

Jonathan Blum
"2015 Changes to the Medicare Advantage and the
Medicare Prescription Drug Benefit Programs"
U.S. House Committee on Energy & Commerce, Subcommittee on Health
February 26, 2014

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 In the December 6 draft guidance on Part D and hospice, I also noticed that CMS repeatedly cited the perspective that a beneficiary's need for medications unrelated to their terminal condition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.**

Answer: CMS issued the December 6, 2013 memorandum in order to clarify the criteria for determining payment responsibility under the Part A hospice benefit and Part D for drugs for hospice beneficiaries. We issued this guidance for industry review and comment. The comment period ended on January 6, 2014. As we finalize the December 6 memorandum, we will take into consideration all comments and the various clinical scenarios in order to minimize any barriers to access to prescription drugs at the end of life.

- 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 Also related to proposed changes to Part D in the December 6 draft guidance from CMS on the intersection of Part D and hospice, the OIG looked at the programs and found some duplication in billing for drugs related to terminal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 And while OIG recommended education to the stakeholder community, my read of the draft guidance and related directives from CMS is that there is currently a recoupment effort underway that assumes all analgesics prescribed to a patient on hospice must be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?**

Answer: In 2013, CMS instructed Part D sponsors to delete questionable Prescription Drug Event records identified as duplicate payments for analgesic prescriptions filled within the dates of the beneficiary's Medicare Hospice election during the 2011 and 2012 plan years. This

recoupment effort has been completed. There is no recoupment effort currently underway for duplicate Part D payments for beneficiaries enrolled in hospice. For prescription drugs to be covered under Part D when the enrollee has elected hospice, the drug must be for treatment of a condition that is completely unrelated to the terminal condition(s) or related conditions; in other words, the drug is unrelated to the terminal prognosis of the individual. We expect drugs covered under Part D for hospice beneficiaries will be extremely rare. Therefore, the sponsor should place beneficiary-level Prior Authorization requirements on all drugs for hospice beneficiaries to determine whether the drugs are coverable under Part D. As a general rule, hospice providers are expected to cover virtually *all* drugs for hospice beneficiaries during the hospice election. The hospice provider will be responsible for coordinating with Part D plan sponsors for those drugs they believe are completely unrelated to the terminal illness and/or related conditions to determine payment responsibility. Any drug, including analgesics, may be unrelated to the terminal illness and/or related conditions and, therefore, coverable under Part D. As a result, coverage determinations must be made on a case-by-case basis for each drug.

- 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?

Answer: We have heard a number of comments in response to this proposal. We appreciate your concerns and look forward to reviewing all comments. We will take all views into account when deciding whether and how to finalize this proposal.

- 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?

Answer: These changes in the payment rates for epidural injections in the office setting were made as part of our efforts to improve payment accuracy by reviewing potentially misvalued codes. CMS has adopted a process to consider and, as appropriate, revise values for codes that are considered as part of 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 on the interim final values received in response to the final rule, and respond to those comments in the final rule for the following year. In accordance with this process, we have established interim final values for these epidural injection services in the Calendar Year (CY) 2014 Physician Fee Schedule (PFS) Final Rule with comment period. The comment period on these values closed on January 27, 2014. We will consider public comments in establishing values for the codes in the CY 2015 PFS Final Rule. We intend to address public comments on these and other interim value codes adopted in the CY 2014 PFS Final Rule with comment period in the CY 2015 PFS rulemaking process.

b. In light of AMA RUC's recommendations of these two codes, why did CMS choose to move forward against RUC recommendation?

Answer: In our CY 2012 PFS Final Rule with comment period, we identified epidural injections as a high expenditure service that had not been recently reviewed. We used the survey times submitted by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC), which were based on surveys of a sample of physicians who furnish the service, and recommended practice expense inputs to establish interim final values for the epidural injection code family in the CY 2014 PFS Final Rule with comment period. The interim final revised work and practice expense values established in the CY 2014 PFS Final Rule with comment period reflect the reductions in time required to furnish the service as a result of the surveys submitted with the AMA-RUC-recommended values and the expectation that reductions in the time required to furnish the service reasonably results in reductions to the work and practice expense values associated with the service.

