

**Secretary Sebelius Questions for the Record  
House Committee on Ways & Means  
February 28, 2012**

**The Honorable Kenny Marchant**

**1. What is the current status of HHS's review of the waiver for the Texas Women's Health Program?**

**Answer:** As you know, Texas has elected to move forward with a State rule that will restrict freedom of choice of health care providers for women enrolled in the Women's Health Program effective March 14, 2012. Consistent with longstanding statutory provisions that assure free choice of family planning providers, the Demonstration does not provide the State the authority to impose such a limitation, and we advised the State in letters dated December 12, 2011 and March 15, 2012 that such authority would not be granted. In light of the State's preference to move forward in implementing the State rule, the Centers for Medicare & Medicaid Services (CMS) is not in a position to extend or renew the current Demonstration, except for purposes of phasing out the Demonstration.

**2. Please tell me about HHS's main reasoning behind its review for the current Texas waiver request? Is this reasoning consistent with other waiver requests for similar health programs from other states?**

**Answer:** Initially implemented in January 2007, Texas' Women's Health Program 1115 Medicaid Family Planning Demonstration was set to expire on December 31, 2011. CMS granted Texas a temporary extension of the Demonstration until March 31, 2012. As the State has elected to move forward with a State rule that restricts freedom of choice of health care providers for women enrolled in the Women's Health Program, CMS is not in a position to extend or renew the current Demonstration, except for purposes of phasing out the Demonstration.

**3. In the past, hasn't HHS allowed states to make decisions about who can be a qualified provider? Has HHS ever tried to overturn a state law about who can be a qualified provider?**

**Answer:** One of the fundamental aspects of the Medicaid program is the statutory provision at section 1902(a)(23)(A) of the Social Security Act which provides that Medicaid beneficiaries may obtain covered services from any qualified provider willing to undertake the service. Section 1902(a)(23)(B) sets forth additional protections for a beneficiary's free choice of family planning providers. Texas requested approval to limit access to specific providers for reasons not related to their qualifications to provide such services.

**4. Is the waiver being refused because of Texas law that prohibits state money from going to Planned Parenthood?**

**Answer:** CMS was unable to extend or renew the current Demonstration, except for the purposes of phasing out the Demonstration, because the State has elected to move forward with a State rule that will restrict the freedom of choice of health care providers for women enrolled in the Women's Health Program.

## The Honorable Dave Reichert

**1. Lymphedema affects an estimated 1.5 to 3 million Medicare beneficiaries. Individuals often need constant care to avoid recurrent infections. While Medicare does cover and pay for statutorily limited therapy and sequential compression pumps, many patients suffer from recurrent infections, progressive degradation in their condition and eventual disability because they cannot afford the compression bandages and garments required for everyday self-care. I have heard from patients and providers that state compression garments are a necessary form of treatment for patients with Lymphedema. They state compression garments help to improve the quality of life and stave off reoccurring infections for patients. Why does CMS not cover these treatments? Does CMS need a statutory change in order to provide coverage for these garments?**

**Answer:** Currently, Medicare covers durable pneumatic compressors, referred to as lymphedema pumps, and appliances used in conjunction with these pumps under the Part B benefit for durable medical equipment. These equipment and accessories are used to treat lymphedema and are covered because they fall under a defined Medicare benefit category. In order for items to be covered by Medicare, they must meet the definition of a Medicare-covered benefit defined in the statute. However, it is important to note that although Medicare provides coverage for certain items, it does not provide coverage for every item with potential use for a person with a medical problem, even if a physician prescribes the item. Other devices used to treat lymphedema, such as sleeves and stockings, are not covered by Medicare because they do not meet the definition of durable medical equipment or any other Medicare benefit category established by law.

**2. It's my understanding that there is currently no benefit category for coverage of disposable negative pressure wound therapy even though such technology was approved by the FDA in 2009. I understand that this disposable technology can save Medicare money because, unlike the currently covered durable medical equipment which is paid for on a monthly rental basis, it does not require payment for unused medical days. Where is CMS in the process of revising the benefit category so that Medicare beneficiaries have access to disposable negative pressure wound therapy devices?**

**Answer:** In order for items to be covered by Medicare, they must meet the definition of a Medicare-covered benefit. However, it is important to note that although Medicare provides coverage for certain items, it does not provide coverage for every item with potential use for a person with a medical problem, even if a physician prescribes the item. Disposable negative pressure wound therapy devices are not covered by Medicare because they do not meet the definition of durable medical equipment.

