**Secretary Sebelius Questions for the Record**
**House Energy & Commerce Subcommittee on Health**
**December 11, 2013**

**The Honorable Michael C. Burgess**

1. **On November 27, 2013, CMS published a final rule for CY for physician payments, hospital outpatient and ambulatory surgical center payments. The final rule included a cut to epidural injections: a 36% reduction for physician payment and 58% reduction for procedures performed in an office setting. However hospitals will be reimbursed at $669.90 for the epidural procedure performed in the hospital setting.**

   **Has CMS assessed how the inconsistent payments across settings could affect beneficiary access to epidural injections, especially interventional pain management services?**

   **Answer:** The calendar year (CY) 2014 Physician Fee Schedule Final Rule with comment period continued our implementation of the misvalued code initiative in which certain codes are reviewed to determine if they are appropriately valued. Part of our misvalued code review for that rule resulted in reductions in payment for four epidural injection codes. These reductions are based upon data on the time it takes and the resources used in furnishing the service. In making these reductions, we considered information from the American Medical Association Relative Value Scale Update Committee (RUC). The physician payment when the procedure is furnished in the office was reduced for these services between 35 and 56 percent (compared to payment for the prior year). When furnished in a hospital or an Ambulatory Surgical Center, the physician payment is also reduced but by a lesser amount (17 to 33 percent).

   The higher payment for epidural injections to hospitals is due, in part, to the different statutory basis for each fee schedule and to the different structures of the physician fee schedule and the hospital outpatient prospective payment system (OPPS). For CY 2014, we finalized a significant increase in the number of packaged services in the hospital outpatient settings, including laboratory services and services always performed with a primary procedure such as additional injections furnished in the same session. The OPPS also does not make separate payment for low cost drugs and biologicals. The epidural injection codes are included in hospital outpatient payment groups that experienced an increase in payment as a result of our final packaging policy. Hospitals will receive higher payment for these outpatient injections than they did last year, but will not receive a separate payment for a number of other items and services for which a physician office would receive a separate payment. For instance, some drugs used for these injections are packaged for the OPPS payment to hospitals while physicians would be paid separately for these drugs and for the administration of the epidural injection, and for the office visit.

   We believe the physician payments are appropriate based upon our estimates of the resources used in furnishing the services in the physician office and our usual methodology and thus do not believe these reductions will affect patient access.

2. **Did CMS consider the recommendations in the MedPAC report to Congress in June 2013 entitled, "Medicare and the Health Care Delivery System," in which they advocate for multiple differences across ambulatory surgery center services with hospital outpatient services and the other office-based services with outpatient prospective payment system (OPPS) schedules?**

   **Answer:** There are different statutory frameworks for each payment system and each one is structured differently. CMS is aware of the MedPAC recommendations and believes that implementing the MedPAC June 2013 recommendations would require a statutory change.

**<u>The Honorable Ed Whitfield</u>**

1. **CMS posted the CY2014 final rules for physician payments, hospital outpatient and ambulatory surgical center payments on its website on November 27, 2013, for the new rates to be effective January 1, 2014, a day before Thanksgiving. Included in this final rule was a draconian cut to epidural injections with a 36% reduction for physician payment and 58% reduction for procedures performed in an office setting.**

   **What type of evidence was used to determine these payment rates?**

   **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. We began this initiative in response to concerns raised by Congress, the Medicare Payment Advisory Commission and others. Potentially misvalued codes are reviewed with input from the American Medical Association/Specialty Society Resource-Based Relative Value Scale Update Committee (AMA RUC) and public stakeholders. Each year since 2009, we have identified codes for review by looking for codes with specific attributes, such as those originally valued as inpatient services but that are typically furnished on an outpatient basis, services frequently billed together in one encounter, and high expenditure services that have not been recently reviewed.

   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. The comment period on these values will close on January 27, 2014. We will consider public comments in establishing values for the codes in the Physician Fee Schedule (PFS) Final Rule for CY 2015.

   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 AMA 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.

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 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.

2. **Did CMS look at what impact this proposal would have on patient's access to care?**

   **Answer:** We believe the physician payments are appropriate based upon our estimates of the resources used in furnishing the services in the physician office and our usual methodology and thus do not believe these reductions will affect patient access. We note that the payment rates in 2014 for epidural injections in the physician office setting are interim final values established by CMS. There is a 60-day comment period on these values which will close on January 27, 2014. We will consider and address the public comments we receive, including any comments on patient access to these services, in establishing the final values for the codes in the PFS rulemaking for CY 2015.

