

September 2, 2014

Ms. Marilyn B. Tavenner  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services  
Attention: CMS-1612-P  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: 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 Proposed Rule for CY 2015

Dear Ms. Tavenner:

On behalf of the Endocrine Society (Society), representing more than 16,500 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed revisions to the payment policies under the Medicare physician fee schedule for calendar year 2015. Founded in 1916, the Society represents physicians and scientists engaged in the treatment and research of endocrine disorders, such as osteoporosis, diabetes, hypertension, infertility, obesity, and thyroid disease.

The Society looks forward to working closely with CMS as this proposed rule moves toward implementation and offers the following comments which focus on areas of particular importance to our members:

1. Chronic Care Management Code
2. Improving the Valuation and Coding of the Surgical Global Packages
3. Quality Reporting Programs
4. Physician Quality Reporting System
5. Value-Based Payment Modifier
6. Open Payments Program (Sunshine Act)

**Chronic Care Management Codes**

The Society appreciates CMS' recognition of the need to begin reimbursing physicians for non-face-to-face chronic care management (CCM) services and the revisions CMS made to this proposal in response to comments received during last year's rulemaking process. Many of these revisions will



ultimately help improve outcomes for chronically ill Medicare beneficiaries. Endocrinologists provide care for many Medicare beneficiaries with chronic and complex conditions, like diabetes and thyroid disease, and often take on the role of the primary provider in disease management. We believe that our members and their patients will benefit from the creation of this code.

While we are supportive of CMS' efforts, we have several concerns with the G-code as proposed. The proposed work RVU of 0.61 and practice expense RVU of 0.57, which is approximately \$42 in reimbursement for the service, undervalues the service. We are concerned that the reimbursement level is so low that it will not support the costs of the staffing and technology requirements for the service. The Society is also concerned with the revision to the services in this year's proposed rule, which revised the code to reflect 20 minutes of service provided over a 30 day period. This requirement may prove inefficient and impractical in practice. Patient care coordination needs may vary considerably from month to month. Over a year, the average time spent on non-face-to-face services may be 20 minutes per month. However, it could vary widely from month to month, some months only a 5 minute phone call may be required and other months calls as long as 45 minutes may be required to manage a patient's condition. The requirement of 20 minutes per month will impose an unrealistic expectation that will challenge practices and potentially lead to unnecessary documentation. Documenting short phone calls or other interactions could interrupt the workflow of a practice and potentially disrupt the care delivered to patients. As such, the Society recommends that the reporting period be one year, and that the payment is based on a monthly average of 20 minutes across the year.

To address these concerns, we recommend that CMS adopt the RUC valued CPT code 99490X with a work RVU of 1.0 in place of the proposed G-code. This CPT code was developed based on the guidance CMS provided during last year's rulemaking process. If CMS decides to use the proposed G-code, we recommend that CMS establish a second chronic care G-code that could be billed for more complex patients requiring more time each month.

### **Improving the Valuation and Coding of the Surgical Global Packages**

The Society commends CMS for proposing to evaluate reimbursement for the global surgical packages and its plan to transition all the 10- and 90-day global codes to 0-day global codes. Since these packages have not been updated since 1992, they are overdue for a review. These packages include evaluation and management services that may not be provided to patients during their pre- or post-operative care. Because our members primarily bill evaluation and management services, it is in our interest to ensure that they are being billed appropriately in all circumstances.

While we support CMS' review of these packages, there are many unanswered questions that the Society would like to see addressed before we can comment on how these packages should be revised:

- Should evaluation and management codes be removed from the revised 0-day global packages?
- Should there be separate surgical evaluation and management services?



- Should there be separate evaluation and management codes for cognitive services provided by specialists?

The Society looks forward to working with CMS as these questions are addressed and the global packages are revised.

