January 28, 2012

Via Electronic Submission

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Coverage with Evidence Development Draft Guidance

Dear Acting 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market, I am submitting the following comments in response to the Centers for Medicare & Medicaid Services’ (CMS) Draft Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development (CED) in the Context of Coverage Decisions (CED Draft Guidance). 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.

Introduction and Summary of Recommendations

MDMA appreciates this opportunity to comment on the CED Draft Guidance. Medical devices are a critically important part of the health care system, and MDMA’s members devote considerable resources and effort to improving and expanding the clinical evidence to help Medicare beneficiaries and providers make the most appropriate diagnostic and therapeutic decisions. MDMA therefore supports CMS’s efforts to improve the CED process to reduce

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barriers to innovation and improve health outcomes for Medicare beneficiaries. Our primary concern is that such efforts do not inadvertently limit patient access to advanced medical technologies. MDMA’s comments and recommendations focus on the following issues:

- **Principles Governing the Application of CED**
  - CMS should identify the principles governing the application of CED set forth in its 2006 CED guidance document that it believes are moot and explain the basis for that determination so stakeholders can provide meaningful feedback;
  - CMS should adhere to the principles governing the application of CED set forth in its 2006 CED guidance document because they were developed with extensive stakeholder input and continue to be relevant today;

- **Applying CED**
  - CMS should proceed cautiously and in collaboration with manufacturers when considering the use of CED for a particular item or service to ensure that it does not hinder access to appropriate care and the development of clinical evidence through other means, including the local coverage process;
  - CMS should clarify that when CED is applied, it will occur within the national coverage determination (NCD) process;
  - In instances where manufacturers have worked collaboratively and transparently with the Medicare Administrative Contractors (MACs) in a manner that has not been burdensome and has expanded patient access to innovative treatments, CMS should ensure that these local coverage determinations (LCDs) with evidence collection requirements may continue under the final CED Guidance.
  - In applying the standards of scientific integrity, CMS should carefully analyze the value of additional information and require only the minimum amount of data necessary to enable the agency to make an informed “reasonable and necessary” determination;

- **Ending CED**
  - CMS should clarify that it will clearly define the endpoint for data collection at the outset of each application of CED;
  - CMS should clarify the process by which it will make a coverage decision after CED ends;
o CMS should find a less burdensome means of covering an item or service after the end of CED study until a coverage determination is made than requiring other, ongoing studies;

- **Role of the Agency for Healthcare Research and Quality (AHRQ)**
  o CMS should more clearly define the role of AHRQ in the CED process and in particular how it will provide funding through public/private partnerships;

- **Formal Evidentiary Criteria**
  o CMS should define evidentiary thresholds in general terms in its final guidance document;
  o CMS should involve stakeholders in defining the specific evidentiary threshold necessary to invoke CED for a particular item or service;
  o CMS should make explicit that thresholds for invoking CED will be established at levels that ensure that CED continues to be used infrequently and not when other forms of coverage are justified by the available evidence; and

- **Existing National Non-Coverage Decisions**
  o CMS should review its existing national non-coverage decisions and remove any provisions that deny coverage to new technologies that CMS has not specifically reviewed.

**Principles Governing the Application of CED**

CMS includes in the CED Draft Guidance information related to goals, history, and authority for CED; however, the agency fails to include principles to guide the application of CED, such as those included in the 2006 CED guidance document. CMS indicates that “some” of these principles are now “moot.” CMS does not identify the specific principles that it believes are moot nor does it discuss its basis for finding them to be so. MDMA would like CMS to provide more discussion around its decision to not include the principles CED Draft Guidance so that MDMA and other stakeholders can provide specific input to the agency on that decision.

