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August 29, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Attention CMS-1612-P
Mail Stop C4-26-05
7500 Security Blvd
Baltimore MD 21244-1850

Dear Ms. Tavenner:

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule on the *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015 (CMS-1612-P)* as published in the Federal Register on July 11, 2014.

ASH represents more than 15,000 clinicians and scientists worldwide committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma and non-malignant conditions such as sickle cell anemia, thalassemia, aplastic anemia, venous thromboembolism, and hemophilia. In addition, hematologists have been pioneers in the fields of stem cell biology, regenerative medicine, bone marrow transplantation, transfusion medicine, gene therapy, and the development of many drugs for the prevention and treatment of heart attacks and strokes. ASH membership is comprised of basic scientists, physician scientists, and physicians working in diverse settings, including universities, hospitals and private practices.

Using OPPS and ASC rates in Developing PE RVUs

Last year, the Centers for Medicare and Medicaid Services (CMS) proposed to limit the payment for certain services provided in the office setting so that they are not be paid at a higher rate than in the outpatient hospital setting. ASH and other organizations pointed out the many issues with this proposal and CMS did not implement the proposal. While CMS is not revisiting that proposal, CMS is requesting comment on the use of cost data from the hospital system to inform payment rates for the physician office setting. ASH supports the use of hospital cost data as a validation measure rather than a primary data source for setting payment rates. The hospital cost reports are established in a way that does not accurately reflect the costs actually incurred within a physician practice. Costs that may be spread among various departments within a hospital could be more concentrated within a physician practice. However, data gathered from hospitals does have an advantage of being updated on a regular basis and capable of demonstrating changes in resources over time. Since this information would merely be a validation method, ASH believes that direct practice expenses continue to be established through the existing process that identifies the precise inputs within a typical physician practice.

The current method for establishing payment is based on a combination of direct expenses for individual services and indirect expenses established from data from the AMA/Specialty Society Physician Practice Information Survey (PPIS). ASH believes that attempts to repeat this survey will be impossible. The 2007 version of this survey already provided problematic data for specialties with significant practice expense that had started to move into hospital employment.
In an attempt to better gather information on what services are being provided in physician clinics owned by hospitals, CMS has proposed to require a modifier to be appended to all claims submitted in this environment. ASH is supportive of this approach if CMS takes attempts to ensure that data collection is accurate. Previous experience has shown that the use of modifiers or billing codes that do not affect payment has been spotty and inconsistent. If this modifier was to be used in the same fashion, flawed conclusions could be drawn from the data.

Potentially Misvalued Codes under the Physician Fee Schedule

Over the past five years, CMS has used a series of screens to identify services in the physician fee schedule that may be potentially misvalued. These services are then examined in collaboration with the AMA Relative Value Scale Update Committee (RUC) process and often have their payments adjusted. In this year's rule, CMS has proposed to review services that have high utilization and high spending in a particular specialty that have not been examined in the past five years. Of the codes identified by CMS, four are commonly provided by hematologists (96372, 96375, 96401, 96409). All of these services were reviewed for the 2006 payment year as part of a complete review of infusion and drug administration services. ASH believes that the review at that time was thorough and reflected modern RUC practices for both work and practice expense. For this reason the Society requests that these services be removed from the list of potentially misvalued. There has been no considerable change in volume or type of service that would cause one to believe that the service is misvalued. These services all have extremely low work values and stable practice inputs. ASH believes that CMS would be better served examining services in which there has been rapid technological improvement or significant changes in practice.

