comment period, along with a summary of the comments received on the proposed rule and our responses. We anticipate issuing a final rule in the near future.

I appreciate your interest in this important issue as we work towards our mutual goal of strengthening the Medicare program for all beneficiaries. I will also provide this response to the co-signers of your letter.

Sincerely,

Christina Smith Ritter, Ph.D.  
Deputy Director  
Hospital and Ambulatory Policy Group  
Center for Medicare
Dear Administrator Tavenner:

We are writing this letter to support the Centers for Medicare and Medicaid Services' (CMS) efforts to promote efficiency in the delivery of healthcare services and long-term cost containment by packaging payment for skin substitutes used in advanced wound care in the 2014 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule. As stewards of our taxpaying constituents' dollars, we are committed to ensuring public programs such as Medicare are administered in the most efficient manner. We believe this proposal will reduce waste, extending the solvency of the program.

Under the current system, CMS reimburses skin substitutes on a per square centimeter basis. The use of "size appropriate" skin substitutes should have minimized cost. However, some manufacturers of the products in the skin substitute category have taken advantage of this reimbursement system by offering their products in only one size, which is fifteen to twenty times larger than that needed to cover the average size wound. In the hospital outpatient setting alone, this has resulted in an estimated $75M in wasted product and lost taxpayer dollars in CY2011. In the physician setting, considerable waste also occurs. Your proposal represents an important step in reducing this waste by removing the incentive to use skin substitutes significantly larger than the size needed to care for a Medicare beneficiary's wound.

Other comments from industry stakeholders may propose a payment structure based on how a product is regulated by the Food and Drug Administration (FDA). However, the FDA regulates all of the skin substitutes covered by Medicare in some way. The regulatory pathway that a particular product takes to market should not be relevant for payment. The FDA determines how a product is to be regulated. The pathway taken does not necessarily correlate with clinical effectiveness. For example, some products regulated as tissues have been shown to heal wounds more rapidly and more effectively than other products regulated as devices. Therefore, no product should be exempted from the packaging proposal based on its regulatory status.

We further understand that some stakeholders have expressed concerns that the proposed packaging policy would undermine the provider's ability to treat large and complex wounds. With only one adult bundled price, hospital outpatient centers may opt to use...
less effective products that are offered at a lower price, particularly if the wound is large and difficult to treat. In order to address these concerns, we urge you to create a tiered packaging structure based on wound size that would adequately reimburse providers for the treatment of larger wounds, such as advanced venous leg ulcers.

At this time in history, with continuing financial challenges and an aging population, it is more important than ever to act now to eliminate wasted dollars from our healthcare system, a system that is already overburdened. We support you in your efforts to promote efficiency and cost-containment in the delivery of healthcare services and maximize the effectiveness of taxpayers' contributions to Medicare. As you finalize the CY2014 OPPS rule, we ask that you continue these efforts while also taking into account the need to protect beneficiaries' access to the most appropriate treatment for large and complex wounds. Tiered packaging based on wound size is a more refined approach that will allow for the most effective product to be used on each wound, while significantly reducing waste in the Medicare program.

Due to the substantial and ongoing nature of the wastage that has occurred with certain skin substitutes over the years, it is imperative that you make these proposed payment changes as soon as possible. Thank you for your attention to this important matter.

We look forward to your positive response.

Sincerely,

Tom Price, M.D.
Member of Congress

Phil Gingrey, MD
Member of Congress

Phil Roe, MD
Member of Congress

Dan Benishek, MD
Member of Congress
The Honorable Tom Price, M.D.
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

Thank you for your letter regarding Medicare payment for total knee and total hip replacements under the Physician Fee Schedule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

The CMS is reviewing payment for total and hip and knee replacements under the potentially misvalued code initiative. This initiative was developed in response to concerns raised by Congress, the Medicare Payment Advisory Commission, and other stakeholders. We identified these services as potentially misvalued in our calendar year (CY) 2012 Medicare PFS final rule, along with many other services, because these are high expenditure services that had not been reviewed since CY 2006. Under the potentially misvalued code initiative, CMS reviews recommendations made to us by American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC) as well as recommendations made by other stakeholders when available. For codes being reviewed under the potentially misvalued code process, we typically do not receive AMA RUC recommendations in time for us to fully review them and include our proposals in the proposed rule.

