

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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April 1, 2014

Mr. Jonathan Blum  
Principal Deputy Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Blum:

Thank you for appearing before the Subcommittee on Health on Wednesday, February 26, 2014, to testify at the hearing entitled "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choice for Seniors."

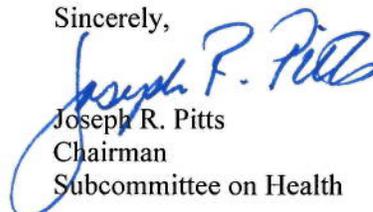
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Tuesday, April 15, 2014. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to [Sydne.Harwick@mail.house.gov](mailto:Sydne.Harwick@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

## Attachment 1—Additional Questions for the Record

### The Honorable Michael C. Burgess

1. In the December 6 draft guidance on Part D and hospice, I also noticed that CMS repeatedly cited the perspective that a beneficiary's need for medications unrelated to their terminal condition will be "extremely rare." As a physician, I can tell you that this perspective does not align with the clinical reality of patients with multiple chronic conditions who are approaching the end of life. Much depends on the timing of the hospice admission and varies on a patient by patient basis. The final months and weeks of life are extremely complex, if anything. Please tell me how CMS is going to ensure that the physician's clinical judgment and the sacred relationship between a physician and patient is going to be preserved once CMS moves forward with a policy rooted in such a problematic assumption.
2. Also related to proposed changes to Part D in the December 6 draft guidance from CMS on the intersection of Part D and hospice, the OIG looked at the programs and found some duplication in billing for drugs related to terminal condition. And while OIG recommended education to the stakeholder community, my read of the draft guidance and related directives from CMS is that there is currently a recoupment effort underway that assumes all analgesics prescribed to a patient on hospice must be related to a patient's terminal illness. Is this correct? CMS is making a blanket clinical determination that if a patient is dying—any pain they are having couldn't possibly pre-date the terminal condition? So, if a septuagenarian who is dying of a condition that rarely presents with pain, such as congestive heart failure (CHF), has also been suffering with a 30 year old back trauma and related surgeries, it is CMS' opinion that the analgesics used to relieve that back pain are related to the terminal diagnosis of CHF?
3. CMS proposes to require Part D sponsors to offer and publicly post standard terms and conditions for network participation that list all combinations of cost sharing and negotiated prices, similar to the way fee schedules work in traditional Medicare. CMS has suggested through the proposed rule that opening up the preferred pharmacy arrangements to all pharmacies would lower overall costs by allowing more pharmacies to participate in the preferred cost sharing reimbursement rate.

However, we understand that basic contracting strategy in the private sector requires that a Part D plan provide incentives to increase the volume of prescriptions and general customer foot traffic expected before a pharmacy agrees to lower costs. This is the experience of pharmacies and plans not only in Medicare Part D, but also in the private insurance marketplace. CMS seems to believe that this is not true. On what economic principles or negotiating experience is CMS basing this belief?

4. CMS has significantly reduced the reimbursement level for some commonly performed procedures, specifically two epidural injections in the neck and lower back (CPT 62310 and 62311). The rule states that reimbursement will be \$42 for a physician for 31 minutes of work, 20 minutes of preoperative and 11 minutes intraoperative time, and nothing for postoperative follow-up. Many physicians are unable to function and provide these services. It will soon affect the patients and these services will be moved into different locations or different procedures will be provided with a much higher expense, or they may even be stopped altogether.

Based on a request from CMS in 2012, the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) surveyed these codes. The AMA stated that the data was inaccurate and recommended NOT to reduce reimbursement for the 2 codes. CMS did not accept

the RUC recommendations with the only stated reason being the reduction from the current work RVU was not comparable to the reduction in time being recommended by the AMA RUC.

- a. Does CMS have any plans to review the new rates it has proposed?
  - b. In light of AMA RUC's recommendations of these two codes, why did CMS choose to move forward against RUC recommendation?
  - c. Has CMS considered the tremendous risk associated with these procedures and the skill required to perform these procedures and the extremely high risk of malpractice suits with poor outcomes?
5. Immunosuppressive therapies are not only highly specialized, but also have widely varied patient tolerance and response. In fact, I know that the toxicity associated with one type of drug is more significant for some patients than for others. And the consequences of formulary changes for these particularly fragile patients can often mean four results: severe pain, rejection of the organ, a return to dialysis, or even death.
- a. Was there a major medical breakthrough or change in the science on immunosuppressive drug treatments since 2005?
  - b. So, why *now* does CMS find it advisable, or in any way acceptable, to allow Part D plans to limit the availability of these medications to specific drugs at the discretion of the insurers?

#### **The Honorable Jim Matheson**

1. The Committee heard a great deal about how important it is for vulnerable patients to have access to needed drugs, and how flawed Medicare policies can inhibit that access. When it comes to medical devices, limited or absent Medicare coverage policies and inadequate payment for medical devices can result in physicians being unable to offer certain new technologies to their patients without navigating a complex and often burdensome administrative process. This is true even when the patient is anxious to obtain the medical device on a self-pay basis. I have worked with Congressman Erik Paulsen to develop legislation, H.R. 3681, the Accelerating Innovation in Medicine Act, that would provide physicians and patients with the opportunity to cut through this red tape in circumstances where the manufacturer of a product has elected to make the device available on a self-pay basis while they undertake the clinical studies in order to obtain Medicare coverage and payment for their medical device. Are you familiar with this proposal, and do you feel it would expand the ability for doctors to offer new technologies to their patients?

