

September 2, 2014

Via Electronic Transmission

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 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 Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am filing the following comments to the proposed policies under the Medicare Physician Fee Schedule (PFS) for calendar year (CY) 2015 (the “proposed rule”).¹ MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

I. Summary of Recommendations

Our comments focus on several key areas of interest to manufacturers of innovative medical technologies.

¹ 79 Fed. Reg. 40318 (July 11, 2014).

- The Centers for Medicare & Medicaid Services (CMS) proposes a number of codes for review as potentially misvalued under the PFS. MDMA urges CMS to exercise caution in reviewing these codes and in selecting codes for review in the future and to ensure that Medicare reimbursement for each service adequately accounts for equipment, supplies, and all other costs incurred by physicians in providing the service.
- Currently, physicians bill for the use of non-coronary intravascular ultrasound (IVUS) in the physician office setting using codes for which CMS has not established relative value units (RVUs) for physician practice expense in the non-facility setting. MDMA urges CMS to establish such a value to ensure that this critical diagnostic tool is adequately reimbursed and widely available for the treatment of venous and arterial disease.
- CMS proposes to revise the coding and reimbursement for stereotactic radiosurgery (SRS) services under the PFS in a manner that threatens adequate reimbursement for those services. MDMA urges CMS not to finalize this proposal, which would have a severe negative impact on physicians' ability to offer SRS services to Medicare beneficiaries.
- CMS should clarify and expand coverage and reimbursement for remote patient monitoring.
- CMS proposes a new process for adopting new and revised Current Procedural Terminology (CPT[®])² codes under the PFS. MDMA appreciates CMS's efforts to improve transparency and allow for stakeholder input into the valuation of new and revised codes, but asks CMS to work with American Medical Association (AMA) and others to refine the proposed process.

² CPT copyright 2013 American Medical Association (AMA). All rights reserved. CPT[®] is a registered trademark of the AMA.

- The proposed rule includes two proposed revisions to the rules for manufacturer reporting of payments and transfers of value to physicians and teaching hospitals: a proposal to eliminate the current exemption for continuing medical education (CME) and a proposal to require manufacturers to report a “marketed name” for all related products, including medical devices. MDMA believes that these proposals would create unnecessary confusion for manufacturers and consumers and discourage support for CME programs, and we urge CMS not to finalize either proposal.

II. CMS should ensure that device costs are appropriately included in the valuation of any codes reviewed as potentially misvalued.

For CY 2015, CMS proposes to review a number of codes as potentially misvalued, including approximately 65 CPT and Healthcare Common Procedure Coding System (HCPCS) codes that CMS identifies as a prioritized subset of the newly established statutory category for “codes that account for the majority of spending under the physician fee schedule.”³

MDMA urges CMS to exercise caution in reviewing the proposed codes and in selecting codes for review as potentially misvalued in the future. Many of the services represented by codes proposed for review are complex procedures that require considerable professional time and effort as well as a broad range of equipment and supplies. We ask CMS, in reviewing these codes, to ensure that all equipment and supplies needed to complete the procedure are included in the inputs under the PFS and are correctly valued based on available data, including appropriate data submitted by manufacturers. In addition, although we recognize the statutory criteria that CMS has been given in selecting codes for review, MDMA urges CMS not to rely on higher costs alone in selecting codes for review or proposing revisions in valuation. We encourage the agency to ensure that reimbursement for each code under the PFS is adequate in light of all the costs and resources incurred by physicians in providing the service, so that Medicare beneficiaries will continue to have access to effective and innovative treatment.

³ 79 Fed. Reg. at 40337.

III. CMS should support the revaluation of CPT codes 37250 and 37251 to account for non-physician work and the other practice expenses involved in performance of non-coronary IVUS in the non-facility setting.

IVUS is a critical diagnostic tool in the treatment of peripheral arterial/venous disease, as both the medical literature and physicians' personal clinical experience attest. In recent years, the physician office has become an increasingly important setting for treating patients with peripheral arterial/venous disease, a development that CMS has recognized by including physician practice expenses in the Medicare reimbursement amount when physicians use angioplasty and stenting to treat venous and arterial occlusive disease in the office setting. It is equally important for the effective treatment of venous and arterial disease that physicians receive adequate reimbursement for the appropriate use of IVUS to diagnose venous and arterial occlusive disease in the office setting. However, while CMS has established physician work and malpractice RVUs for IVUS CPT codes 37250 (intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel) and 37251 (intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel), it has not yet established RVUs for physician practice expense (PE) in the non-facility setting.

MDMA is concerned that the lack of PE RVUs for non-coronary IVUS in the non-facility setting creates a significant barrier to adequate reimbursement for office-based IVUS use and therefore to effective diagnosis and treatment of peripheral arterial/venous disease in Medicare patients. The practice expense for performing IVUS in the office setting includes the cost of the catheter, nursing and technician time, and the capital cost of the IVUS console, as well as office overhead expenses. Without PE RVUs to account for these expenses in the non-facility setting, physicians are currently reimbursed approximately \$132 for performance of non-coronary IVUS, which is less than a tenth of the actual cost of performing the service.