We have adopted a process to consider and, as appropriate, revise values for all codes considered under the potentially misvalued codes initiative. Under that process, we establish values for misvalued codes on an interim basis in the final rule subject to public comment. We consider public comments received on the interim values in the final rule and respond to those comments in the final rule for the following year.

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I appreciate your interest in this important issue as we work toward our mutual goal of strengthening the Medicare program. I will also provide this response to the co-signers of your letter.

Sincerely,

Marilyn Tavenner
The Honorable Randy Neugebauer  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Neugebauer:

Thank you for your letter regarding Medicare payment for total knee and total hip replacements under the Physician Fee Schedule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

The CMS is reviewing payment for total and hip and knee replacements under the potentially misvalued code initiative. This initiative was developed in response to concerns raised by Congress, the Medicare Payment Advisory Commission, and other stakeholders. We identified these services as potentially misvalued in our calendar year (CY) 2012 Medicare PFS final rule, along with many other services, because these are high expenditure services that had not been reviewed since CY 2006. Under the potentially misvalued code initiative, CMS reviews recommendations made to us by American Medical Association/Specialty Society Relative Value Update Committee (AMA RUC) as well as recommendations made by other stakeholders when available. For codes being reviewed under the potentially misvalued code process, we typically do not receive AMA RUC recommendations in time for us to fully review them and include our proposals in the proposed rule.

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Sincerely,

Marilyn Tavenner
The Honorable Marlin Stutzman  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Stutzman:

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Sincerely,

Marilyn Tavenner
The Honorable C.A. Dutch Ruppersberger  
U.S. House of Representatives  
Washington, DC 20515 

Dear Representative Ruppersberger:

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Sincerely,

Marilyn Tavenner
The Honorable Ron Kind  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Kind:

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Sincerely,

Marilyn Tavenner

Marilyn Tavenner
NOV 19 2013

The Honorable Trey Radel
U.S. House of Representatives
Washington, DC 20515

Dear Representative Radel:

Thank you for your letter regarding Medicare payment for total knee and total hip replacements under the Physician Fee Schedule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Marilyn Tavenner
The Honorable Vern Buchanan  
U.S. House of Representatives
Washington, DC 20515

Dear Representative Buchanan:

Thank you for your letter regarding Medicare payment for total knee and total hip replacements under the Physician Fee Schedule. The Centers for Medicare & Medicaid Services (CMS) greatly appreciates your bringing these concerns to our attention.

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Sincerely,

Marilyn Tavenner
Congress of the United States  
Washington, DC 20515

October 15, 2013

Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Tavenner:

We are writing to express our concern about the potential for the Centers for Medicaid & Medicare Services (CMS) to make significant cuts in Medicare reimbursement for total hip and knee replacement procedures in 2014 without adequate public notice and comment opportunity.

We have long believed that CMS policy should be shaped by careful consideration of public comments. We believe doctors who perform these procedures should have an opportunity to examine CMS’s recommendations and underlying data and offer their analysis and comments before any rate changes go into effect. When considering rate changes, it is important to keep in mind that Medicare payments for hip and knee replacement procedures have not kept up with inflation. In real dollars, the payment rate has decreased 20% over the last 10 years.

This issue has far-reaching implications for patient care. Total hip and total knee replacement surgery is highly effective, provides a net economic benefit to society by virtue of eliminating the indirect costs associated with the disability of severe hip and knee arthritis, and transforms the lives of patients so afflicted from dependency and immobility to independence and pain-free activity. If Medicare cuts physician payment for total hip and knee replacement surgery, beneficiary access will be severely limited. Medicare cuts would accelerate and exacerbate the trend of physicians opting out of Medicare or reducing the number of Medicare patients they are able to care for, as was recently reported in the Wall Street Journal. Limiting access of the most vulnerable segment of our society by cuts in Medicare reimbursement for these transformative and cost saving procedures is bad public policy.