## **The Honorable Vern Buchanan**

### **1. Following up on our discussion on the deadly outbreak of prescription drug abuse.**

**In addition to going after "pill mills," is it wise to examine ways to keep people off these addictive prescription drugs from the start?**

**Can you tell me why, with such a focus on limiting the use of narcotic pain killers, that the Centers for Medicare and Medicaid Services (CMS) has initiated a coverage review to possibly limit access to a cost-effective, non-invasive alternative for pain treatment for Medicare patients called TENS or Transcutaneous Electrical Nerve Stimulation?**

**This therapy has been available to Medicare patients for decades and has even been supported by CMS thru a National Coverage Determination in 1995. TENS is available to all federal employees through the government health plans, to Veterans thru the VA and Tricare, and to most Americans thru their private health insurance.**

**Is it wise to be pushing more people toward addictive substances when other options are available?**

**Answer:** CMS recognizes the burden of chronic pain and the importance of supporting pain management strategies that are founded on scientific evidence. Following the publication of a report by the American Academy of Neurology in 2010, which found that TENS was ineffective for chronic lower back pain, we believed it was important to open a national coverage analysis to review the available evidence.

A description of the proposed review was posted on the CMS coverage website on September 13, 2011, as the first step in the national coverage determination process. Public comments were invited on the review proposal for a 30 day period and 359 comments were received. We are continuing to review the comments received and will move forward with the coverage determination process in the future.

## **The Honorable Peter Roskam**

**1. Please confirm that CMS's broad demonstration authority would permit the development and utilization of a physician medical necessity template in some or all areas of the demonstration project?**

**Answer:** CMS has the authority to develop a template for Medicare-funded items or services that comply with all applicable rules, policies, and regulations.

**2. Please confirm that, under CMS's broad demonstration authority, the agency would not need Paperwork Reduction Act (PRA) approval to develop/utilize such a template?**

**Answer:** CMS demonstration authority, Section 402 of the Social Security Amendments of 1967, permits the Secretary to waive only certain requirements from Titles XVIII and XIX of the Social Security Act. The waiver authority does not extend to the Paperwork Reduction Act.

As noted above, CMS does not believe the development of a clinical template is necessary to implement the demonstration. Nevertheless, CMS continues to work collaboratively with its industry partners to explore ways to ensure compliance with existing coverage guidelines including those related to the documentation of the face-to-face encounter.

**3. Is it not accurate that many private payers and Medicaid programs utilize a medical necessity physician template?**

**Answer:** Many private payers and Medicaid programs utilize a medical necessity physician template.

**4. Please confirm that the model template that I have previously sent to your office meets all of the requirements described in CGS's *Dear Physician* letter.**

**Answer:** There is no single diagnosis that confirms the need for a power mobility device (PMD). This makes it difficult to create a standard generalized form to ensure that the beneficiary's clinical condition meets the Medicare requirements. To be covered by Medicare, a beneficiary must require a PMD to complete their activities of daily living in the home. CMS and its contractors have created a series of educational materials to assist physicians with establishing medical necessity when completing the congressionally mandated face-to-face examination. However, forms such as the one previously sent tend to be too general to show a beneficiaries' clinical condition. Medicare policy requires a more detailed narrative assessment that provides a clinical picture of the beneficiary's condition related to mobility needs.

**5. Will CMS include a template in the demonstration program and if not, why not?**

**Answer:** CMS does not believe the development of a clinical template is necessary to implement the demonstration. This demonstration is not introducing new Medicare documentation requirements; instead, it is simply collecting the documentation earlier in the

process. The documentation requirements are outlined in the existing local coverage determination (LCD).

CMS looks forward to continuing to engage stakeholders in exploring ways to clarify existing coverage guidelines, including those related to the documentation of the face-to-face encounter. Any clinical template resulting from these discussions would be available for nationwide use.

## The Honorable Adrian Smith

**1. The President's budget proposes a 17 percent spending increase for the Food and Drug Administration over 2012. However, 98 percent of that increase comes from a new regulatory tax on food producers. Under this proposed registration fee, companies would pay the government merely for existing as a food producer or manufacturer. In Nebraska alone this new tax would hit 1,754 facilities. At USDA, Secretary Vilsack has been discussing for weeks the savings he procured from increased operational efficiencies within USDA. He reduced travel, utilized early retirement programs, and consolidated cell phone contracts. Secretary Vilsack saved approximately \$90 million with these actions. Have you and the leadership at FDA considered any actions like these, as opposed to raising taxes on food makers? Why is a food tax on consumers the only answer?**

**Answer:** I assure you that HHS also has been looking at operational efficiencies and other belt-tightening measures. As part of our cost-saving measures, HHS is implementing the Executive Order on Promoting Efficient Spending to achieve savings related to travel, vehicles, IT, printing, and other costs.

Regarding FDA, the FY 2013 President's Budget includes significant savings related to FDA's information technology (IT) expenditures. The estimate of IT savings for FDA for FY 2013 is \$19.7 million, and the savings will occur in three areas.

First, FDA has been working to consolidate its IT infrastructure into more modern data center facilities. During FY 2013, we will realize \$6.0 million in savings as due to our consolidation efforts.

Second, FDA is launching an initiative to reduce the number of redundant laptops and other IT devices. This effort will produce \$5.1 million in savings.

