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September 6, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1600-P: Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory and Other Revisions to Part B for CY 2014

Dear Administrator Tavenner:

The American Society of Hematology (ASH) is pleased to have the opportunity to comment on the proposed changes to the Medicare Physician Fee Schedule for CY 2014. ASH represents approximately 14,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases, including blood cancers such as leukemia, lymphoma and myeloma, and other serious disorders such as anemias, thrombosis and bleeding disorders. ASH members include hematologists and hematologist/oncologists who regularly render services to Medicare beneficiaries

ASH's comments focus on the Society's concerns regarding several provisions in the proposed rule: (1) Use of the Hospital Outpatient Prospective Payment System (OPPS) payment rate as a cap on the practice expense (PE) relative value units (RVUs) of services provided in the office setting; (2) The requirements for complex chronic care management services; and (3) Proposed changes to the Physician Quality Reporting System (PQRS).

Proposal to Use HOPPS Payment Rates to Cap PE for Office-Based Services

Under CMS' proposal, the non-facility practice expense RVUs would be capped if the total non-facility physician fee schedule payment exceeds the OPPS rate plus physician fee schedule payment in the facility setting. This proposal would affect approximately 200 codes, including several chemotherapy codes and a therapeutic phlebotomy code of critical importance to hematologists. **ASH asks that CMS withdraw this proposal in the final rule as it is not an accurate means of evaluating the cost of individual services provided in physician offices.**

The Society's major concerns with the proposal follow:

- In the Society's judgment, the proposal is inconsistent with the intent and purpose of the resource-based system for determining practice expenses under the physician fee schedule. Under the Resource-Based Relative Value Scale, PE values are calculated using solid estimates of the actual direct costs of providing a service including clinical staff time, disposable supplies and equipment costs. To the direct costs, CMS adds a factor for indirect costs based on survey data of the actual indirect costs incurred by the specialties that perform the particular service.

In contrast, the OPPS APC rates are derived from hospital charges. Hospital charges may or may not be based on solid cost studies and there is no consistency in the markup of charges above costs across procedures by hospitals. CMS presented no evidence to support a conclusion that the OPPS APC rates are a more accurate representation of the costs of furnishing an individual procedure code in the office than the RB-RVS in determining practice expense values.

- Not only are APC payments not a reflection of actual costs, they do not reflect an individual procedure code. APC rates represent an average of the "costs" for the various procedures and services grouped under the APC. While the procedures assigned to an APC are supposed to be fairly homogenous from a resource use standpoint, the so-called "2X" rule allows procedures to be grouped into an APC where the costs vary by a factor of two or less. Yet, there are numerous exceptions to the 2X rule for lower volume procedures.

  For example, APC 0438, Level III Drug Administration, has 6 procedures assigned to that APC whose geometric mean costs vary from $46 to $306. The payment rate for APC 0438 is $155.87. It is totally inappropriate to consider the APC rate representing an average for a wide array of codes as the "gold standard" for assessing the reasonableness of the PE of an individual procedure code. The APC rates clearly do not represent a resource based estimate of the costs for performing an individual procedure.

- The volatility of individual APC rates year to year, which often change by 10%-20%, is further evidence that the APC rates are not an appropriate tool to determine whether PE values for an individual procedure code are misvalued. This volatility is evidenced across the entire range of APCs including the APCs of interest to ASH.

  CMS is proposing to use the 2013 APC rates for the cap rather than the 2014 APC rates. This makes little sense to ASH and certainly if OPPS is to be a cap on physician practice expense, it should be based on the most current rate (2014) and APC classification available. In its proposal, four hematology procedures were affected by the OPPS cap proposal (CPT Codes 96405, 96440, 96446, and 99195). The proposed 2014 APC rates for these procedures are being increased by 55 to 64 percent as compared to the 2013 rates. If CMS were to use the 2014 APC rates as a cap, the impact of this policy would have been significantly reduced, if not eliminated.

- The unfairness of the proposed OPPS cap on office based practice expenses is clearly demonstrated by considering its application to Code, 96440, a chemotherapy code. The practice expense RVUs for this code would be reduced by about 77 percent as a result of the cap in 2014. This code is currently assigned to APC 439 with a 2013 rate of $146.21. (The APC rate is actually being increased in 2014 to $201.73 but CMS is using the 2013 rate to determine the cap.)