**<u>The Honorable Cathy McMorris Rodgers</u>**

1. **The Medicare Advantage program provides health insurance to more than 14 million seniors and individuals with disabilities (28 percent of all Medicare beneficiaries). People chose these policies because of the better service and additional benefits which are provided.**

   **Despite people liking their plans, and despite being told that "If you like your plan, you can keep your plan. No matter what. Period." Obamacare includes more than $200 billion cuts to the Medicare Advantage program, with many of the cuts beginning in 2014. The result of these cuts will eliminate some of the plans that patients like. USA Today reported that there will be 5.3 percent fewer Medicare Advantage Plans for beneficiaries to choose from beginning in 2014.**

   **Will you explain to my constituents, who like their Medicare Advantage plans, why they will not be able to keep them?**

**Answer:** With Medicare Advantage enrollment at an all-time high and costs remaining stable, concerns that recent changes to the MA program would result in lower enrollment and higher costs now appear unfounded. Nationwide, over 15 million Medicare beneficiaries[1] are now enrolled in an MA plan. This is a 30 percent increase in enrollment since 2010, and enrollment is projected to continue increasing.[2] Plan participation continues to be robust with 99.1 percent of beneficiaries having access to an MA plan in their area. The average MA premium in 2014 is projected to increase by only $1.64 from last year, coming to $32.60.[3] At the same time, the average number of plan choices will remain about the same in 2014, and access to supplemental benefits remains stable.[4] Additionally, since passage of the Affordable Care Act, average MA premiums are down by 9.8 percent.[5]

2. **Just days before Thanksgiving, you issued a final rule (CMS-1450F) which reduces Medicare payments under the Home Health Prospective Payment System. As you know, this regulation is to implement a provision in Obamacare—section 3131.**

   **You have previously stated this rule will cause "approximately 40 percent" of all home health agencies nationwide to suffer net losses and face bankruptcy.**

   **In my home state of Washington, it is projected that 34 (of 56, or 61 percent) of home health providers who serve over 24,000 Washington seniors will go bankrupt and 5,581 people will lose their job.**

   **At a time when our nation continues to experience a tenuous economic recovery and the number of homebound seniors continues to increase, will you please provide a justification to my constituents why their access to home healthcare services is being scaled back or eliminated?**

   **Answer:** The rebasing you reference is required under section 1895 of the Social Security Act and we do not have the authority to rescind or delay rebasing once implemented. In the CY 2014 Home Health PPS Final Rule (78 FR 72256), we estimated that approximately 40 percent of home health providers will have negative Medicare margins in CY 2017. We further noted that of the approximately 40 percent of home health providers predicted to have negative Medicare margins, 83 percent already reported negative Medicare margins in 2011. Therefore, the vast majority of home health agencies with estimated negative Medicare margins in CY 2017 had negative Medicare margins before the rebasing efforts finalized in the CY 2014 Home Health PPS Final Rule.

   In its March 2013 Report to Congress,[6] MedPAC stated that during the interim payment system (1997–2000), when payments dropped by about 50 percent in two years, many

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2013-11.html?DLPage=1&DLSort=1&DLSortDir=descending
[2] 2013 Trustees Report pp. 166, 198. http://downloads.cms.gov/files/TR2013.pdf
[3] http://www.hhs.gov/news/press/2013pres/09/20130919b.html
[4] http://www.hhs.gov/news/press/2013pres/09/20130919b.html
[5] http://www.hhs.gov/news/press/2013pres/09/20130919b.html
[6] http://www.medpac.gov/documents/Mar13_EntireReport.pdf

agencies exited the program. However, new agencies entered the program (about 200 new agencies a year) and existing agencies expanded their service areas to enter markets left by exiting agencies. This is due in part to the low capital requirements for home health care services that allow the industry to react rapidly when the supply of agencies changes or contracts. MedPAC reviews found that access to care remained adequate during this period. In addition, since their 2011 Report to Congress, MedPAC has consistently recommended accelerating the rebasing of home health payments by phasing-in these adjustments over 2 years instead of 4 years.