MDMA respectfully requests that CMS support the revaluation of CPT codes 37250 and 37251 to account for non-physician work and the other practice expenses involved in performance of non-coronary IVUS in the non-facility setting. We would request CMS pursue such a

reevaluation to take effect January 1, 2015 (because of the current zero value attributed to practice expense), utilizing objective data available on IVUS catheter and console costs, and non-physician work time using the physician work time currently in codes 37250 and 37251.

IV. CMS should not implement the proposed changes to coding and reimbursement for stereotactic radiosurgery services.

For CY 2015, CMS proposes to replace HCPCS codes G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of treatment in one session or first session of fractionated treatment) and G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment) with CPT codes 77372 (radiation treatment delivery, stereotactic radiosurgery (SRS) complete course of treatment of cranial lesions consisting of 1 session, linear accelerator based) and 77373 (stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions).⁴ CMS also would use the RVUs developed for the CPT codes by the Relative Value Update Committee (RUC) instead of contractor pricing, as is currently used for G0339 and G0340. If implemented, these RVUs would reduce payment for these procedures by as much as 65 percent in some parts of the country.

MDMA urges CMS not to implement this proposal because it would threaten access to an important cancer therapy by slashing reimbursement rates. MDMA urges CMS to continue to use the G-codes for radiosurgery at contractor-priced rates for CY 2015. We recommend that CMS work with stakeholders to understand the costs of the resources used in these procedures. Radiosurgery involves particularly high-technology equipment that is designed to serve a unique and relatively limited patient population that often cannot be treated safely using other types of equipment. CMS's standard process for calculating practice expense values may not produce appropriate RVUs for this kind of service. CMS has chosen to allow other radiation therapy services, such as Cobalt-60 radiosurgery and proton beam therapy, to remain contractor priced,

⁴ *Id.* at 40332.

and it should continue to allow radiosurgery to be contractor priced as well, until a full analysis of the resources used in these procedures can be completed.

V. CMS should clarify and expand coverage and reimbursement for remote patient monitoring.

For 2015, CMS proposes to implement, with refinements, payment for Chronic Care Management (CCM) services for patients with two or more chronic conditions, as discussed in the final rule for 2014.⁵ We agree with CMS that “effective care management can be accomplished only through regular monitoring of the patient’s health status, needs, and services, and through frequent communication and exchange of information with the beneficiary and among health care practitioners treating the beneficiary.”⁶ To support this kind of monitoring and communication, we ask CMS to clarify the scope of services described by the CCM codes and to introduce a new standalone code to provide coverage and reimbursement for remote patient monitoring (RPM) for patients not eligible for the CCM services. RPM, also known as telemonitoring, involves the use of various technologies to monitor patients while in the home or another non-clinical setting. RPM can help improve care management for patients with chronic and difficult to control conditions by providing physicians and other practitioners with more direct, consistent, and reliable access to information about their patients’ conditions.⁷ RPM helps physicians achieve exactly the kind of communication and information exchange that CMS believes is critical to effective care management, and it should be included in the services described by the CCM codes. We ask CMS to clarify this and consider creating a new code and reimbursement for standalone remote patient monitoring services for individuals with chronic diseases such as hypertension to allow other Medicare beneficiaries to benefit from this important service.

⁵ *Id.* at 40365.

⁶ *Id.* at 40367.

⁷ *See, e.g.,* Margolis et al, Effect of Home Blood Pressure Telemonitoring and Pharmacist Management on Blood Pressure Control, A Cluster Randomized Clinical Trial, *Journal of the American Medical Association*, July 3, 2013, Vol. 310, No. 1, finding that a home blood pressure monitoring program with pharmacist management was associated with enhanced clinical and patient experience outcomes. A meta-analysis, published in the *Journal of the American College of Cardiology*, (Klersy, A Meta-Analysis of Remote Monitoring of Heart Failure Patients, *J Am Coll Cardiol.* 2009;54(18):1683-1694) examined the literature on remote patient monitoring of chronic heart failure patients, and similarly found that RPM was associated with significant protective clinical effect.

VI. CMS should work with the AMA to refine the proposed revisions to the process for adopting new and revised CPT codes to provide maximum transparency and minimum use of G-codes for revised and deleted codes.

In the proposed rule, CMS acknowledges the concerns that many stakeholders have expressed about the current process for establishing and valuing new and revised CPT codes under the PFS.⁸ In response, CMS lays out detailed revisions to the process for adopting new and revised codes, which would take effect beginning with rulemaking for CY 2016.⁹ Under the proposed process, each proposed code revision would be submitted for public review through a proposed rule, comment, and final rule. For new and revised codes that CMS does not receive early enough in a given year to include in the proposed PFS rule for that year, CMS would delay revaluing the code until it receives input from the RUC early enough to include the code in the proposed rule. For codes that are revised or deleted through annual CPT code changes, CMS would create HCPCS G-codes to reflect the predecessor CPT codes and retain the current payment rate for the following year.

