September 2, 2014

Marilyn B. Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
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 for CY 2015 [CMS-1612-P]

Dear Administrator Tavenner:

On behalf of the 24,000 physician, resident and medical student members of the Massachusetts Medical Society (MMS) I appreciate the opportunity to offer comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Proposed Rule entitled 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]. We believe this proposed rule has very important implications for physicians, patients and our healthcare delivery system.

The MMS urges CMS to carefully consider the extensive and detailed recommendations submitted by the American Medical Association several of which are highlighted below. Our specific comments focus on proposed changes to the regulations implementing the Sunshine Act, Section XIV.

I. Resource-Based Practice Expense (PD) Relative Value Units:

   A Practice Expense Relative Value Methodology

The MMS joins with the AMA in supporting the increased percentage of direct costs that will be calculated as part of the physician fee schedule but urge CMS to revise its payment methodology to pay the actual direct practice expense costs for a service. Obtaining accurate data to pay physicians for the
real and direct costs of their services has been a longstanding concern of both the AMA and MMS.

C Off Campus Provider-Based outpatient Departments

In order to understand trends in hospital acquisitions of physician practices, CMS proposes to create a HCPCS modifier to be reported with every code for physician and hospital services furnished in an off-campus provider-based department of a hospital. The modifier would be reported on both the CMS-1500 claim form for physicians’ services and the UB-04 (CMS form 1450) for hospital outpatient claims.

We have serious concerns about the administrative burden that this proposal would impose on physician practices, and strongly urge CMS to rescind this proposal and instead engage with stakeholders to develop alternative methodologies for understanding trends in hospital acquisitions of physician practices.

*II. Potentially Misvalued Services under the Physician Fee Schedule

The majority of this section deals with extensive changes to the valuation and coding of the global service package. The MMS supports increasing the accuracy of physician payment and supports efforts to develop methods to more accurately measure and pay physicians for the services they provide. We share the concerns detailed in the AMA comments that the proposed rule would not accurately account for physician work, practice expenses, and the malpractice risk for services performed under the current surgical global period. We also share their concern that the proposed changes could adversely impact Medicare beneficiary’s access to care. At a minimum, unbundling these services would require an additional co-payment for follow up visits, which fixed income Medicare beneficiaries, may prefer to avoid.

V. Valuing New, Revised and Potentially Misvalued Codes

We support the AMA recommendation that the timeline for reviewing potentially misvalued codes should be better aligned with the regulatory process but strongly urge CMS to begin implementing the new timeline and procedures for the CPT 2017 cycle and the 2017 Medicare Physician Payment Schedule. As their comments detail making these changes sooner would be difficult to implement and disruptive to physician practices. We also urge CMS to adopt the AMA proposal for modifications in CPT/RUC workflow to accommodate publication in the Proposed Rule, while ensuring that new technology may be described and valued in an efficient and timely manner. We further recommend that CMS consider these issues and create a fair, objective, and consistently applied appeals process that would be open to any commenting organization.

*XIV. Reports of Payments or other Transfers of Value to Covered Recipients

CMS should retain the CME exemption
Marilyn B. Tavenner  
September 2, 2014  
Page 3

The MMS joins with the number of groups in the medical and health care community opposing the provisions in the proposed rule to eliminate the CME exemption for programs provided by accredited and certified CME organizations. We believe the proposed rule will significantly impede physician’s ability to both present at and participate in necessary continuing education programs. This clearly was not the intent of the Sunshine Act.

In lieu of the exemption for certified CME programs, the proposed rule creates a new awareness standard for indirect payments that allows exemptions through third party transfers only where an industry donor is unaware of the recipients/beneficiaries before and up to 18 months after the funds are transferred. The MMS joined with the AMA and other state and national medical specialty groups in writing to the Secretary to oppose this standard which we believe is unworkable and would in effect make all CME programs reportable. As the letter states “Our organizations believe that this raises concerns as industry could learn the identities of speakers/faculty and potential participates after the funds have been transferred through brochures, programs and other publications” as well as other means. We agree with the comments submitted by the Council of Medical Specialties which state that “as faculty are selected and identified during the planning process by an accredited CME provider, their names are promoted in the activity programming to the intended audience. It is not realistic nor would it be perceived as transparent if faculty names were withheld until the day of the conference. “ Their letter goes on to state “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 in accredited and certified CME to the ACCME SCS. Therefore, it is not necessary to undermine the recognition of the protection of the faculty by eliminating from the rule mention of the Standards which create the firewall, and replacing them with an arbitrary and unworkable proxy.” This same principle applies to conference attendees.