In the economic impact assessment section of the CY 2014 Home Health PPS Final Rule, we estimate that HHAs will experience an overall 1.05 percent decrease in payments in CY 2014. However, we note that estimated payments to providers in the Pacific census region (of which Washington is included) are actually estimated to increase 0.34 percent in CY 2014. While we do not anticipate significant negative impacts of this rule, we note that, under section 3131(a) of the Affordable Care Act, MedPAC will conduct a study on the rebasing implementation, which will include impact analysis on access to care and quality outcomes, and will submit a Report to Congress. CMS is committed to closely monitoring the effects of these payment adjustments on beneficiaries' access and quality of care.

**<u>The Honorable H. Morgan Griffith</u>**

1. **The National Academy of Sciences (NAS) peer review committees, that are examining the Report on Carcinogens (RoC), are expected to release their reports in August-September, 2014. U.S. EPA, in responding to the recommendations in the NAS Formaldehyde Report (2011) for significant reforms to its IRIS assessment process, has increased opportunities for public input into both proposed enhancements and how they should be implemented, including a public stakeholder meeting in September 2012 as well as initiating bimonthly meetings on the IRIS process. These initial efforts are helpful as EPA awaits the formal report on the NAS IRIS Process Review. In responding to any reforms to the RoC program recommended by the NAS committees, will you agree to solicit and consider public comment on your Department's response?**
2. **Will the NTP review the NAS IRIS Process Review Report to consider adoption of the conclusions and recommendations identified by the panel?**
3. **Will you agree to provide regular reports to this committee regarding the implementation of any RoC reforms made in response to the recommendations of the NAS committees?**

**Answer to Qs 1-3:** The Joint Explanatory Statement (JES) for the Consolidated Appropriations Act, FY 2012 instructs the Assistant Secretary of Health "to contract with the National Academy of Sciences (NAS) to conduct a scientific peer review of the 12th Report on Carcinogens (RoC) determinations related to formaldehyde and styrene. Included in the review should be all relevant, peer-reviewed research related to both formaldehyde and styrene." Consistent with the JES, the NAS Statement of Task for the two review committees specifically provides that they are to undertake a scientific peer review of the listings for formaldehyde and styrene in the 12th RoC Notably, following publication of the

12th RoC in June 2011, the Department solicited and considered public comment on proposed revisions to the RoC review process, which were announced on January 11, 2012,[7] and have been implemented for purposes of developing the forthcoming 13th RoC. The changes are intended to enhance transparency and efficiency of the RoC review process, while maintaining critical elements of the existing process including external scientific and public involvement, scientific rigor, and external peer review.

Once released, the National Toxicology Program (NTP) will review the NAS IRIS Process Review Report and would consider any information that may be helpful in further strengthening its RoC review and listing process in the future. Any future changes to the process would likely follow NTP's normal procedures, which include soliciting public comment, gathering input from the NTP Board of Scientific Counselors, and announcing any final changes in the *Federal Register*. Should additional changes be announced in the future, the NTP would be pleased to provide the Committee with an update.

4. **Because this is the very first review of the Report on Carcinogens ever undertaken by the NAS, will you agree to commission additional NAS expert reviews to provide continuing guidance and feedback on the scientific validity of the RoC and other assessments prepared by the National Toxicology Program?**

   **Answer:** The RoC process is designed to include multiple opportunities for input from scientific experts, as well as the public at large. These opportunities include initial and final review by the NTP Board of Scientific Counselors, review by peer review panels selected for expertise on substances under review, interagency review by Federal scientific experts, and review by the NTP Executive Committee. The NTP works hard to ensure that the scientific rigor these experts provide to the review process are weighed against the statutory mandate to publish the RoC every two years and the importance of providing timely health information to the public. By contrast, the current NAS reviews for 2011 styrene and formaldehyde listings requested in the JES for the Consolidated Appropriations Act, FY 2012, are not yet completed and are expected to take 24 months each at an additional cost of $1 million. While we plan to review the committees' reports on styrene and formaldehyde carefully, it is unlikely that NAS review of future RoC listings would be feasible under ordinary circumstances, given their time and expense when weighed against the Department's statutory mandate.

[7] More information on revisions at http://ntp.niehs.nih.gov/go/rocprocess