Finally, other initiatives across all FDA programs will yield an additional \$8.6 million in IT savings. The other initiatives include retiring legacy IT systems, modifying IT business processes, and other forms of IT database savings.

Regarding the proposed registration fee, FDA is still engaging with industry to design a user fee program related to food facilities. We believe that the result of this engagement will be a fee program modeled on other successful user fee programs that Congress enacted for FDA. As FDA intends for the user fee to support food safety activities that provide benefit to the industry paying the fee, it would be considered a "user fee" rather than a "tax."

These fees will allow FDA to reduce the risk of illness associated with food and feed, decrease the frequency and severity of food- and feed-borne illness outbreaks, reduce instances of contamination, and greatly diminish the burden on American businesses and the U.S. economy due to foodborne illness events. Without sufficient and reliable fee revenue, we can expect the unacceptably high human toll of foodborne illness to continue, with the resulting disruptions to the food system and the economic burdens to the food industry that result from foodborne illness outbreaks.

These proposed user fee investments are quite modest compared to the economic value of the nation's food and feed supplies and the costs that the public, industry, government, and the health care system experience during an outbreak. FDA is engaging with the food industry and other food safety stakeholders to develop a workable fee structure that will have broad support within the food industry, other stakeholders, and Congress.

## The Honorable Tom Price

**1. Madam Secretary, I was pleased to see the sections of the recently released 2013 Call Letter pertaining to medication therapy management. The improvements included a greater focus on outreach and education, to ensure Part D beneficiaries are aware of the MTM benefit, as well as an expansion of the number of targeted conditions. I think access to MTM services from local pharmacists is critical to controlling prescription drug expenditures in Medicare Part D, and to keeping seniors healthy. The Call Letter also states that CMS will be conducting an analysis of the Part D MTM program. With respect to that analysis, I understand that the agency has contracted with an outside firm to investigate the benefits of MTM on the current eligible population. Can you help me to understand why we have been told it may take another few years for this study to be available? Under current restrictions, seniors must suffer from "multiple chronic conditions" and be prescribed "multiple medications" before they are eligible for Part D MTM services. This study could be instrumental in helping us to determine how we can best target Medicare beneficiaries who would benefit the most from MTM services. What can we do to speed up to timeframe for study results?**

**Answer::** Thank you for your inquiry regarding the Part D Medication Therapy Management (MTM) and your support for the improvements to the program CMS is instituting for the 2013 plan year. CMS is evaluating the impact of MTM in a chronically ill population through a two year study that began in August 2011. A final report is due at the end of the study, with an interim report due to CMS after the first 14 months.

While I understand your enthusiasm for moving forward expeditiously with this study, this is a very labor intensive study that involves both quantitative and qualitative analyses.

For additional information, I invite you to review the scope of work for the project available at the following address:

[https://www.fbo.gov/?s=opportunity&mode=form&tab=core&id=cffd547191ee03de49aade9b9ed20405&\\_cvview=0](https://www.fbo.gov/?s=opportunity&mode=form&tab=core&id=cffd547191ee03de49aade9b9ed20405&_cvview=0). (Once at this address, click on "SBRAD\_IDIQ\_Sections\_B\_thru\_M.docx." The SOW for the MTM project starts on page 68 of the document.)

**2. Secretary Sebelius, as you know, Congress, first through the Deficit Reduction and later through the Affordable Care Act, changed the way in which pharmacies would be reimbursed for generic drugs in the Medicaid program. Federal Upper Limits are to be calculated using Average Manufacturer Price. The intent of Congress was to more accurately reimburse pharmacies for the cost of generic drugs. It is the role of states however, to adjust dispensing fees to ensure pharmacies are also accurately reimbursed for the cost to dispense prescription drugs to Medicaid patients. Can you tell me what steps you are taking to ensure that states adjust pharmacy dispensing fees before Federal Upper Limits based on Average Manufacturer Price go into effect?**

**Answer:** We agree that pharmacists should be appropriately reimbursed for the cost to dispense prescription drugs to Medicaid patients. Payment for Medicaid covered drugs is dependent on the methodologies set forth in each State's individual Medicaid State plan, and a State can

exercise its flexibility in determining the actual reimbursement for a specific drug. Further, while CMS does not establish specific criteria for States to use when setting their dispensing fees, dispensing fees must be approved by CMS as part of the Medicaid State plan. States are responsible for setting reasonable dispensing fees to appropriately reimburse pharmacy providers for the services they provide in dispensing a prescription to a Medicaid beneficiary.

We have proposed in our recently published notice of proposed rulemaking (NPRM) ("Medicaid Program; Covered Outpatient Drugs" (CMS-2345-P), that once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's professional services and costs.