The MMS urges CMS to retain the original provisions in the final rule which exempt CME activities by providers of certified and accredited CME who strictly adhere to the firewalls established by the Standards for Commercial Support as promulgated by the ACCME. Recognizing that CMS needs to also address CE programs, we urge the agency to adopt the key provisions of these standards which state that the commercial supporter:

- Does not pay covered recipient speakers or attendees directly;
- Does not select covered recipient speakers or provide a third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers or attendees for the CE program; and
- Does not control the program content.

In order to strike a balance that acknowledges CMS’ concerns while also safeguarding independent CE, we strongly urge modification of the agency’s proposal to exclude from the Open Payments Program reporting where the above criteria are met. For those CE programs that are not ACCME certified, we also encourage CMS to look to the existing inter-professional coalitions for accreditors of continuing education known as Joint Accreditation which has been convened since 2009 and includes the AACME, Accreditation Council for Pharmacy Education and the American Nurses Credentialing Center.
Reporting of Reprints from Peer Reviewed Medical Journals and Text Books

The MMS and AMA continue to urge CMS to reverse its decision that reprints from scientific medical journals and medical textbooks are reportable under the Sunshine Act. Over 76 state medical societies and national medical specialty organizations as well as a number of other health care organizations and Members of Congress have contacted the Secretary to urge reconsideration of this flawed policy. We continue to believe the regulations in this regard are contrary to both the statute and congressional intent. We further believe these rules will potentially harm patient care by impeding ongoing efforts to improve the quality of care through timely medical education.

The Sunshine Act was designed to promote transparency with regard to payments and other financial transfers of value between physicians and the medical product industry. As part of this provision, Congress outlined twelve specific exclusions from the reporting requirement, including “educational materials that directly benefit patients or are intended for patient use.” In its interpretation of the statute, 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 statutory language on its face, congressional intent, and the reality of clinical practice where patients benefit directly from improved physician medical knowledge.

The importance of up-to-date, peer reviewed scientific medical information as the foundation for good medical care is well documented. Scientific peer-reviewed journal reprints, supplements, and medical textbooks have long been considered essential tools for clinicians to remain informed about the latest in medical practice and patient care. Independent, peer reviewed journal article supplements, reprints and textbooks represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients. It is now clear that the design of the reporting requirement presents a clear disincentive for clinicians to accept high quality, independent educational materials; an outcome that was unintended when the provision was passed into law.

The Food and Drug Administration (FDA)’s 2009 industry guidance titled “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices” underscores the importance of this scientific peer reviewed information. The FDA noted the “important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications.” FDA guidelines for reprints provide that medical reprints should be distributed separately from information that is promotional in nature, specifically because the reprints are designed to promote the science of medicine, are educational, and intended to benefit patients. We believe the Sunshine Act was designed to support the dissemination of this type of educational material.

As we have commented previously to the agency, there is no transfer of value, as contemplated by the law, to the physician from reprints from scientific peer reviewed medical journal reprints. A physician may have already purchased a subscription to the journal, they may have access to the material for free through an institutional site license or through their group practice or network. It is also critical to underscore that many of the leading medical journals, including the NEJM and JAMA, make research articles available for free after six months on the web. That is anyone, can obtain this information for free
after six months on the internet. We continue to question how CMS can maintain that there is any transfer of value when the information is available for free or the physician has already paid for the information. It is notable that the CMS’s guidance on this issue states that the reportable value is determined by the price paid by the industry. We continue to maintain that the final rule is fatally flawed in this interpretation - the value to the pharmaceutical company, eg what they paid, is irrelevant to and not a valid determinant of the value to the physician. At a minimum we urge CMS to eliminate the reporting of reprints from the Sunshine Act as there is no transfer of value as contemplated by the law.

It is important to underscore our overriding concerns with the CME issue and reporting of reprints and textbooks. We continue to be concerned that by misinterpreting the law, CMS is in essence thwarting physician’s ability to learn and keep up to date with the most current medical information. By any and all accounts this was not the purpose of the Sunshine Act. In fact Congress purposely included 12 exceptions to the law to ensure that the public reporting did not have a chilling effect on legitimate activities involving commercial support or indirect payments. At the same time, by creating a data base that is overwhelmed with data, which has no context, CMS is making the public disclosure aspect of the law unworkable.