#### **The Honorable Tim Murphy**

1. Were any other stakeholders, agencies, professionals, or others consulted when formulating this proposed rule?
2. Who were the Protected Classes Review Panel members and why were they chosen to serve on the panel?
3. Who was the contractor and how did the Review Panel use the contractor's research/information? What other steps and process did the panel undergo in conducting this analysis? Did it just rely solely on the information from the contractor?

4. How specifically will the proposed removal of the protected class status for anti-depressants, immunosuppressants, and anti-psychotics achieve cost-savings for the agency?
5. CMS states that the Medicare appeals process will ensure that beneficiaries have adequate access to medications outside of the protected classes, including antidepressants, immunosuppressants, and antipsychotics. Yet, the CMS appeals process is time consuming and subject to significant delay. On January 3, 2014, the CMS Office of Medicare Hearings and Appeals (OMHA)—the office responsible for the third level of Part D reviews—announced a public meeting to discuss “a growing backlog in the processing of Medicare appeals.” How is an office that already has a significant appeals backlog going to provide beneficiary protection?
6. In the proposed rule, CMS claims that cut-backs in access to medications for vulnerable classes of clinical concern will result in cost savings. It is well-established that money saved by restricting access to medicines in Part D will be overrun by additional costs to Parts A and B through increased non-drug medical spending, in addition to clinical and societal costs that result from not managing serious and chronic conditions effectively through medication. As one example of the strong data contrary to CMS’ position, a November 2012 CBO report on prescription drug savings announced a change to its cost-estimating methodology to reflect evidence showing that increases in prescription drug use by Medicare beneficiaries lead to offsetting reductions in Medicare’s spending for medical services. Looking at the Medicare program as a whole, therefore, and balancing beneficiary access with cost considerations, how and why does CMS think the proposed changes to the six protected classes policy make sense, particularly on the asserted basis of cost considerations?

**The Honorable Gene Green**

1. Serious mental illness continues to pose a significant public health and safety issue in our country. Access to all treatments that have been proven safe and effective for people with mental illness is critical to addressing this challenge. CMS Administrator Marilyn Tavenner stated that “Medicare beneficiaries have access to FDA approved products” in response to a question asked during her Senate Finance Committee confirmation hearing last year. Respectfully, there are indeed FDA-approved treatment options that are not covered by Medicare, and therefore, not accessible to Medicare beneficiaries. How does CMS intend to correct this issue and make approved treatment options, such as medical devices that are approved for the treatment of severe, chronic treatment-resistant depression, available to Medicare beneficiaries (including beneficiaries who are disabled due to their illness)?

**The Honorable Phil Gingrey**

1. The Part D prescription drug program began in January 2006 and by all accounts, has worked well. However, as the Part D Program has evolved, access to pharmacies is now being limited through use of artificial price disparities. The concern is that many of our seniors are being forced to leave pharmacies they have frequented for years. Aside from aggravation, this dynamic has a more problematic impact on seniors in rural areas, who may not have anyone other than an independent pharmacy to fill their prescriptions. My understanding is that most local pharmacies are willing to participate in a manner that would have no additional costs to the Part D program. Does CMS agree with that position and if so, how did you come to that conclusion?
2. In your view, are Part D preferred pharmacy networks decreasing or increasing patient access to pharmacy services?
3. Pharmacy Benefits Managers are claiming credit for the fact that Part D programmatic costs are coming in far below government estimates. Is it CMS’ position that the reduced costs are

primarily attributable to the role played by PBMs? Or are there other factors that have contributed to the reduced cost estimates?

4. With regard to many Part D Plan sponsors and pharmacy relationships, it appears that CMS has conducted a number of internal or blind studies concerning PBM operations. Some of those findings allege inconsistencies in important areas of the program, including PBMs misreporting or gaming contracts, shifting low income cost sharing, etc. According to one study, CMS has observed these practices and found them to have limited market competition, created barriers to entry, and undermined program transparency. Please submit copies of such studies that have been conducted by CMS from 2006 forward.
5. When concluding that the protected classes policy increases costs to Medicare Part D, what analysis did CMS conduct to estimate the offsetting costs to Parts A and B that may result from increased hospitalizations, physician visits, and other interventions when beneficiaries' access to antidepressants or immunosuppressants to prevent rejection of transplanted organs is restricted?
6. MedPAC's staff conducted beneficiary focus groups regarding Part D appeals, the findings of which were discussed at the September 2013 MedPAC meeting. MedPAC staff found that a majority of beneficiaries did not know they had appeal rights. MedPAC staff also found that most beneficiary counselors saw the Part D appeals process as a "last resort" and instead encouraged beneficiaries to switch plans (if low-income subsidy eligible), apply to manufacturers' assistance programs, or ask physicians for samples. Given these findings, how can CMS claim that seniors and disabled people suffering from depression are going to maneuver successfully through this process and win an appeal in 7 days? (All this while the patient is going without his or her prescribed antidepressant during this 7-day period.)