**3. Secretary Sebelius, Thank you for responding to the December 9, 2011 letter I sent along with 39 bipartisan House Members regarding the U.S. Preventive Service Task Force draft recommendation against prostate-specific-antigen (PSA) based screening. We were concerned that PSA screening, while imperfect, has been enormously helpful in improving men's chance of survival of prostate cancer by more than 40 percent since its widespread adoption.**

**In your response, you stated that "The Department has the discretion to modify or eliminate coverage for the PSA test based on the Task Force recommendation, (but) I do not intend to eliminate coverage of this screening test under Medicare at this time."**

**I would like you to clarify what benefits the statute actually allows the Secretary to "modify or eliminate," as it appears the PSA test is not one of them. The Secretary was granted authority under section 4105 of PPACA to modify or eliminate Medicare coverage of any preventative service as defined in 1861(d)(3) that "has not received a grade of A, B, C, or I by [the] Task Force." However, Section 4105 explicitly states that the Secretary's new authority does not apply to the coverage of diagnostic or treatment services. Because the PSA test is a diagnostic blood test categorized in a separate section of the statute -- 1861 (d)(2)(B) of the Social Security Act -- they are, therefore, outside the scope of the Task Force and Secretary's ability to modify Medicare coverage. How then can you write a letter saying that you have discretion to eliminate or alter coverage of this vital test from our seniors, but just have chosen not to do it at this time?**

**Although HHS has touted its "exemption" to the preventive services mandate as mirroring those of the states, unlike the newly imposed federal mandate, many states do not require coverage for all FDA-approved contraceptives and multiple states have explicitly chosen to reject certain FDA-labeled "contraceptives" from their mandates. For example, Arkansas and North Carolina clearly exclude from their mandates so-called "emergency contraception," while Texas' law excludes "abortifacients or any other drug or device that terminates a pregnancy."**

**Other state laws - including Georgia, Maine, and Rhode Island - clarify that their mandates are not to include abortion-inducing drugs. Keeping in mind that these laws explicitly exclude the abortion drug RU-486 and pre-date the approval of a substantially similar**

**drug, ella, that the FDA has labeled as "contraception," the HHS mandated coverage preempts the principles, if not the letter, of these laws.**

**Was any consideration given by your office to the conflict between the broad new federal contraceptive mandate and the clear, duly enacted exclusions of so-called "emergency contraceptives" and "abortifacient drugs" contained in the laws of these several states?**

**Request that any communication/discussion regarding state exclusions of so-called "emergency contraceptives" and "abortifacient drugs" be disclosed to the Committee.**

**Answer:** We have taken into consideration the input of States, religious organizations, women's groups and others, and comments we received on an amendment to the 2011 Interim Final Rules regarding women's preventive services, and considered before we finalized that amendment, which provides for a religious employer exemption from the contraceptive coverage requirement.

With respect to your comment about Medicare coverage of services that the USPSTF does not recommend, Section 4105 of the Affordable Care Act provides authority to modify or eliminate coverage of certain preventive services that are described in section 1861(ddd)(3). Such "preventive services" include, among other things, "the screening and preventive services described in 1861(ww)(2)," other than an electrocardiogram. Prostate cancer screening tests are included by this cross-reference because those tests are listed in section 1861(ww)(2)(D). While the Department has discretion to modify or eliminate Medicare coverage for the screening PSA test based on the US Preventive Services Task Force's recommendation, I do not intend to propose any changes to coverage of this screening test under Medicare at this time. With respect to private plans, the Affordable Care Act permits plans or issuers to provide coverage for services in addition to those recommended by the Task Force, thereby allowing coverage for PSA screening to continue. As indicated by the Affordable Care Act, the USPSTF recommendations are an important source of information regarding the modification or elimination of coverage for certain preventive services. I expect providers would use these recommendations, as well as other information on best practices, to educate their patients on the clinical appropriateness of any service, test, or course of treatment they recommend as part of an ongoing discussion of each patient's care.

**4. My office continues to have concerns with the reported 50-90% audited error rates being released by CMS' contractors. I am advised that this error rate is a direct result of confusion among physicians as to the proper paperwork needed to properly prescribe PMDs (Power Mobility Devices) on behalf of their patients. In fact, I regularly hear from stakeholders regarding a lack of clarity and consistency associated with the paperwork needed to properly file PMD claims on a beneficiary's behalf. To that end, physicians and physician associations have long recognized the significance of utilizing clinical templates for patient examinations. Likewise, several members of Congress, in an attempt to reduce the error rate, have specifically requested that CMS develop a standard template for doctors to use in prescribing a PMD. Although CMS has agreed to develop such a template, it has yet to be released. When will CMS release the PMD face-to-face evaluation template that physicians can rely on to establish medical necessity and validates that the treating**

**physician conducted the congressionally mandated face-to-face medical evaluation of the patient?**

**Answer:** CMS is in the process of developing an electronic clinical template as part of provider's electronic health records (EHR). An initial draft of the template is available on the CMS website at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/ElectronicClinicalTemplate.html> CMS is actively seeking input on this template and stakeholders can submit comments on the draft to [eclinicaltemplate@cms.hhs.gov](mailto:eclinicaltemplate@cms.hhs.gov). In addition, CMS will host a series of Open Door Forums to allow suppliers to comment and submit feedback on the draft template; the schedule for future ODFs can be found on the CMS website.