As always we would welcome the opportunity to work with the agency to find a workable solution to these problems. The MMS, AMA and number of the groups who have expressed concerns about these regulations were in fact very supportive of the law and involved in the its drafting and would like to work with the agency to help ensure its appropriate implementation. Given all the problems to date with the Open Payment system, we continue to ask CMS to delay the publication of the reported information and to rescind the reporting requirements for reprints from scientific medical journals and textbooks.

*XV. Physician Compare Website*

CMS proposes a significant number of changes and additions to the Physician Compare Website starting in 2015 or 2016. We oppose these proposals to extensively expand the website when serious and fundamental flaws with the program remain unaddressed. Physicians experience with the website and the problems with the agency’s ability to correct even demographic errors in a timely fashion, gives us great concern about CMS ability to post accurate data on quality measurements and other performance measurements. To this end the AMA makes a number of recommendations which we urge the agency to implement. These include:

1) Expand the period of time to 90 days when an EP or group practice can review their data. If the EP or group files and appeal or flags either their demographic or quality information as problematic, CMS should postpone posting the information until the issues are resolved.

2) Urge CMS to test measures and composites with 20 patients and to provide opportunity for public comment and review. We share the AMA’s concerns that this sample size per physician may be too small. Testing by Acumen for CMS was based on a 25 patients. Strongly urge CMS to move forward with expanding its risk adjustment methodology to incorporate race, income, and region. The lack of adjustment can lead to inaccurate and misleading conclusions about quality and performance and ultimately increase disparities in health care.
XVI. Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System (PQRS)

The AMA comments in detail on the numerous proposed changes to the PQRS program. We support these recommendations in full. It is important to underscore that the PQRS program, coupled with meaningful use, and the value based modifier carry considerable weight with respect to a physician’s payment. The maximum cumulative penalty in 2017 from these programs, including sequestration, is 11 percent. Given the serious flaws with each of these programs, we believe it is critical that CMS make every effort to fix design problems and maintain stability with the programs by not changing requirements on a yearly basis. It is also critical that all of these programs be aligned, so that physicians do not have to report multiple times to avoid payment adjustments. This is not the case at this time.

Other recommendations include:

1. Maintain claims reporting option for 2015 for PQRS and future years as it continues to be the most popular reporting option particularly for small practices
2. At a minimum, keep PQRS requirements the same for 3 years
3. Oppose increasing the number of measures from 3 to 9 given the lack of meaningful measures relevant to every specialty
4. It is critical that CMS maintain the option of reporting three measures or elections reporting via administrative claims to avoid the 2017 penalty
5. In order to streamline reporting, physicians who successfully participate in PQRS, regardless of the reporting mechanism, should be deemed as successfully meeting the Meaningful Use quality measure requirements, and vice versa. We also urge CMS to reduce the number of quality measures required to report until there are enough Econs that work for all physician specialties.
6. Supporting using non-NQF measures in the PQRS program
7. Oppose removing measures simply because they are “topped out.”

XIX. Value-Based Payment Modifier and Physician Feedback Program

The MMS has consistently expressed concerns about the value based modifier programs from its inception which we believe is inherently flawed and unworkable. Given the significant financial impact of this program on physician practices, we are very concerned by the agency’s continued failure to conduct a rigorous impact analysis of its VM framework before proceeding with plans to increase the VM penalty from two percent to four percent, leaving some practices vulnerable to total Medicare payment cuts of 11 percent in 2017.

As the AMA comments details: “What data we do have suggests that the modifier discriminates against Medicare’s frailest patients and their physicians. Studies to date have not attempted to gauge the combined impact of PQRS, VM and other penalties on vulnerable practices. Numbers cited in the NPRM to justify the rapid adoption and escalation of VM penalties focus on “average” impacts. They fail to provide reasonable assurances that the VM will not routinely penalize certain categories of patients and physicians. “
The MMS strongly supports the AMA recommendations which oppose increasing the VM penalty from two percent to four percent; mandating participation in the tiering competition; and continuing the use of cost and outcome measures that have never been tested for use in physician offices. We also believe that it is not necessary to compound the complexity of the VM by extending it to ACOs and other alternative payment and delivery models.

There a number of issues in the proposed rule which the MMS also looks forward to working with both CMS and the AMA in implementing. These include implementation for ICD 10, changes to the Medicare Savings program to make sure and how to make EHR more accessible and workable in the physicians’ offices.

As always we appreciate the opportunity to comment and look forward to working with you on these critical issues which will impact physicians and patient care.

Sincerely,

Richard S. Pieters, MD