

September 6, 2013

**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 & Other Revisions to Part B for CY 2014 [CMS-1600-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 Revisions to Payment Policies under the Physician Fee Schedule (PFS), Clinical Laboratory Fee Schedule & Other Revisions to Part B for calendar year (CY) 2014 proposed rule (the “Proposed Rule”).<sup>1</sup> 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.

**Summary of Recommendations**

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

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<sup>1</sup> 78 Fed. Reg. 43282 (July 19, 2013).

- The Centers for Medicare & Medicaid Services (CMS) proposes a significant revision in policy regarding coverage for items and services used in investigational device exemption (IDE) clinical studies and calls for a centralized review within CMS for all studies. MDMA has serious concerns with CMS's proposal and recommends that CMS not finalize it.
- In the Proposed Rule, CMS is proposing an arbitrary cap on non-facility PFS payments. Although MDMA shares CMS's concern about the accuracy and timeliness of the data used in established practice expense (PE) relative value units (RVUs), we are concerned that the proposal undoubtedly will lead to challenges for Medicare beneficiaries in accessing necessary medical technologies. We urge CMS to not implement this proposal.

### **Proposed Revision to Coverage Policy for IDE Clinical Studies and Centralized Review for IDE Studies**

In 1995, CMS (then known as the Health Care Financing Administration) and the Food and Drug Administration (FDA) entered into an interagency agreement in which the FDA agreed to categorize IDEs for purposes of Medicare coverage. CMS then issued a regulation establishing coverage of certain IDEs and certain services related to those devices.<sup>2</sup> The FDA assigns IDEs to one of two categories: Category A for innovative devices believed to be in class II for which absolute risk of the device type has not been established, and Category B for non-experimental and/or investigational devices believed to be in classes I or II or devices believed to be in class III where the incremental risk is the primary risk in question. For coverage purposes, Medicare does not cover Category A devices but may cover routine costs associated with these clinical trials if the Category A device is intended for the diagnosis, monitoring, or treatment of an immediate life-threatening disease or condition. Medicare covers Category B devices and routine care related to the use of the covered device if the device is the subject of an

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<sup>2</sup> 60 Fed. Reg. 48417 (Sept. 19, 1995).

FDA approved clinical trial protocol and used in accordance with that protocol; is medically necessary for the particular patient and medically appropriate in amount, duration and frequency of use; and if it will be furnished in a setting that is appropriate for the particular patient's needs and condition. The process currently is maintained by local contractors who make the determinations. Local contractors also must consider whether any restrictions concerning site of service, indications for use, or any other list of conditions for coverage have been placed on the device's use.

### *Proposed Coverage Criteria*

In the Proposed Rule for CY 2014, CMS proposes to make significant revisions to these long-established coverage policies that have worked successfully for almost two decades. Specifically, CMS is proposing to require that all Category A and B devices meet the following minimum standards for coverage in clinical studies:

1. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the Medicare-enrolled subjects.
2. The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The study results are not anticipated to unjustifiably duplicate existing knowledge.
4. The study design is methodologically appropriate and the anticipated number of enrolled subjects is appropriate to answer the research question(s) being asked in the study.

5. The study is sponsored by an organization or individual capable of completing it successfully.
6. The study is in compliance with all applicable federal regulations concerning the protection of human subjects found at 45 CFR part 46.
7. All aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors.
8. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
9. Where appropriate, the clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this standard only if the disease or condition being studied is life threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.
10. The study is registered on the ClinicalTrials.gov website and/or the Registry of Patient Registries (RoPR) by the principal sponsor/investigator prior to the enrollment of the first study subject.
11. The study protocol specifies the method and timing of public release of results on all pre-specified outcomes, including release of negative outcomes. The release should be hastened if the study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>). However, a full report of the outcomes must be made public no later than three years after the end of data collection.