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?

Answer: CMS understands that this change in the physician fee schedule has resulted in CY 2014 payment reductions for the epidural injection services when furnished in the physician office. However, we believe that it is critical to continue to refine Medicare payments to more accurately pay for physicians' services. We assigned values based upon our estimates of the resources used in furnishing the services in the physician office and our usual methodology. We note that the payment rates in 2014 for epidural injections in the physician office setting are interim final values established by CMS. There was a 60-day comment period on these values which closed on January 27, 2014. We will consider and address the public comments we

received, including any comments on the risks and skills associated with these services, in establishing the values for the codes in the PFS rulemaking for CY 2015.

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?**

Answer: In the CY 2015 Parts C and D Notice of Proposed Rulemaking, CMS set out to revise the regulations governing the Parts C and D programs as part of our annual rulemaking cycle. We periodically revise the regulations governing the Parts C and D Programs to implement statutory directives and to incorporate knowledge obtained through experience with each program. This proposed rule included provisions meant to reduce program costs and improve the quality of care for Part C and D enrollees.

We have heard a number of comments in response to this proposal. We appreciate your concerns and look forward to reviewing all comments. We will take all views into account when deciding whether and how to finalize this proposal.

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?

Answer: We are not aware of any provision of current law or policy that would prohibit Medicare beneficiaries from voluntarily purchasing a non-covered medical device on a self-pay basis. We have not fully examined H.R. 3681, but we would be happy to provide technical assistance, upon request, on any legislative proposals addressing this issue.

The Honorable Tim Murphy

1. Were any other stakeholders, agencies, professionals, or others consulted when formulating this proposed rule?

Answer: Yes, CMS consulted with beneficiaries, pharmacies, drug manufacturers, insurers, and other stakeholders in formulating this proposed rule. As the notice and comment period is still open, CMS has heard from only a segment of stakeholders. We will carefully consider the comments from all stakeholders when finalizing this rule.

2. Who were the Protected Classes Review Panel members and why were they chosen to serve on the panel?

Answer: Members of the Protected Classes Review Panel included CMS pharmacists and the Chief Medical Officer for the Center for Medicare. They were chosen for expertise that enabled them to identify which drug categories or classes met the proposed criteria to qualify as a protected class.

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?

Answer: The panel was supported by Fu Associates, Ltd. and by Strategic Health Solutions (SHS). These contractors performed background research and provided specific information on Part D utilization and analyses of widely-accepted treatment guidelines for each drug category or class, when available. Fu Associates, Ltd. analyzed CY 2012 prescription drug event data to provide the following data elements: (1) the number of beneficiaries utilizing a drug within each American Hospital Formulary Service (AHFS)-6 class; (2) the number of beneficiaries utilizing more than one drug within an AHFS-6 class at the same time; and (3) the percentage of beneficiaries that utilized more than one drug at the same time. Strategic Health Solutions analyzed widely accepted treatment guidelines for the disease states treated by the AHFS-6 classes from which beneficiaries most commonly took multiple drugs. For each guideline, SHS determined whether the guideline supported concurrent use of multiple drugs within the class. If multiple drugs were supported, SHS then determined whether failure to obtain access to a drug within the class would result in major or life threatening clinical consequences.

The panel reviewed all Part D drugs that were included on the CY 2013 CMS formulary reference file and that had utilization in CY 2012, using the AHFS-6 classification system. The panel chose the AHFS-6 classification system as a framework because it allows for the grouping of drugs based on similar pharmacologic, therapeutic, and/or chemical characteristics; and,

therefore providing CMS with a tool to logically, and in stepwise fashion, apply the criteria to all Part D drugs.