### **Quality Reporting Programs**

While the Society is aware that CMS must implement the Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VM) and Meaningful Use in accordance with existing statute, we are deeply concerned about the cumulative penalties that physicians could face if they report incorrectly. If a physician were to fail to satisfy the requirements for all these programs, a 9 percent penalty will be applied two calendar years after the close of the reporting period. This is a serious cause for concern because of the amount of the penalty and the time lapse between reporting and the penalty's application.

While we understand that the Agency is taking steps to harmonize these quality reporting programs and provide more frequent feedback, it is critical that physicians receive as close to real time feedback as possible to have sufficient time to correct any deficits and successfully report before the close of the reporting period. The Society urges CMS to provide participating providers with one comprehensive feedback report on a quarterly basis, and ensure that the final report is provided no later than October 1 of the reporting year. This would provide more regular feedback, and also allow those participating to have a more complete picture of where they are succeeding and areas in which they may be subject to penalties.

As the penalties associated with these programs increase, we remain concerned about risk adjustment. We understand that the VM cost measure includes a formula for risk adjustment, but we believe this methodology and any that may be applied to the other quality programs must be consistently evaluated and refined. Endocrinologists treat chronically ill patients, whose outcomes are largely influenced by patient compliance. We remind CMS that risk adjustment must account for geographic location and socioeconomic status as well as the patient's diagnoses and severity of disease. Comparisons of risk should consider variations within specialties to ensure performance is measured appropriately.

### **Physician Quality Reporting System**

CMS has stated that it will remove the measures below from the PQRS measure list in 2015 because the sponsor of the measure will no longer maintain the measure. We encourage CMS to identify a new sponsor or alternative means to maintain the measures.

Hypertension: Diabetes Mellitus Screening

Hypertension: Blood Pressure Control



These measures must be included for endocrinologists to participate in the PQRS program, as endocrinologists lack a robust set of measures that reflect their practice patterns. The two measures above may be the most important and relevant measure sets available to endocrinologists and their removal would severely impair the ability of endocrinologists to participate in physician quality reporting. Furthermore, the Society believes that screening in patients with known risk factors for diabetes is vital to creating a system of care that is grounded in early detection and prevention. The Centers for Disease Control and Prevention (CDC) has estimated that 8.1 million people have undiagnosed diabetes mellitus and that greater than 25 percent of people age 65 and older have diabetes. Screening patients with known risk factors, like hypertension, for diabetes is critical to addressing this gap in care. Hypertension is an extremely common comorbid condition of diabetes, affecting an estimated 20 to 60 percent of diabetes patients.<sup>1</sup> Improving screening and early detection of diabetes or prediabetes can help ensure that patients with either of these conditions can receive necessary treatment, including behavioral management programs.

The Society also encourages CMS to work with the medical community to develop measures for those specialties who may lack a wide breadth of measures related to the work of their specialty. For example, many endocrinologists subspecialize in specific conditions, such as thyroid disease. For these physicians who see very few patients with diabetes, the number of measures from which they have to choose is very small. CMS must continue to work with specialty organizations to identify alternative methods for measure development and testing. Many small organizations lack the resources to undertake the time-intensive and costly process to develop measures specific to their specialty. We commend CMS for the recent changes to their submission process but urge even greater flexibility for those specialties with few measures specific to their work.

The Society does commend CMS for removing the *Diabetes Composite measure: Hemoglobin A1c control (<8 percent)* from the ACO and Group Practice Reporting Option measures lists. As physicians realize the benefits of individualized goals for patients with diabetes, a measure that is based on a specific A1c level is no longer an accurate measure of a physician's ability to provide high quality care for their patients. Any measure related to control of a patient's diabetes must be based on improvements over time.

#### **Value-Based Payment Modifier**

CMS is proposing to complete the phased-in implementation of the VM in 2015 by applying the program to all physicians. We commend CMS for taking a similar approach as in past years by not

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<sup>1</sup> Treatment of Hypertension in Adults With Diabetes. *Diabetes Care*. 2002;25(suppl 1):s71-s73.



putting solo practitioners and groups of 2-10 at risk for a negative adjustment. Given the complexity of the program, we agree with CMS that new participants should receive the same grace period as larger groups received and not face a 4 percent penalty.