## The Honorable Aaron Schock

**1. Madame Secretary, effective January 1st of 2014, the current health law (section 9010) will impose an annual fee on certain health insurance providers, including Medicaid Managed Care plans. This fee, treated as an excise tax under the tax code, will be apportioned among health insurance providers subject to the tax, which will be a set dollar amount for a given year, based on the total amount of "net premiums written" by the provider for the previous year (ex. the tax will be imposed on 2015 for net premiums written in 2014). I am concerned about the effect of this tax on states' Medicaid budgets since Medicaid Managed Care plans collect "premiums" through direct payments from state Medicaid programs instead of through individual beneficiaries. I fear this tax will impact state Medicaid budgets on a dollar for dollar basis since states are required to pay an actuarially sound rate to Medicaid plans. Thus, states who already are struggling under the burden of the current Medicaid Maintenance of Effort (MOE) agreement, will have to use additional state funds to compensate for the federal fees paid by Medicaid plans that area already in financial distress. How does the Department of Health and Human Services plan to account for the increase in Medicaid expenditures solely due to the tax both at the federal and state level without impacting Medicaid beneficiaries' access to care?**

**Answer:** We are currently working with the Treasury Department to analyze the various provisions of section 9010 of the Affordable Care Act on Medicaid managed care plans, including the provision that exempts certain entities that focus on public programs from the fee. The statute specifies that the entity must be a non-profit organization licensed in a State, comply with lobbying provisions under IRS code 501(c)(3), and derive at least 80 percent of its revenue from Medicare, Medicaid, or the Children's Health Insurance Program (CHIP). We are assisting the Treasury Department as they prepare to implement Section 9010.

**2. My office has received many constituent communications opposing the 25% multiple procedure payment reduction to the professional component of certain advanced diagnostic imaging services interpreted by the same physician, on the same patient, during the same session. This reduction, which went into effect on January 1,2012, impacts patients who are often the most challenging, such as trauma patients or ones with possible cancer metastasis. According to a recent study published in the Journal of the American College of Radiology, any efficiencies that may exist in the professional component of advanced diagnostic imaging are in the 3-5% range. Is CMS conducting any statistical or data analysis that justifies the decision to apply a 25% cut on the professional component? As a follow up, does HHS plan to share the specific data set that was used in support of the payment reduction?**

**Answer:** CMS based this policy on a rigorous analysis of the data, which showed that there are efficiencies when physicians take multiple images in the same session. While CMS acknowledged that efficiencies may vary across code pairs, the analysis demonstrated that a 25 percent reduction in the professional component of the payment is reasonable. In fact, the data suggest that the efficiencies may even be higher than 25 percent. This is further supported by the comments the Medicare Payment Advisory Commission (MedPAC) submitted on the CY 2012

Physician Fee Schedule proposed rule, which recommended a reduction of 50 percent in the professional component.

Medicare spending for imaging services paid under the physician fee schedule has grown dramatically in recent years due to an increase in the number and intensity of these services. MedPAC has stated that this volume growth may signal that these services are mispriced.

Further, CMS described the data and methodology it used in the Calendar Year (CY) 2012 Physician Fee Schedule final rule and met with industry representatives to further describe its methodology in December 2011 (subsequent to publication of the final rule).

**3. It has come to my attention that former CMS Administrator, Dr. Donald Berwick, visited two diagnostic imaging facilities in the Midwest in August 2011. During those visits, Dr. Berwick had the opportunity to witness, first-hand the process radiologists undertake when they interpret multiple images from the challenging patients who require multiple tests during the same session, on the same day. According to individuals present, Dr. Berwick admitted that there are virtually no efficiencies within the professional component when a single radiologist interprets multiple images from the same patient, during the same session, on the same day. In light of these conclusions, would it not make sense for CMS to consider rescinding the 25% MPPR on the professional component? Would you be willing to visit a diagnostic imaging facility to see the work of radiologists' first-hand?**

**Answer:** As mentioned above, CMS' payment policy is supported by the data CMS analyzed, as well as MedPAC analyses.

**4. I was pleased to see sections of the 2013 Call Letter included a greater focus on outreach and education to Part D beneficiaries so they are aware of the medication therapy management benefit, as well as the expansion of the number of targeted conditions. I believe access to medication therapy management services from a local pharmacist is critical to controlling prescription drug expenditures while also keeping seniors healthy. The 2013 Call Letter also stated that CMS will be conducting an analysis of the Part D medication therapy management program. It is my understanding that CMS has already contracted with an outside firm in order to investigate the benefits of medication therapy management on the currently eligible population. While I understand the need for a thorough investigation, can you explain why we have been told it will take a few years for this study to be available? Given the current restrictions on Part D medication therapy management services, this study could be instrumental in helping us to determine how we can best target this service for those beneficiaries that would benefit the most. What can we do to speed up the timeframe for the study results?**

**Answer:** Thank you for your inquiry regarding the Part D Medication Therapy Management (MTM) and your support for the improvements to the program CMS is instituting for the 2013 plan year. CMS is evaluating the impact of MTM in a chronically ill population through a two year study that began in August 2011. A final report is due at the end of the study, with an interim report due to CMS after the first 14 months.