Chronic Care Management

Hematologists treat patients with acute disease as well as those with chronic needs. A hematologist may be required to manage the ongoing treatment of a patient with a chronic blood disease such as hemophilia or sickle cell disease. In those cases, the hematologist often manages care because the chronic blood disease can provide complications for other medical issues. ASH is very pleased to see the ongoing work associated with chronic care management finally recognized as a billable service within the Medicare system. However, the Society is concerned that the extensive level of work and documentation required are not commensurate with the proposed payment of approximately $42. In order for a physician to bill for this service, he or she must be managing the care of a patient with two or more chronic conditions and the physician and/or the clinical staff must spend at least 20 minutes per month coordinating care. The practice must meet advanced criteria for meaningful use of electronic health records that go well beyond the current requirements. The practice must be able to provide care management services at all times, including at night and on weekends. ASH believes that many practices will provide the majority of these services but decline to bill for care management fearing that their documentation will not support all of the elements. Practices that are providing excellent care management may still go unpaid for their services. ASH encourages CMS to develop a code that recognizes the extensive care management associated with very sick patients that would be paid at a higher rate than this service.

ASH believes that ongoing specialty care requires particular attention as an issue to be addressed in the payment system. To this end, the Society will continue to work with the Center for Medicare and Medicaid Innovation on models that allow for the dispersion of specialty medical knowledge across a wide population that does not necessarily require a patient to travel great distances on a regular basis.

Local Coverage Determination Process for Clinical Diagnostic Laboratory Testing

CMS proposes to change the local coverage determination (LCD) process for laboratory testing so that it more closely resembles the national coverage determination process. ASH is opposed to this change and believes that the local coverage determination process has served Medicare well since inception and should be maintained.

Specifically, CMS proposes to make two important changes. First, CMS proposes to eliminate the requirement for local Contractor Advisory Committee (CAC) to review proposed coverage determinations at an in-person meeting. Instead, CMS proposes that they may not be convened at all. ASH believes that the in-person CAC meeting provides the best forum for honest and robust discussion of the clinical utility of laboratory tests. Merely calling for public comment does not provide the same level of discourse.

Second, CMS calls for a reduction in the public comment period from 45 days to 30 days, noting that this is the standard for national coverage determinations. ASH also opposes this change. Thirty days is a very short time period in which an organization could review a proposal, consider the evidence, and make recommendations for changes. ASH understands the interest in moving this process along as quickly as possible to ensure appropriate access. However, the society is very interested in the rational dispersal of new technology and a coverage process that allows for timely consideration of all evidence and expert opinion.

In the rule, CMS notes the recent pilot experience with molecular diagnostic tests as an example of the effectiveness of this process. ASH has followed this issue extensively as a number of molecular tests contribute to diagnosis of hematologic conditions. ASH believes the molecular diagnostics pilot experience would have been greatly improved had it gone through the typical LCD development process. The Society has had difficulty in tracking the status of determinations and there has not been a discussion among stakeholders that might be similar to the CAC process. ASH encourages CMS to not finalize this proposal and maintain the existing LCD development processes for all services.

Reports of Payments or Other Transfers of Value to Covered Recipients

ASH opposes the proposal to remove the existing reporting exclusion for continuing medical education (CME) activities (§403.904(g)) provided by the five accredited organizations, including Accreditation Council for Continuing Medical Education (ACCME), American Academy of Family Physicians, American Dental Association's Continuing Education Recognition Program, American Medical Association, and American Osteopathic Association. ASH does not believe that §403.904(i) alone sufficiently covers CMS' concerns over independence and separation of commercial support from educational activities.

ASH strongly supports that CMS keep intact §403.904(g) and continue to clearly exempt funding of CME programs provided by organizations accredited by the groups noted above. These organizations all follow strict standards for commercial support (SCS) that have effective principles and processes to eliminate bias and require reporting to ensure transparency. Accredited CME is transparent because commercial supporters need to be identified and conflicts of interest managed and disclosed. There is a clear separation between the individual physician and the commercial supporter, and definitive requirements are mandated for the accredited providers assuring non-control by commercial entities, the elimination of bias, and transparency in relationships. ASH programs follow the ACCME SCS, which include requirements on: Independence; Resolution of Personal Conflicts of Interest; Appropriate Use of Commercial Support; Appropriate Management of Associated Commercial Promotion; Content and Format without Commercial Bias; and Disclosures Relevant to Potential Commercial Bias.