However, we are very concerned about the proposed increase in the VM penalty from a maximum of 2 to 4 percent. This 4 percent penalty taken in aggregate with the penalties for the other quality reporting program would likely have a significant impact on all practices, especially the smaller practices. We believe that CMS should delay the increase to 4 percent for at least three years until administrators can further analyze the data from the program's implementation to date to ensure the program is properly designed and implemented

#### **Open Payments Program (Sunshine Act)**

CMS is proposing to revoke the Sunshine Act reporting exclusion for continuing medical education (CME) activities. The proposal would exempt third party transfers for CME only in circumstances where the industry donor is unaware of the recipients before and after the funds are transferred. We believe that this proposal is not only unworkable, but will have a detrimental impact on the Society's continuing education activities and those of other specialty societies. If implemented as outlined in the proposed rule, CME faculty and learners may decide not to engage with accredited CME because they do not want to be reported as receiving a transfer of value. Supporters of CME may cease funding CME activities if the reporting requirements increase. We believe the decrease in CME funding and the increase in reporting requirements would necessitate a reduction of activities offered by CME providers like the Society.

We believe that it will be virtually impossible for industry not to learn the identities of speakers, other faculty and potentially participants after the funds have been transferred as they will likely be able to view brochures, programs, and other publications online or through other media outlets. This will directly impact the Society and ultimately the public whose physicians will not be educated on state of the art medical practices. Without sponsorships, the Society would not be able to provide the CME events that our membership requires to maintain their licensure and certifications and to stay on the cutting edge of our field.

The Society believes that such stringent reporting requirements are unnecessary because, as an Accreditation Council for Continuing Medical Education (ACCME) accredited provider, the Society ensures independence of its activities from the influence of industry through its adherence to the ACCME's Standards for Commercial Support. The standards for commercial support (SCS) are designed to protect the individuals engaging in CME from influence of industry within the educational space. Mandatory reporting of these individuals to industry undermines the sanctity of that educational space, allowing industry to potentially influence physicians based on what the companies learn through the learners' engagement in education.

We urge CMS to maintain the existing clear exemption of CME under the open payments program. If CMS feels that some action must be taken with respect to CME, we recommend that the proposal



be revised so that the exemption will still apply when the industry sponsor is unaware of the CME faculty and learners prior to committing to fund the activity.

The Society is also concerned about CMS' interpretation of the statute as it relates to exclusions of “[e]ducational materials that directly benefit patients or are intended for patient use.” In its interpretation, CMS concluded that medical textbooks, reprints of peer reviewed scientific clinical journal articles and abstracts of these articles are “not directly beneficial to patients, nor are they intended for patient use.” We believe this conclusion is inconsistent with the Congressional intent of the original statutory language, and urge CMS to exclude these sources from the reporting requirements.

When presented with an unfamiliar or new medical situation, a clinician will often consult a medical textbook or journal reprint at the point of care delivery, which immediately and directly assists the clinician in diagnosing and treating the patient in real-time. For instance, a physician may consult a text book or reprint for the most recently identified diagnostic procedures and treatment of a disease.

Physicians rely on scientific peer-reviewed journal reprints, supplements, and medical text books to stay informed about the latest medical knowledge to provide better care to their patients. CMS' interpretation of the statute creates a disincentive for clinicians to accept high quality, independent educational materials.

The Society appreciates the opportunity to provide comments to CMS on the 2015 Medicare Physician Fee Schedule proposed rule and appreciates the hard work that went into drafting it. Please do not hesitate to contact Meredith Dyer, Associate Director, Health Policy, at [mdyer@endocrine.org](mailto:mdyer@endocrine.org), if we may provide any additional information or assistance as CMS moves forward in developing this rule.

Sincerely,

Jason Wexler, MD  
Chair, Clinical Affairs Core Committee  
Endocrine Society