While I understand your enthusiasm for moving forward expeditiously with this study, this is a very labor intensive study that involves both quantitative and qualitative analyses.

For additional information, I invite you to review the scope of work for the project available at the following address:

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**5. As you know, Congress revised the formula for how pharmacies are to be reimbursed for generic drugs and multiple source drugs in the Medicaid program in recent years. Under current law, the Average Manufacturer Price (AMP) is used to set the Federal Upper Limits (FULs). Thus, an accurate calculation of both AMP and FULs are dependent on one another. We understand that CMS continues to delay action on a final AMP rule until 2013 as that is the time when providers are expected to comply with the related FULs. Current law requires CMS to implement a smoothing process for the AMP as reimbursements are calculated yet CMS has yet to comply with this statutory requirement. Why has CMS said via the proposed rule that it will not make the AMP a final rule until 2013 when the regulation was published in early 2012? Does CMS plan to publish FUL's as final based on the weighted AMPs before a final regulation has been issued? What impact analysis, if any, has CMS done on pharmacy reimbursement that is based on the most recent FULs?**

**Answer:** Effective October 1, 2010, the Affordable Care Act modified the previous statutory provisions that provide for the establishment of a Federal Upper Limit (FUL) for multiple source drugs. The proposed rule would establish the FUL reimbursement for multiple source drugs at 175 percent of weighted monthly average manufacturer price (AMP) in the aggregate. We believe that this policy will result in adequate reimbursement for pharmacy providers, while achieving savings for the Medicaid program. A recent report from the Government Accountability Office (GAO) showed that the FUL reimbursement level under the Affordable Care Act is 35 percent higher than what pharmacists pay for the drug in the aggregate. We believe that these levels are generally in excess of the actual acquisition cost of the drug, as detailed in the analysis in the proposed rule, and that our findings are consistent with those of the GAO.

Section 2503(d) of the Affordable Care Act specifies that the FUL amendments “shall take effect...without regard to whether or not final regulations to carry out such amendments have been promulgated.” In order to facilitate this change, last fall, CMS began publishing draft FUL files on our Web site for review and comment. These draft FUL prices are based on the most recently reported AMP and AMP unit data. We have stressed that the draft Affordable Care Act FUL methodology and reimbursement files are drafts, and until such time as they are made final, the December 31, 2006 FULs will remain in effect.

CMS published the proposed rule on February 2, 2012, with a 60 day public comment period. Following the comment period, CMS will carefully review and consider all comments before issuing a final rule.

The proposed rule also addresses the smoothing process for the FULs for multiple source drugs. I also note that CMS previously issued sub-regulatory guidance to manufacturers on the AMP smoothing process. This manufacturer release can be found on CMS's Web site at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Program-Releases.html>.

**6. Congress' intent in changing the way pharmacies are reimbursed for generic drugs in the Medicaid program, was to more accurately reimburse pharmacies for the cost of generic drugs. Current law requires Federal Upper Limits (FULs) to be calculated using the Average Manufacture Price (AMP). However, it is the role of the states to adjust their dispensing fees to ensure pharmacies can be accurately reimbursed for the cost of dispensing prescription drugs to Medicaid patients. Can you explain what steps CMS is taking to ensure that states adjust the pharmacy dispensing fees before FULs based on AMP go into effect?**

**Answer:** We agree that pharmacists should be appropriately reimbursed for the cost of dispensing prescription drugs to Medicaid recipients. Payment for Medicaid covered drugs is dependent on the methodologies set forth in each State's Medicaid State plan, and a State can exercise its flexibility in determining the actual reimbursement for a specific drug. Further, while CMS does not establish specific criteria for States to use when setting their dispensing fees, CMS must approve dispensing fees as part of the Medicaid State plan, and States are responsible for setting reasonable dispensing fees to appropriately reimburse pharmacy providers.

CMS proposed in its recently published notice of proposed rulemaking (NPRM) ("Medicaid Program; Covered Outpatient Drugs" (CMS-2345-P), that once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's professional services and costs.