12. The study protocol explicitly discusses subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the study. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
  
13. The study protocol explicitly discusses how the results are or are not expected to be generalizable to subsections of the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.<sup>3</sup>

CMS also is proposing to approve an IDE study automatically when the study meets the 13 aforementioned criteria and the study is a pivotal study and the study has a superiority study design.<sup>4</sup> CMS does note that for studies that do not meet the superiority design study/pivotal study criteria, coverage is possible if a sponsors attains the 13 newly established criteria in a manner that is “sufficient to mitigate the failure” to have a pivotal study with a superiority design.<sup>5</sup>

*Comment*

MDMA appreciates the agency’s willingness to review its current coverage criteria for clinical studies and its desire to increase administrative efficiencies in the IDE coverage process. We agree that periodic review of current policies and standards is necessary to ensure that Medicare

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<sup>3</sup> 78 Fed. Reg. at 43344.

<sup>4</sup> *Id.* at 43345.

<sup>5</sup> *Id.*

beneficiaries have timely access to medical therapies and processes to deliver such care are efficient. However, we believe that the new criteria for establishing coverage for IDE will lead to actual access problems for beneficiaries. Moreover, we also have concerns with the centralized review process and believe that the intended goal of increased administrative efficiencies will not be achieved.

#### *MDMA's Concerns about the Proposed Coverage Criteria*

MDMA is extremely concerned that CMS does not have a full appreciation of the impact that the new coverage criteria will have not only on small, innovative medical device companies or on the many Medicare beneficiaries who benefit from use of these products in clinical trials. Moreover, we are concerned about the overall lack of clarity in the proposed guidelines for coverage of IDE devices in clinical trials.

In conflict with CMS's longstanding policy of encouraging inclusion of Medicare beneficiaries in clinical trials, the requirement that a device in an IDE study not only attain the 13 proposed criteria but also that the study be a pivotal study and have a superiority study design will inhibit access to innovative care in a number of ways. First, CMS fails to recognize that, under the FDA's regulations and guidance, medical device trials generally are not structured as superiority trials. Non-inferiority trials typically are considered to be the most appropriate trial designs for IDE trials because these trials compare a current treatment and an improvement to that treatment, not a placebo and a new treatment. Thus, the proposed policy is inconsistent with the FDA's policies on IDEs, and requiring trials to be designed as superiority studies for Medicare coverage would create conflicts between the FDA's data collection requirements and CMS's coverage criteria. Indeed, few, if any, devices currently covered under Medicare's IDE regulations would meet this requirement.

Second, requiring superiority trial designs would create an incredibly high barrier for smaller companies that are targeting specific and sometimes underserved patient populations, yet that have similar clinical characteristics to existing technologies. These trials require larger patient populations and longer duration than non-inferiority trials. If Medicare's coverage requirements

become more stringent, manufacturers will be discouraged from conducting these trials and including Medicare beneficiaries in the studies. We believe that after nearly 20 years of encouraging manufacturers to include Medicare beneficiaries in their trials and expanding access to innovative devices, the proposed policy would be a misguided change.

CMS also proposes to require that “the principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of patients who are represented by the Medicare-enrolled subjects.”<sup>6</sup> CMS appears to be proposing to apply the criteria it uses to evaluate devices after they receive FDA approval or clearance to IDEs, but these criteria are ill-suited for these trials. IDE trials conducted to support a premarket approval (PMA) application simply do not, as their principal purpose, demonstrate health outcomes improvements. Instead, these trials are designed to demonstrate whether the device is safe and effective. Moreover, this requirement is particularly inappropriate for diagnostics as diagnostic information, by itself, does not show health outcomes improvements. We recommend that CMS not apply this requirement to coverage of IDEs and related services.

CMS states that for studies that do not meet the superiority design study/pivotal study criteria, coverage is possible if a sponsor attains the 13 newly established criteria in a manner that is “sufficient to mitigate the failure”<sup>7</sup> to have a pivotal study with a superiority design. CMS does not offer any additional clarity, guidelines or comment as to what “sufficient to mitigate” entails for each of the proposed 13 criteria. This lack of clarity likely will lead to significant confusion among potential sponsors of clinical trials and in most cases will discourage sponsors from including Medicare beneficiaries in trials for medical technologies.