MDMA commends CMS for recognizing the need for increased transparency regarding payment for new codes. We support the proposed new process and look forward to commenting on the proposed valuation of new and revised CPT codes under future proposed rules. However, we are concerned that the use of temporary G-codes, which would require providers to adjust to coding changes for the same service two years in a row, would be burdensome for providers. We urge CMS to work with the AMA to develop a timeline that allows for maximum transparency and minimum use of G-codes for revised and deleted codes.

⁸ 79 Fed. Reg. at 40360.

⁹ *Id.* at 40363.

VII. CMS should not finalize the proposed revisions to rules on reporting payments and transfers of value under the Federal Open Payments Program.

CMS proposes two key revisions to the regulations adopted to implement the federal Open Payments program, which requires certain manufacturers of covered products to publicly report payments and other transfers of value to physicians and teaching hospitals. MDMA has considerable concerns about each of these proposed revisions.

A. Related Product Name for Medical Devices and Supplies

The proposed rule would revise the requirement to report the name of product(s) related to a given payment or transfer of value to require manufacturers to report the “marketed name” of any related covered product that they report, even if the product is a medical device or supply.¹⁰ Under the current rule, manufacturers are permitted to report the product category or therapeutic area for covered products that are medical devices or supplies. CMS adopted this rule in response to comments on the initial proposed rule to implement the Open Payments program, recognizing the concerns of manufacturers and others that it would be extremely difficult to identify and report a “marketed name” for medical devices because many complex medical devices consist of multiple reimbursable components and attachments, each of which has a marketed name. In addition, as CMS recognized in adopting the existing rule, requiring a “marketed name” for medical devices would not serve the purpose of the Open Payments program because device manufacturers often do not advertise complex devices directly to the general public; reporting the therapeutic area or product category would allow consumers, researchers, and others to develop a more cohesive understanding of the type of products to which a given set of payments relates than if manufacturers reported a multitude of market names not familiar to the public.

MDMA is deeply concerned about CMS’s proposal to eliminate this rule for reporting related product names for medical devices and supplies. The proposed rule does not explain why CMS proposes to abandon the current rule, other than stating generally that the proposed change will

¹⁰ *Id.* at 40384.

“make the data fields consistent within the system” and “enhance consumer’s use of the data.”¹¹ We believe exactly the opposite is true – that the proposed changes will decrease consistency between manufacturers and make it more difficult for consumers to understand and aggregate the data that device manufacturers report. In addition, the change will create considerable confusion among device manufacturers, who will be forced to spend time and resources to restructure the policies and systems that they have developed to capture and report data under the Open Payments program. **MDMA strongly urges CMS to retain the current regulatory provisions regarding reporting of related product names.**

B. CME Exemption

The proposed rule would remove the explicit reporting exemption for payments to the provider of an accredited CME program that are used as compensation for a physician speaker, provided that the manufacturer does not pay the physician speaker directly and does not select the speaker or give the CME provider a distinct, identifiable set of individuals to be considered as speaker. In the preamble to the proposed rule, CMS explains that this proposal is based in part on CMS’s view that the explicit CME exemption is “redundant” with another reporting exemption, which exempts reporting of indirect payments to a covered recipient through a third party where the manufacturer is “unaware” of the identity of the ultimate recipient for the next 18-month period.

MDMA is concerned that removing the explicit exemption for CME could expand manufacturers’ obligation to report payments for accredited CME and thereby discourage manufacturers from supporting these important educational programs. We are concerned that removing the exemption for CME from the text of the rule itself will create legal ambiguity as to whether such payments continue to be reportable, leaving manufacturers to rely on CMS’s statements in the preamble to the proposed rule, which carry less weight than the regulation itself under the law. Moreover, even if it were adopted in the rule itself, CMS’s position that a manufacturer that meets the requirements of the existing CME exemption would be “unaware” of the ultimate recipients of CME funding is inconsistent with the reality that manufacturers almost always learn the identity of physician speakers at CME programs that they fund because

¹¹ *Id.*

those physicians are publicly listed. Finally, the proposed rule does not address how elimination of the existing CME exemption would affect other CMS guidance that currently limits manufacturer reporting obligations, particularly guidance on payments to CME sponsors that are used to provide tuition support, meals, or other items for physician attendees of the CME program.

Accordingly, MDMA urges CMS to retain in the text of the regulation itself a reporting exemption for payments to CME providers that meet the criteria currently laid out in the Open Payments regulations, rather than forcing manufacturers to rely on statements in the preamble regarding the scope of the separate exemption for indirect payments. To the extent CMS chooses to revise the CME exemption to address its concern about not endorsing a particular set of CME providers, we would encourage CMS to revise the exemption in a manner that promotes broad access to and industry support for independent, accredited CME.

VIII. Conclusion

MDMA appreciates the opportunity to comment on the proposed Medicare PFS and looks forward to working with CMS as it develops the final rule.

Sincerely,

/s/

Mark B. Leahey
President & CEO, MDMA