**7. I continue to hear about the concerns and problems being experienced over the marketing of Part D preferred network plans for the 2012 plan year, such as employees of the Senior Health Insurance Information Program who do not inform beneficiaries that they need to go to a specific pharmacy in order to receive a network discount. Additionally, the Medicare Plan Finder tool does not include any obvious information for Medicare beneficiaries to go to a specific pharmacy within their preferred network plan in order to receive a lower-prescription drug co-payment. Is this information true, and if so, why is CMS allowing employees of the Senior Health Insurance Information Program to steer patients to specific plans? Does CMS plan to reform its current policies so that the Medicare Plan Finder provides clear and obvious education, on its front page for example, that will provide beneficiaries with an explanation of preferred network plans and the cost implications of choosing one? Finally, what is the rationale for CMS not requiring a beneficiary to input both a preferred and non-preferred pharmacy network into the Medicare Plan Finder so a senior will be able to see the actual difference in costs?**

**Answer:** The Medicare Plan Finder (MPF) is a valuable tool that allows beneficiaries, as well as the mostly volunteer counselors in the State Health Insurance Assistance Programs (SHIPs), to compare Medicare prescription health and drug plans on the basis of costs, quality and coverage.

Most Part D plans offer one network, with no preference between network and out-of-network pharmacies. Because this information is not applicable to most plans, it would not be useful to most Medicare beneficiaries. However, the MPF does provide information about preferred pharmacies at various points in the tool:

- In MPF, beneficiaries have the opportunity to select a pharmacy in Step 3 of 4: Select Your Pharmacies. Under this step there is a note: “Please select up to two pharmacies. If the beneficiary’s pharmacy isn’t in a plan’s network, the cost they will see is the full price of the drug with no insurance. Note that some plans may charge lower drug prices at preferred pharmacies and higher prices at non-preferred pharmacies.”
- Prior to April 19, 2012, if the beneficiary chose the “I don’t want to add pharmacies now” button, a pop-up box displayed. The pop-up again references that selecting a pharmacy will provide a more accurate estimate of the drug costs. Beginning on April 19, 2012, the beneficiary will be required to select a pharmacy.
- The beneficiary can look at the “Your Plan Details” page under the Drug Costs & Coverage tab for pharmacy information.
- Beneficiaries can review the “What You Pay” section and click onto each pharmacy tab to see the pharmacy type. The pharmacy will be described as Preferred-Network Pharmacy, Network Pharmacy, or Out-of-Network Pharmacy.
- Additionally, under the Pharmacy & Mail Order Information, if a user clicks onto the pharmacy hyperlink, the chart shows the pharmacy name, pharmacy type and if the pharmacy is preferred. Next to the word preferred there is a question mark. If a user clicks onto the question mark, the definition of Preferred Pharmacies is indicated (“If your plan has preferred pharmacies, you may save money by using them. Your prescription drug costs (such as copayment or coinsurance) may be less at a preferred pharmacy because it has agreed with your plan to charge less.”). There are three options that appear under the Preferred heading. A “Yes” displayed under Preferred Column, indicates that the pharmacy is a “Preferred” pharmacy and the beneficiary may save money by using them because it has agreed with the plan to charge less. If there is a “NO” listed, that means it is not a preferred-network pharmacy, rather a network pharmacy. However, “NO” also indicates that there are preferred-network pharmacies available in the plan’s network. If a “Not applicable” displays in the column then the plan does not offer any preferred pharmacies in their network.

As mentioned above, beginning on April 19, 2012, beneficiaries will be required to select a pharmacy when using the MPF. This will assist beneficiaries and counselors in selecting the proper pharmacy and understanding how the price estimate of the Plan Finder is based on that pharmacy. CMS is continuously evaluating the MPF to ensure that beneficiaries, SHIPs, and other users have the most up-to-date and useful information to make the most informed drug plan choices based on their individual needs.

## The Honorable Charles Rangel

**1. I understand that in 2013 available funding for Puerto Rico Medicare Advantage (MA) in Puerto Rico is going to be cut by over \$200 million. With over 70 percent of the Medicare beneficiaries in Puerto Rico being covered under MA, this could have a devastating impact on access to health care, especially services such as dental, vision, rural transportation and subsidized co-payments and deductibles that Medicare Fee for Service does not offer.**

**With the high poverty rate and these potential cuts what can HHS and CMS do to help the people of Puerto Rico for the 2013 MA plan year?**

**Answer:** I understand your concern about Medicare Advantage (MA) payment rates in Puerto Rico. In the fall of 2010, CMS conducted a detailed analysis of Medicare Fee-For-Service (FFS) spending in Puerto Rico. The results of that analysis confirm that Medicare enrollment, cost, and use patterns in Puerto Rico are different than those in the States. More specifically, beneficiaries in Puerto Rico are required to opt into Part B coverage whereas on the mainland, beneficiaries are automatically enrolled in Part B and must opt out to decline it. The result of this enrollment difference is that the proportion of the Medicare population with Part B coverage is lower in Puerto Rico (46 percent) as compared to the mainland (91 percent). Given this differential, and because beneficiaries who enroll in Medicare Advantage are enrolled in both Part A and Part B, we concluded the FFS rate calculation in Puerto Rico should be based exclusively on beneficiaries who are enrolled in both Part A and Part B. This refinement was included in the FFS rates that CMS' Office of the Actuary calculated and was announced in the 2012 Rate Announcement published on April 4, 2011. This change resulted in an increase of 0.4% in the blended benchmark for Puerto Rico in 2012.