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<sup>6</sup> Id. at 43344.

<sup>7</sup> Id. at 43524.

### *MDMA's Concerns about Centralized Review of IDE Trials*

CMS is proposing a centralized review process for the purpose of being “more efficient by reducing the burden for stakeholders interested in conducting nationwide trials.”<sup>8</sup> With a centralized process, CMS states that there would be “a single entity making the IDE coverage decision.”<sup>9</sup> CMS believes that this will enhance administrative efficiency by eliminating the need for duplicative reviews by local contractors.

MDMA appreciates and shares the Agency’s interest in creating administrative efficiencies and looks forward to working with CMS in doing so. However, we believe that a centralized review process is not needed and may be especially problematic for smaller companies, the majority of which are creating truly novel and innovative medical treatments for patients. MDMA has expressed concerns in the past over similar proposals of a centralized process (most notably in CMS’s pending proposal on Coverage with Evidence Development). CMS historically has noted that local contractors are required to maintain a level of confidentiality regarding proprietary information about a product in a clinical trial. CMS currently does not maintain such a requirement, and the proposal provides no assurance to stakeholders that potentially competitive proprietary information would be protected.

In addition, the prospect of conducting national trials instead of local ones could affect a small company’s ability to obtain appropriate funding. The proposal seems to offer an “all or nothing” proposition in terms of obtaining appropriate coverage for a clinical trial. This prospect, versus the ability to obtain coverage locally, ultimately could discourage many companies, especially smaller, single product companies, from participating at all.

Many of MDMA’s members were surprised by comments by CMS in the proposal that obtaining coverage of the device and the costs of routine items and services was “inefficient.” The overall experience in working with local contractors by the majority of MDMA members has been

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<sup>8</sup> Id. at 43343.

<sup>9</sup> Id.

relatively positive and historically efficient. Moreover, where there have been incidental issues in administration, these problems have been resolved quickly and efficiently.

Finally, we are concerned that CMS does not provide any specific administrative guidance or details with respect to its decision-making process, timelines associated with the process, required materials, or whether there is an appeals process available. MDMA members are deeply concerned that this lack of clarity will lead to significant confusion for applicants seeking coverage of these devices and trials. Moreover, given the considerable level of unknown variables, many have indicated that they would likely forego the inclusion of Medicare beneficiaries in the clinical trial process.

MDMA would welcome a more pronounced discussion about how to improve the perceived administrative inefficiencies within the IDE coverage process. We agree that it is in the best interest of all stakeholders to have a process that is efficient. **However, MDMA cannot support CMS's proposal for a centralized review process at this time given our stated concerns with the proposal.**

**Given the nature and realities of IDE clinical trials' use of non-inferiority designs, the lack of clarity for attainment of the 13 proposed criteria, and the lack of administrative guidance and appeals procedures, MDMA does not support CMS proposed revision to the coverage process for medical devices in IDE clinical trials.** Although we are supportive of discussions surrounding ways to improve the process so Medicare beneficiaries can have access to innovative medical treatments, we believe that this discussion should be given considerably more time and discussed in an appropriate manner. Specifically, we believe that this discussion should be conducted as an independent proposal in which more stakeholders can participate and have the ability to provide comments in a public setting. We believe that the Physician Fee Schedule rule is not the appropriate venue for such a significant revision to longstanding Medicare policy.