As the panel reviewed therapeutic classes, the criteria were applied in order. Generally, with the exception of a few classes, if the panel determined that a class did not meet the first criterion, the determination of whether the class met the other criteria was unnecessary. Only if the panel concluded that a therapeutic class met all defined criteria, then the class was deemed as a protected class.

During the panel's review, additional consideration was given to CMS' current formulary review checks (*e.g.*, treatment guidelines review) which are intended to ensure beneficiary access to medically-necessary Part D drugs. The panel considered whether a more specific CMS formulary requirement than requiring all drugs in a class was already implemented or could be implemented to ensure appropriate access to classes of drugs.

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?

Answer: One goal of the proposed removal of the protected class status for anti-depressants, immunosuppressants, and anti-psychotics, is to introduce competition into the market for drugs in these currently protected classes. Because the current protected classes of drugs have guaranteed Part D formulary placement, manufacturers have no incentive to negotiate on price, or obtain price concessions such as manufacturer drug rebates which drives up costs. By removing protected class status for certain classes of drugs, manufacturers would negotiate Part D formulary placement of these drugs, achieving cost-savings for taxpayers. However, CMS is aware that stakeholders have expressed concerns about this proposed policy's potential impact on access to drugs in the current protected classes. We will carefully consider all stakeholder comments when determining whether to finalize this proposal.

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?

Answer to #s 5 and 6: CMS does not believe the proposed change to the protected class policy would adversely impact beneficiary access to needed medications, but we are aware of stakeholders’ concerns about access to needed drugs. Among the current 134 non-protected classes of drugs, we have not observed problems maintaining a broad availability of drugs, including brand-name drugs. If the proposal is finalized, beneficiaries will still be able to receive the medications they need, and we observe that more than 80 percent of drugs in a class are included on formularies on average. Additionally, under current law, if a beneficiary needs a non-formulary drug, CMS has a formulary exceptions process in place that helps ensure beneficiaries can get the drugs they need. It is important to understand that this exceptions process is part of the upfront coverage determination process managed by Part D plan sponsors, and that exception requests need not progress into the appeals process as long as the prescriber provides the case-specific justification as to why the beneficiary cannot use a formulary alternative.

The comment period for this proposed rule is still open, and CMS welcomes stakeholder input. We will carefully consider all stakeholder comments when determining whether to finalize this proposed rule.

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)?**

Answer: We share your commitment to services for persons with serious mental illnesses including beneficiaries who qualify for Medicare by reason of disability. We are also committed to providing timely access to new technology that meets the statutory criteria for coverage under Medicare. The primary avenue for such coverage is through the National Coverage Determination (NCD) process, in which CMS undertakes a comprehensive review all available

clinical and scientific evidence. Any person may request that CMS initiate such a review along with submission of relevant evidence.

While in many cases, Medicare coverage may follow FDA approval of an item or device, the statutory obligations and standards are different for each agency. In particular, Medicare coverage is only authorized for items and services determined to be reasonable and necessary for the diagnosis or treatment of illness or injury in Medicare beneficiaries (or for screening and preventive services under limited circumstances). In some cases, an FDA-approved device may not meet this statutory standard. Any person may request reconsideration of an NCD with submission of appropriate new evidence.

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?**

Answer: We heard from many pharmacies, many of them small independent community pharmacies, that plans do not offer any willing pharmacy the opportunity to offer preferred cost-sharing. Instead, some pharmacies are being offered only the plan's standard terms and conditions, at the highest level of beneficiary cost-sharing. Our analysis of the 2012 claims shows that there is wide variation in discounting across sponsors. Consistent savings are not seen uniformly. In some cases, pharmacies extending high discounts are ones that have been excluded from limited networks offering preferred cost-sharing, while some pharmacies within the limited networks offer effectively no discounts compared to the rest of the network. Given the variation, we will carefully evaluate the comments we receive on this proposal, including any economic analyses, and would re-examine our position if warranted.