We have thoroughly reviewed the methodology used to calculate FFS rates and believe that with the refinements made last year we have achieved the best and most accurate estimate of FFS costs in Puerto Rico. Therefore, for 2013 we are already using the best methodology to calculate FFS rates in Puerto Rico, meaning as MA payments begin to be tied to FFS rates, the island has already benefited from this special and targeted methodology. I appreciate the concerns you have raised regarding Puerto Rico and look forward to working with you in the future to ensure a strong MA program exists on the island.

## The Honorable Earl Blumenauer

**1. Secretary Sebelius, among its many other achievements, the Affordable Care Act provided new options to improve the quality of care for Medicare patients near the end of their lives. Under the Concurrent Care Demonstration authorized under section 3140, Medicare can choose fifteen hospice providers to provide concurrent curative benefits alongside their hospice benefits, a benefit which several private insurers already offer. In designing this demonstration, it is important to ensure that hospice providers be able to participate by allowing payment for curative services to be distinct from reimbursement for hospice services. I look forward to receiving an update from your agency on the design of this demonstration program.**

**Answer:** Thank you for your feedback; we will certainly take into consideration your ideas for payment of curative services when we begin the design phase of this demonstration.

**2. Secretary Sebelius, since 2004, the Government Accountability Office has issued twelve reports documenting Medicare program vulnerabilities for improper payments and fraud. While it is impossible to calculate precisely, the cost of fraud likely runs into the billions of dollars annually. To assist your agency's tremendous efforts to limit fraud and abuse, I have introduced, together with Mr. Gerlach of Pennsylvania and Sens. Kirk and Wyden, legislation providing for a common access card for Medicare beneficiaries. The Medicare Common Access Card Act of 2011, H.R. 2925, establishes a pilot project examining the ability of smart card technology to eliminate fraud and protect beneficiary information. Replacing the paper Medicare card with a smart card that securely stores a Medicare beneficiary's personal information allows beneficiaries and providers to confirm receipt of services at the time services are rendered and helps to prevent fraudulent claims. Please provide your views on how improved transaction security can reduce fraud and abuse within the provision of Medicare services.**

**Answer:** I share your commitment to stopping waste, fraud and abuse in the Medicare program and your interest in learning what technologies can help us achieve this goal. The Affordable Care Act provided the Centers for Medicare & Medicaid Services (CMS) with significant new authorities to enhance its oversight of Medicare, helping shift the focus to fraud prevention by providing new authorities to increase screening of providers and suppliers before they enroll in any of these health programs, implement temporary moratoria on new providers in high risk areas, and establish requirements for compliance programs. These new activities are complemented by the passage of the Small Business Jobs Act of 2010, which required CMS to implement predictive analytics technology, and provided financial resources to do so. CMS is now deploying predictive analytics technology in its Fraud Prevention System (FPS) to review all Medicare FFS claims prior to payment. For the first time, CMS has a real-time view of FFS claims across claim types and the geographic zones of its claims processing contractors. This allows CMS to more easily identify fraudulent providers by detecting patterns and aberrancies.

CMS has begun investigating the potential application of smart card technology to the Medicare program, including the possible benefits in preventing fraud, the costs of implementation, and

whether a successful pilot could be extended to meet the needs of the 50.2 million beneficiaries and 1.5 million providers we serve in 2012.

**The Honorable Richard Neal**

**1. In April of 2009, Congress passed the Genetic Information Non-Discrimination Act of 2008 (GINA). GINA imposes underwriting restrictions on the use of genetic information on health insurers and employers only. In addition, GINA's legislative history reflects clear Congressional intent to track the HIPAA framework, and not to subject long-term care insurers to any of the substantive prohibitions applicable to health insurance.**

**However, in HHS' proposed rule regarding GINA, HHS explicitly extends GINA's prohibition on the use and disclosure of genetic information to long term care insurance and issuers of long term care insurance policies.**

**Secretary Sebelius, GINA is written to exclude long-term care insurance from the restrictions on underwriting using genetic information, and the legislative history in both the Senate and House affirm that congressional intent. This is critical to ensure the viability of the long-term care insurance product. I wrote to you in November of last year to join in the expression of congressional concern that the Department has exceeded its statutory authority by proposing to apply the GINA rule to long-term care insurers. I understand that the Department is getting close to finalizing these regulations. Can you tell me how you plan to address this issue?**

**Answer:** I appreciate your concerns with the Department's proposed rule, which would prohibit long-term care insurers from using genetic information for underwriting purposes. As the final rule to implement the GINA protections has not yet been published, the Department is not in a position to discuss the final policies. However, be assured that in developing the final rule, the Department is carefully considering the views expressed in response to the proposed rule and the potential impact of the proposed rule on the long-term care market.