ASH strongly supports CMS' role in recognizing and approving accrediting organizations that utilize rigorous standards for CME. The Qualified Clinical Data Registry Data Submission Criteria (QCDR) is one example where CMS has taken a rigorous, standardized approach in recognizing Qualified Clinical Data Registries under the Physician Quality Reporting System. The Agency developed set standards for a CMS-approved entity that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. ASH encourages CMS to utilize a similar

model to recognize CME accrediting bodies that adhere to the SCS. The American Nurses Credentialing Center and Accreditation Council for Pharmacy Education also follow these same rigorous standards and ASH recommends that these organizations be considered exempt under this provision.

In the rule, CMS has proposed that the elimination of §403.904(g) is justified by referring to the timing of a transfer of value, be it indirect or direct. ASH does not support CMS' justification for the following reasons:

First, CME programs are planned months, and sometimes years, and promoted in advance. Many CME programs are planned and promoted to their intended audiences far enough in advance that attainment of commercial support grants by the CME provider is incomplete. Moreover, as faculty are selected and identified during the activity planning process by the accredited CME provider, their names are promoted in the activity programing to the intended audience. It is not realistic, nor would it be perceived as transparent, if faculty names were hidden until the day of the program, nor would physicians be likely to attend such programs. As a result, over time during the planning process, even if the company does not request faculty names, companies providing commercial support to CME providers could potentially learn the names of the faculty, before the program, and certainly within two quarters after the program, through promotion of the program itself. Therefore, establishing a policy whereby an arbitrary determination of the presence of a relationship is made based on the timing of learning of the faculty names is unworkable – the names of faculty at CME programing cannot and should not be hidden.

Second, CMS has agreed that a grant from a company to an accredited and certified CME provider does not establish a relationship with the faculty, due to the firewall established by strict universal adherence to the SCS by ACCME certified CME providers. Therefore, it is not necessary to eliminate the Standards in the rule, which would eliminate the firewall, and replace it with an arbitrary and unworkable timing proxy.

Lastly, the same can be said for attendees. While attendees might not be identified in advance of a CME program, they are certainly identifiable during and after the program. However, CMS has always recognized that attendees have no relationship with companies which might choose to provide grants of commercial support to CME providers for accredited and certified CME. Therefore, it is not necessary to establish an arbitrary timing proxy for attendees. Attending accredited and certified CME does not establish a relationship with any supporting companies. Reporting names of attendees at CME meetings would not further the goals of the Sunshine Act but instead would obscure reports of the financial relationships with volumes of information about meeting attendees.

ASH asks that CMS maintain a clear exemption of CME programs from open payments reporting. In addition to ASH's comments about the Reports of Payments or Other Transfers of Value to Covered Recipients in the proposed rule, the Society also supports the recommendations outlined in the American Medical Association's letter submitted on August 5, 2014, the Council of Medical Specialty Societies' letter submitted on August 19, 2014, and the ACCME letter submitted on August 21, 2014.

Physician Compare

CMS proposes to continue to expand the public reporting of quality measures on the Physician Compare site so that by 2016, all measures reported through the Physician Quality Reporting System (PQRS) would be eligible to be included on the Physician Compare site. ASH is supportive of public reporting of quality measures. The organization is similarly supportive of the CMS proposal to evaluate all measures to ensure they are valid, reliable, and are understandable to patients. ASH also supports the opportunity to link quality data that comes from specialty societies into the Physician Compare website.