#### **The Honorable Bill Cassidy**

1. If we want to modernize Part D, one thing we should look at is an outdated restriction placed in the law on coverage of obesity therapies. We cover behavioral counseling and gastric bypass surgery, but this key middle ground of care is banned from the program. With next generation products now on the market to combat obesity and with others likely arriving soon, shouldn't we remove this restriction so doctors can prescribe covered obesity therapies to their patients who really need them?

#### **The Honorable H. Morgan Griffith**

1. How does CMS respond to the concerns raised by the FTC in their March 7, 2014 comments on the proposed rule's any willing pharmacy provision for preferred pharmacy networks?
2. In deciding to not move forward with the any willing pharmacy provisions, did CMS make the determination that they did not have the authority to implement these because of the non-interference clause?
3. Does CMS need statutory authority to apply an any willing pharmacy provision within preferred pharmacy networks? If so, what authority is needed?
4. Given the rural and mountainous district that I represent, geography plays a large role in my constituents' lack of access to a preferred network pharmacy. In Southwest Virginia, some seniors have reported travelling upwards of 20 miles to get to a preferred network pharmacy, which might take an hour or more when they have to travel over mountains, especially in adverse weather. For seniors, I feel this is quite a burden, especially when there may be a local pharmacy there in the community where they live. How would CMS recommend narrowly tailoring changes

to preferred pharmacy networks to ensure my constituents and other seniors in rural areas of this country have the same access to low cost drugs through preferred pharmacy networks?

**The Honorable Gus Bilirakis**

1. In December, I sent a letter with my House colleagues about our concerns about CMS' recent guidance related to Medicare Part D hospice care payments. We are concerned that the directive issued on October 30, 2013, to Part D plan sponsors to recoup from hospice providers payments for all pain medication dating back to 2011 is a substantial change in policy and process that goes back to the beginning of the Medicare hospice benefit. Such a significant change should be carefully considered to ensure patient safety and continued access to appropriate care at the end of life. In our letter, we requested that CMS work collaboratively with the Part D and hospice communities and other interested stakeholders on this issue. Please describe what actions CMS plans to take, if any, to work with these stakeholders to ensure any policy change does not impact Medicare hospice patients.
2. In issuing its Part D directive related to hospice care payments, CMS has stated that the existence of unrelated conditions, and therefore, the need for unrelated medications, is "very rare." If this is the case, what is the need for the continued assignment of Part D services once a patient elects hospice care? Why are beneficiaries required to pay premiums to have this coverage if their opportunity to utilize the coverage is "very rare" according to CMS? Has CMS considered suspending the Part D premiums once a patient has elected to invoke the hospice benefit?
3. Has CMS considered the possible unintended consequences to its Part D guidance related to hospice care payments? There is a strong possibility that patients will experience access issues, such as rejections by the pharmacy for medications previously covered by Part D, and will interpret this as a barrier to care associated with the hospice benefit. We have already heard that a number of pharmacies have already been instructed to not bill prescription orders for hospice patients under Part D under any circumstance, secure an alternative source of funding for the medically necessary drugs or deny the prescription order. These access issues are likely to lead to revocation of the hospice benefit and the patient will return to their previous Medicare coverage. With this coverage, they will continue to gain access to all medications through the Part D benefit and will also continue to utilize other Part A covered services such as physician visits, laboratory services, imaging services, emergency room visits, and hospitalizations. It seems counterintuitive to create barriers for access to a proven cost-saving benefit such as the hospice benefit in order to create a relatively small savings generated through the restriction of Part D billing for hospice patients.

## **Attachment 2—Member Requests for the Record**

*During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.*

### **The Honorable Marsha Blackburn**

1. Please cite for me the statute that gives you the opportunity to go in and settle these disputes between the manufacturers and pharmacies.

### **The Honorable Michael C. Burgess**

1. Please provide the Committee with the cost analysis that you did for this rule.
2. In the cost analysis, is there also going to be the delineation of the legal justifications for proposing the rule?
3. Why, after 10 years, did CMS feel it must now reinterpret the non-interference clause? What has changed that propelled you to make this distinction? Please provide the evidence you used to determine this.
4. How do you anticipate how CMS' intervention in these negotiations would improve the program? What is your expectation of improvement?
5. Are you aware of the requirements to keep the proprietary contract terms confidential with the ACA? That is section 3301 of the PPACA. It seems to me that it would be contrary to the policy you are proposing in the Part D proposed rule.
6. Did you, Administrator Tavenner, or Secretary Sebelius receive any legal memoranda that provided you the ability to proceed forward with this rule and the proposed non-interference interpretation? Please provide the memoranda.

### **The Honorable Brett Guthrie**

1. Please provide the full complaint data that you referenced saying seniors do not like their Part D plans.