- 2. In your view, are Part D preferred pharmacy networks decreasing or increasing patient access to pharmacy services?**

Answer: As the number of plans offering preferred cost-sharing has increased, various parties have drawn our attention toward concerns with these arrangements, particularly regarding beneficiaries' access to the advertised lower cost-sharing in these plans. In order to further analyze this issue, we have awarded a contract to study beneficiary access to preferred cost-sharing. This study will analyze beneficiaries' geographic access (*i.e.*, time and distance) to pharmacies offering preferred cost-sharing in plans' networks. . Based on the results of this study and comments received to date on the draft Call Letter and the proposed rule, we will evaluate

whether we should set standards for network adequacy for pharmacies offering preferred cost-sharing, similar to current standards for retail network adequacy.

- 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?**

Answer: Costs in the Part D program are lower than projected for several reasons, including an increase in generic prescribing, as well as the fact that there are fewer blockbuster medications in the market right now than both the CMS actuary and the CBO projected in 2003.

- 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.**

Answer: CMS has not conducted internal or blind studies on Pharmacy Benefit Manager operations in the timeframe referenced.

- 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?**

Answer: In our evaluation of the protected-classes proposal, we assumed there to be no change beneficiary access to clinically-necessary prescription drugs. Accordingly, we assumed that there would be no impact on the usage of Medicare Part A and Part B services.

- 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.)**

Answer: Current Part D formularies maintain broad availability of the drugs seniors rely on, and we expect they would continue to do so under the proposed changes to the six protected classes.

We have heard that beneficiaries are unaware of their appeal rights. In our experience, beneficiaries typically are not aware of their appeal rights until there is a problem accessing a drug, so it makes sense it is not something all beneficiaries are familiar with in advance. That is why, since 2012, we have required sponsors, through their network pharmacies, to hand our beneficiaries printed instructions on how to use their right to a coverage determination whenever a prescription cannot be filled.

Further, it is important to understand that the exceptions process is part of the upfront coverage determination process managed by the sponsors, and that exception requests need not progress into the appeals process as long as the prescriber provides the case-specific justification as to why the beneficiary cannot use a formulary alternative.

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?**

Answer: The statutory definition of a Part D drug under section 1860D-(2)(e) specifically excludes agents used for weight loss.

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?**

Answer to #s 1 and 2: CMS cannot address any one comment outside the rulemaking process. We will carefully consider all comments as we finalize the rule and follow standard procedures to respond to each comment in that forum.

- 3. Does CMS need statutory authority to apply an any willing pharmacy provision within preferred pharmacy networks? If so, what authority is needed?**

Answer: We believe that an alternative reading of sections 1860D-4(b)(1)(A) and 1860D-4(b)(1)(B) to reduce barriers to pharmacy participation in preferred networks is permissible. However, we will carefully evaluate the comments we receive on this proposal, including any economic analyses, and would re-examine this position if warranted.

- 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?**

Answer: CMS' any willing provider proposal would allow any pharmacy, including community pharmacies, to match the competitive prices offered by preferred pharmacy networks, resulting in more competition, better access to lower-priced drugs for seniors, and the ability for seniors to maintain trusted relationships with community providers.

The proposal would mean that local community pharmacies could participate in a preferred network if they were willing to offer the same prices as their big box store competitors, helping beneficiaries who do not have nearby access to a big box retailer.

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.**

Answer: We agree that CMS should work collaboratively with Part D sponsors and hospice communities to achieve shared policy goals that are consistent with current Federal law. Accordingly, we issued the December 6 memorandum for industry review and comment. During the 35-day comment period, we held discussions with stakeholders to listen to their concerns and respond to their questions. We considered all the stakeholder comments received as we finalized the guidance for 2014 and as we undertake our Medicare Hospice rulemaking for 2015.