Physician Quality Reporting System

ASH supports the opportunity for physicians to participate in the Physician Quality Reporting Systeem (PQRS) system using the Qualified Clinical Data Registry (QCDR) option that was created through the passage of the American Taxpayer Relief Act of 2013 (ATRA). This option allows registries to report on measures that are not included on the list of PQRS measures approved by CMS. This opportunity expands the reach of PQRS and would allow certain specialists to participate who would not otherwise have appropriate measures. Many hematologists specialize in one particular disease and could have trouble reporting even on the four measures developed by ASH. The society is troubled by the proposal to increase the burden of participating in PQRS through the QCDR method without even a year of experience.

Notably, CMS proposes to require QCDRs to submit three outcome measures or two outcome measures and one resource use, efficiency, or patient experience measure. The goal of moving to outcome measures is laudable but ASH recommends that CMS evaluate the experience with the first year of QCDR before making this kind of change.

ASH supports the CMS proposal to increase the number of measures that could be reported by the QCDR from 20 to 30. The increased number of measures could allow a QCDR to better serve a population like hematologists by providing measures for all different subspecialties of the discipline.

For the traditional registry option, CMS has proposed a change to require that participants report on at least two cross-cutting measures as part of the required nine measures covering three domains of the National Quality Strategy, as long as the physician has provided at least one face-to-face encounter. ASH believes that this requirement is appropriate for hematologists as there are a number of cross-cutting measures that could be used by hematologists who are treating issues such as blood pressure on their patients with hematologic disease. ASH would not support a move towards exclusive use of these cross-cutting measures because the society believes that the more specialty specific measures also provide valuable information in differentiating specialists on the quality of care provided.

Proposed elimination of claims option for hematology measures

CMS has proposed to eliminate the claims-based reporting option for the measures developed by ASH in collaboration with the American Medical Association (AMA) Physician Consortium for Performance Improvement (PCPI). These measures are PQRS measures 67, 68, 69, and 70, focusing on myelodysplatic syndrome, multiple myeloma, and chronic lymphocytic leukemia. ASH is opposed to the elimination of the claims-based option for these measures at this time. While the Society understands the desire of CMS to eliminate the claims option in the future, ASH recommends that the claims option be retained in 2015. Despite the flaws, the majority of reporters in PQRS still use the claims-based option. For many physicians, this is their only option that does not involve additional cost and for this reason the claims-reporting option should not be removed for these measures in 2015.

Value- based payment modifier and Physician Feedback program

The Affordable Care Act (ACA) requires that CMS begin to adjust payment for quality and cost of services for all physicians by 2017. In this rule, CMS proposes the final step to implement this program, extending the applicability from those in groups of ten or more to those in groups of two or more or solo providers. ASH has found that the value-based payment modifier is not well-understood by physicians, given the many quality and cost measures that are included as well as the annual changes to the program. However, given the requirements of the statute, ASH does not believe that there is an approach that is superior to what proposed. ASH in particular supports the CMS approach to limit downward adjustment for those groups below ten to only those which do not successfully participate in PQRS. This mirrors the implementation policy for groups of between ten and ninety-nine in 2014 and is an appropriate introduction into the pay-for-performance system. The society encourages CMS to

continue to work with medical societies and other stakeholders to ensure that the payment adjustment is understood by those whom will be affected by it.

ASH supports the CMS proposal to apply the value-based payment modifier for both physicians and non-physicians billing under the physician fee schedule. Excluding professionals such as physician assistants and nurse practitioners in the payment adjustment would be confusing and undermine their role in the care of patients within the group setting.

ASH is opposed to the CMS proposal to increase the potential bonus or penalty associated with the value-based payment modifier from two percent to four percent in 2017. ASH believes the program is far too young to double the potential adjustment. 2013 was the first year in which data is to be used for payment adjustment. However, those payment adjustments were limited to those in groups of 100 or more, all of whom had the option to pick whether their payments were adjusted under the value-based payment modifier. Even those groups that have selected to have their payment adjusted have not learned of the size of that payment adjustment. They will only learn of this when quality and resource use reports are released sometime this fall. ASH urges CMS to maintain the adjustment potential to two percent for at least one more year to gain valuable experience.