CMS should not adopt significant Medicare payment reductions without providing meaningful notice and comment opportunity to doctors and the Medicare beneficiaries they serve. This is especially important for total hip and knee replacement procedures given the number of seniors who need this surgery currently and the increasing number who will need it in the future. Thank you for your consideration in this matter.
Sincerely,

Tom Price, M.D.
Member of Congress

C.A. Dutch Ruppersberger
Member of Congress

Vern Buchanan
Member of Congress

Marlin Stutzman
Member of Congress

Trey Radel
Member of Congress

Randy Neugebauer
Member of Congress

Ron Kind
Member of Congress
<table>
<thead>
<tr>
<th>Created By</th>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latasha Douglas</td>
<td>11/29/2010 05:15:09 PM</td>
<td>To OL for processing. NOTE: Congressman would like to meet before the end of 2010.</td>
</tr>
<tr>
<td>Beverly Massey</td>
<td>11/29/2010 05:42:23 PM</td>
<td>I am assigning this meeting request to Al Chadwick in OL.</td>
</tr>
<tr>
<td>Al Chadwick Zunaira</td>
<td>12/7/2010 4:27:04 PM</td>
<td>Meeting acceptance pending with the Dept.</td>
</tr>
<tr>
<td>Khalid Zunaira</td>
<td>3/2/2011 11:01:49 AM</td>
<td>Per Al Chadwick, Maria Martino in OL attended this meeting with Don Berdwick and Rep. Price on 2/17/11. For any further questions, please contact Maria Martino at 202-690-5512.</td>
</tr>
</tbody>
</table>
Fax Cover Sheet
Congressman Tom Price
6th District of Georgia
424 Cannon House Office Building
Washington, DC 20515
Phone: (202) 225-4501
Fax: (202) 225-4656

To: Dr. Donald Berwick

From: Emily Henehan Murry

Comments: Attn: Al Chadwick

Number of Pages including Cover Sheet: 3
November 29, 2010

Dr. Donald Berwick  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Blvd  
Baltimore, MD 21244

Dear Dr. Berwick:

At the Senate Finance Committee hearing on November 17, 2010 you offered to meet with any Member of Congress who reaches out on an individual level.

In your remarks at the Senate Finance hearing, you stated “I want to have dialogue with you and all the Members of Congress...any request at an individual level to meet with any Member of Congress that’s come my way I have said yes to and done it and I look forward to ongoing dialogue and exchange with this committee and all Members of Congress, it’s my job to do that.”

Thank you for your stated desire for ongoing dialogue and exchange with Congressional committees and any Member of Congress.

As a practicing physician for over two decades, author of a comprehensive health care reform proposal, H.R. 3400, the Empowering Patients First Act, and Chairman of the Republican Study Committee (RSC), I believe that an in-depth discussion with you on your work at the Center for Medicare and Medicaid Services, specifically as it relates to patient-centered quality care, would be beneficial to our work on health care in the 112th Congress.

Many are truly concerned about your statement in June 2009, that “the decision is not whether or not we will ration care – the decision is whether we will ration with our eyes open,” the arguments in your book, Escape Fire, and statement in 2006 that Britain’s National Health Service (NHS) “is not just a national treasure; it is a global treasure.”

It is my desire that we may work together to put patients and doctors, rather than the federal bureaucracy, in charge of their personal health care decisions. I urge you to work with Congress and follow through on the Administration’s promise of an “an unmatched level of transparency, participation and accountability across the entire Administration.”
Please follow up with my senior Health Legislative Assistant, Emily Murry, in my office at 202-225-9286 or emily.murry@mail.house.gov, to schedule a meeting before the end of the year.

Yours truly,

Rep. Tom Price, M.D.
Chairman, U.S. House Republican Study Committee

4 "Steadying the NHS" by Donald Berwick and Sheila Leaithman, BMJ July 29, 2006, p. 235