## **Proposed Cap on Non-facility PFS payments**

In the Proposed Rule, CMS expresses concerns about the accuracy and timeliness of the data used to establish PE RVUs. CMS believes that PFS payments in the non-facility setting that exceed payment in the Hospital Outpatient Prospective Payment System (OPPS) or Ambulatory Surgical Center (ASC) setting do not reflect appropriate payment differentials between settings.<sup>10</sup>

The Proposed Rule would limit the total non-facility PFS payment amount, beginning in CY 2014, to no more than the total combined amount that Medicare would pay to practitioners and facilities for the same code in the facility setting, based on the corresponding OPPS or ASC payment rate.<sup>11</sup> Thus, if the non-facility PE RVUs for a given code would result in a higher payment than the corresponding OPPS or ASC payment rate plus the PFS facility PE RVUs for the same code, CMS would reduce the non-facility PE RVU so that the total non-facility payment does not exceed the total Medicare payment made for the service in the facility setting. If a service has no work RVUs, then the comparison would be between total non-facility PFS payment and the OPPS payment rate alone, as there is no PFS payment for those services in the facility setting. CMS proposes to use the current year (CY 2013) conversion factor and OPPS or ASC rates and the CY 2014 pre-adjustment PE RVUS for this comparison.

Although MDMA shares CMS's concern about the accuracy and timeliness of the data used in established PE RVUs, we are concerned that the proposal will undoubtedly lead to challenges for Medicare beneficiaries in accessing necessary medical technologies. Many MDMA members have expressed concern regarding the significant fluctuations in rates for medical technologies, even in the absence of the proposed payment cap. In some cases, rates have decreased close to 50 percent, creating a foreseeable challenge for beneficiaries to maintain access to existing medical treatments.

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<sup>10</sup> Id. at 43296.

<sup>11</sup> Id. at 43297.

Moreover, the proposed payment cap is not justified by the reasons that CMS offers in the Proposed Rule. CMS appears to assume, without providing any supporting detail that the cost of providing a service in the non-facility setting is inherently lower than the cost of providing the same service in the facility setting due to certain additional costs that facilities must bear. CMS concludes that whenever the non-facility payment for a service is higher than the facility payment, the difference must be due to errors or other problems with the way the PFS non-facility rates are calculated, without regard to the particular costs and characteristics of the service at issue. For example, while it is true that facilities bear certain costs that non-facilities do not, facilities also benefit from the power of their larger-scale operations, which helps them to spread certain costs and gain leverage in price negotiations and ultimately reduces the overall cost of providing many services in a way that most non-facility health care providers cannot match.

In addition, CMS appears to assume that using OPPS and ASC data as the basis for a payment cap would more accurately capture the cost of providing services in the non-facility setting than the non-facility PFS rates. However, these data suffer from their own defects. The OPPS and ASC rates are based on fundamentally different data and methodologies than the PE inputs used in the PFS, and to insert those rates into the PFS calculation would introduce incoherence into a reimbursement system that for decades has been based consistently on the resources used by a physician in furnishing each service. In addition, many of the physician services that would be subject to the proposed cap have an extremely low volume in hospitals and ASCs, which means that the costs reported by hospitals and other facilities may be wildly unrepresentative of the actual cost of providing the service. Indeed, the June 2013 report to Congress from the Medicare Payment Advisory Commission (MedPAC), which CMS relies on in part to justify the proposed cap, recommended that where CMS equalizes rates across settings, the capped setting's rates should be based on a setting in which at least 50 percent of procedures of that type are performed.<sup>12</sup>

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<sup>12</sup> MedPAC, Report to the Congress: Medicare and the Health Care Delivery System (June 2013), at 37, available at: [www.medpac.gov/documents/Jun13\\_EntireReport.pdf](http://www.medpac.gov/documents/Jun13_EntireReport.pdf).

**We recommend that CMS withdraw its proposal to cap non-facility PFS payments and ensure that payment rates under the PFS continue to be based on data that account for legitimate reasons for differences in cost between settings and are sufficient to protect access to care in the appropriate setting.**

### **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. If we may be of any assistance, please contact Thomas Novelli at (202) 354-7175.

Sincerely,



Thomas C. Novelli  
Vice President of Government Relations  
Medical Device Manufacturers Association