CMS proposes to alter a hospital readmission measure because of concerns about reliability with low numbers of attributed beneficiaries. ASH supports the CMS proposal to increase the minimum number of attributed beneficiaries for the measure to be included in the value-based payment modifier from 20 to 200. This measure is more appropriate for larger groups or those that focus on hospital-based procedures which would have larger numbers of attributed beneficiaries. The Society appreciates that CMS is taking the time to consider the reliability of these measures and encourages CMS to continue to investigate reliability for all measures, particularly those that are attributed using the claims process rather than directly reported by physicians and other providers.

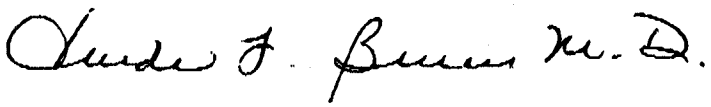
ASH supports the establishment of an informal review process for those groups that believe that their value-based payment modifier was established in error. Given the complexity of establishing the modifier and recent examples of CMS data issues, CMS needs to provide this opportunity. CMS proposes a deadline of January 31, 2015 for those payments adjusted in 2015 to complete the informal review. ASH is not aware of CMS establishing a deadline by which groups will be notified of their scores and payment adjustments on the value-based modifier, other than a fall target date release for quality and resource use reports. The Society believes that groups should have at least 60 days to review their score and access the informal review process. Completing this before the claims year begins would be ideal as it would avoid the hassle of reprocessing claims if an error is identified.

CMS has proposed an adjustment to the attribution model for per-capita measures. This adjustment would maintain the process by which patients are attributed to a group on the basis of primary care visits with primary care providers. If a patient does not see a primary care provider in a given year, the patient could then be attributed to a group on the basis of visits with a specialist such as hematologist. CMS proposes to maintain that standard but begin to include nurse practitioners and physician assistants within the definition of primary care providers. ASH is concerned about the impact of this change on specialty practices and the calculation of the measure. Hematology practices often employ a number of nurse practitioners and physician assistants. Nurse practitioners and physician assistants are not assigned a specialty in Medicare like physicians, so all of them are considered the same. With this change, a patient who is seen twice by a nurse practitioner in a hematology group and once by a family physician would be assigned to the hematology group. If another patient is never seen by a hematology nurse practitioner, but sees a hematologist ten times and a family physician once, that patient would be assigned to the family physician. Without data to review, the Society is unsure how this will change overall scoring within the value-based payment modifier. However, ASH recommends that CMS not finalize this proposal at this time. Instead, the Society recommends that CMS develop a method to identify those nurse practitioners and physician assistants who provide primary care. Those individuals would then appropriately be identified as primary care providers under the first step of cost measure attribution.

CMS also discusses the potential inclusion of Medicare Part D drug data within the per-capita cost measures in the future. ASH encourages CMS to develop methods to include all costs within cost measures. This is particularly important in areas in which some drugs are available as oral drugs under Part D or as physician-administered drugs under Part B. High coinsurance requirements for specialty tier drugs in Medicare Part D plans can make certain oral drugs unaffordable for some patients necessitating the use of physician-administered drugs. In this case, a hematologist group with patients who are unable to afford oral drugs in the specialty may appear as though it has extraordinarily high costs, even if the Part D and Part B drugs have exactly the same cost. CMS discusses difficulties in using Part D data due to many beneficiaries having drug coverage outside of Medicare Part D. If CMS is unable to identify a method to use Part D and other prescription cost data, ASH recommends that physician-administered drugs also be excluded from the cost measure calculation.

ASH appreciates the opportunity to offer these comments and looks forward to working with CMS in the coming year on important issues related to payment for services under the physician fee schedule. If you have any questions about this letter or require further clarification, please contact Brian Whitman, Senior Manager of Policy and Practice at bwhitman@hematology.org or 202 292-0264.

Sincerely,



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