- 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?**

Answer: Although we expect it is extremely rare, beneficiaries who have elected hospice may be prescribed a medication for a condition that is completely unrelated to the terminal illness or related conditions. In such instances, we expect that the hospice provider or prescriber will immediately provide, to the Part D sponsor, the written documentation necessary to satisfy the Prior Authorization.

- 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.**

Answer: CMS takes very seriously the care of Medicare beneficiaries who are hospice-eligible. We strongly believe CMS must take steps to ensure hospice providers and Part D plans understand our policies, have an opportunity to comment on proposed policies, and understand how to prevent improper payments for hospice beneficiaries’ drug costs. It is for these reasons we issued the December 6 memorandum for industry review and comment. During the 35-day comment period, we held discussions with stakeholders to listen to their concerns and respond to their questions. We considered all the stakeholder comments received as we finalized the guidance for 2014 and as we undertake our Medicare Hospice rulemaking for 2015.

As we indicated in our recent guidance, for prescription drugs to be covered under Part D when the enrollee has elected hospice, the drug must be for treatment of a condition that is completely unrelated to the terminal condition(s) or related conditions; in other words, the drug is unrelated to the terminal prognosis of the individual. We expect that the use of drugs covered under Part D for hospice beneficiaries will be extremely rare. As a general rule, hospice providers are expected to cover virtually all drugs for hospice beneficiaries during the hospice election. The hospice provider will be responsible for coordinating with Part D plan sponsors for those drugs

they believe are completely unrelated to the terminal illness and/or related conditions to determine payment responsibility.

CMS is considering proposing through rulemaking certain provisions (*e.g.*, using an independent review entity to assist with the prior-authorization process as needed) that we were unable to finalize through sub-regulatory guidance. In the interim, we are taking steps to make the process easy for hospice providers and our beneficiaries so drug access can be maintained at all times. These efforts include: streamlining the Prior Authorization process in order to expedite the most timely access to drugs unrelated to a beneficiary's terminal illness or related conditions; providing the hospice with around-the-clock support through the sponsor's 24-hour pharmacy help desk; and working with the hospice and sponsor community to help facilitate communication.

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.**

Answer: We proposed to interpret the prohibition in section 1860D–11(i)(1) on interference in negotiations to pertain to discussions between prescription drug manufacturers and pharmacies. Therefore, we proposed that CMS may not be a party to discussions between prescription drug manufacturers and pharmacies, and may not arbitrate the meaning of or compliance with the terms and conditions of agreements reached between these parties, except as necessary to enforce CMS requirements applicable to those agreements. We will carefully review the comments we receive on this proposal.

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?**

Answer to #s 1 and 2: The cost analysis of the provisions of the proposed rule is provided in the Regulatory Impact Analysis. The legal justification is in the proposed rule's preamble.

- 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.**

Answer: CMS proposed to interpret the non-interference provision in section 1860D-11 because we are periodically asked to weigh in on initial negotiations, disputes, and renegotiations. We do not believe this is appropriate, nor is it our role, given the statutory requirement not to “interfere” with negotiations between drug manufacturers and pharmacies and PDP sponsors. We will carefully review the comments we receive on this proposal.

- 4. How do you anticipate how CMS’ intervention in these negotiations would improve the program? What is your expectation of improvement?**

Answer: CMS anticipates that interpreting the non-interference provision will provide needed clarity to drug manufacturers, pharmacies, and PDP sponsors on when we will and will not become involved in their negotiations or disputes. We will carefully review the comments we receive on this proposal.

- 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.**

Answer: Section 3301 of the Affordable Care Act concerns the Part D Coverage Gap Discount Program and does not include any requirements to keep contract terms proprietary. As a result, we do not see any conflict between section 3301 and our 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.**

Answer: No.

The Honorable Brett Guthrie

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

Answer: We will work with your staff to provide information on Medicare complaints.