  There are 10 codes in APC 0439. However, a single service - Code 96365 - represented 90 percent the total volume of claims in this APC and clearly determined the APC rate. (ASH notes that CMS had a total of 4 single claims for code 96440.) Code 96365 is a non-chemotherapy infusion code for which the MPFS payment is only about $75 or about half of the 2013 APC rate. In contrast, Code 96440 has a physician fee schedule rate of $905 or 12 times the rate of Code 96365. Code 96440 has much higher direct cost inputs, including a disposable pleural catheter which has a cost of $329. The cost of this single supply item, (without factoring in any clinical staff time, other supplies, equipment or indirect costs) is more than twice the rate of the proposed APC cap of $146.21.

  To recap, (1) the APC rate is not based on any reliable OPPS cost data for Code 96440 since there were only 4 claims out of a total of more than 1.2 million used in constructing this APC; (2) the APC rate would not even cover the costs for disposable supplies used for Code 96440; and (3) the OPPS rate for this APC is going up by about 50 percent in 2014 but CMS is inexplicably is using 2013 APC rates. For all of these reasons, in

ASH's judgment, there is absolutely no basis for considering the 2013 OPPS rate for APC 0439 to represent a reasonable estimate of the practice expenses incurred for Code 96440.

ASH strongly recommends that OPPS cap proposal not be included in the final rule.

Complex Chronic Care Management Services

ASH appreciates CMS' efforts to recognize the non face-to-face work provided by physicians and their staff in managing the care of complex chronically ill patients. However, the chronic care management services proposed in the rule involve extensive, overly burdensome and proscriptive requirements that will significantly limit a physician's ability to receive payment for these services. Many physicians, including hematologists, who care for complex chronically ill patients will not be able to adjust their practices so as to meet all of the proposed regulatory requirements. **Since this provision does not take effect until January 1, 2015, ASH asks CMS to reconsider this proposal and work with the physician community to develop more reasonable and workable standards for the chronic care management codes.** At a minimum, ASH asks CMS to consider the following:

- Clearly acknowledge that specialists, including hematologists, are eligible to bill for these services in order to remove any ambiguity that it is restricted to primary care physicians.

- Eliminate the requirement that a patient needs to have 2 or more qualifying chronic conditions for this service to be billed. There is no basis for presuming that a severely ill patient with a single complex chronic condition automatically requires less management and coordination of care than a patient with two conditions. As physicians who care for complex chronically ill patients with disorders such as sickle cell disease, leukemia and lymphoma, hematologists recognize that the presence of a single underlying condition can demand a great deal of physician and staff time and effort. ASH asks CMS to recognize alternative criteria for determining whether a patient qualifies for this service.

- Eliminate the requirement that physicians need to employ advance practice nurses or utilize electronic health records to bill for these services. These requirements interfere with the physician's prerogatives and practice and have little, if anything, to do with how effectively a physician manages patients with chronic conditions.

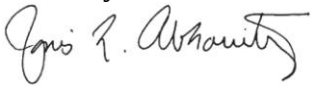
Proposed Changes to PQRS

ASH is supportive of CMS' goals to improve the quality of care provided to Medicare beneficiaries. The PQRS program continues to evolve and ASH wants to assure that Hematologists/Oncologists can participate in the program. ASH is very supportive of CMS' proposal to add a new clinical data registry option to the PQRS program, but is concerned that the requirements set for these registries will make it difficult for most existing registries to participate in 2014. The Society asks that CMS consider phasing in this alternative and allow physicians to participate in PQRS using these registries to, at the very least, avoid penalties in 2014.

ASH also asks CMS to continue to allow physicians to participate in PQRS using claims-based reporting beyond 2017. CMS should not eliminate this option until PQRS participation rates increase significantly.

Thank you for the opportunity to provide these comments. If you have any questions or would like additional information, please contact ASH Government Relations and Practice Manager Stephanie Kaplan at *skaplan@hematology.org* or 202-776-0544.

Sincerely,



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