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2 Although CMS removed this document from its website when it issued the CED Public Solicitation, the agency confirmed that CED continues to remain in place during review.
The principles in the 2006 guidance document were developed with extensive stakeholder input and continue to provide appropriate guideposts for the use of CED today. To ensure that CED does in fact produce gains in innovation that benefit Medicare patients and does not inadvertently stifle new technology, MDMA urges CMS to adhere to those principles, which include the following:

1. NCDs requiring CED will occur within the NCD processes, which is transparent and open to public comment.
2. CED will not be used when other forms of coverage are justified by the available evidence.
3. CED will in general expand access to technologies and treatments for Medicare beneficiaries.
4. CMS expects to use CED infrequently.
5. CED will lead to the production of evidence complementary to existing medical evidence.
6. CED will not duplicate or replace the Food and Drug Administration’s (FDA’s) authority in assuring the safety, efficacy, and security of drugs, biological products, and devices.
7. CED will not assume the NIH’s role in fostering, managing, or prioritizing clinical trials.
8. Any application of CED will be consistent with federal laws, regulations, and patient protections.

By emphasizing that the use of CED will be limited, intended to expand access, and not overlap with or duplicate the efforts of other regulatory agencies, the principles simultaneously facilitate collection of data that help Medicare, as well as patients and providers, make better informed decisions about current diagnostic and treatment options while also ensuring that the collection of additional data does not impede medical technology innovation. These principles should be included in the final guidance document.

**Applying CED**

In the CED Draft Guidance, CMS explains the reasons why Medicare considers applying CED to various items and services. It does not, however, elaborate on how it will implement CED. We
urge CMS to proceed cautiously and in collaboration with manufacturers when considering the use of CED. In many cases, CMS may find that CED is not necessary because evidence of clinical benefit sufficient for Medicare coverage purposes will be developed as new technology makes its way through the local coverage process. Except in cases where there is an existing national non-coverage decision, CMS should give this process time to work before determining whether CED is appropriate.

When CMS does determine CED is appropriate for a particular item or service, MDMA urges the agency to give the public as much information as possible about why CED is being used, what the specific research question is and how the proposed data collection will answer it, when the beginning and ending of evidence collection is anticipated, what the expected cost of the evidence collection is, and what AHRQ’s specific role will be. It is critical for CMS to explain in detail how the CED’s proposed design will answer a specific meaningful clinical question about the particular item or service involved. CMS should give interested stakeholders and the public an opportunity to comment on this information before deciding whether and how to proceed with CED. It is important that this process be open, predictable, and transparent.

One of the principles in the 2006 CED guidance document is that NCDs “requiring CED will occur within the NCD process, which is transparent and open to public comment.” MDMA strongly supports the use of CED through a process that is transparent and open to public comment when the agency determines that the application of CED is appropriate and urges CMS to clarify in the final guidance document that CED will occur in this context. Stakeholder input, particularly from manufacturers, is essential to CMS’s ability to understand the evidence supporting a technology, any gaps in that evidence, and any additional research efforts underway to address those gaps. The manufacturer’s comments are especially important because the manufacturer has the most knowledge of any stakeholder regarding its technology. Only by collaborating with a device’s manufacturer can CMS learn about the full body of evidence on a technology and plans for future studies that could shape the decision of whether and how to apply CED. This input also is critical for ensuring that any data collection requirements established through CED can be implemented successfully.
Although MDMA believes that CED should occur within the NCD process, we are aware of instances in which CED has been applied locally with great success. Manufacturers have worked collaboratively and transparently with the MACs in a manner that has not been burdensome and has expanded patient access to innovative treatments. We ask CMS to ensure that these LCDs with evidence collection requirements may continue under the final CED Guidance.

MDMA supports the standards of scientific integrity and relevance to the Medicare population that are included in the CED Draft Guidance. These standards will help ensure that CED is used appropriately and does not inadvertently inhibit medical technology innovation. CMS should be sure that in applying these standards, it carefully analyzes the value of additional information to the coverage process and require only the minimum amount of data necessary to enable the agency to make an informed “reasonable and necessary” determination. MDMA recognizes the appeal of gathering as much data as possible on a technology, but CMS should not use the coverage process as a means of imposing extensive, open-ended research projects on a technology when a more focused and limited study would provide the data necessary for a Medicare coverage determination. Doing so would unduly burden providers and manufacturers and potentially thwart further innovation by creating uncertainty about coverage and reimbursement and diverting resources from more beneficial research and development.

**Ending CED**

MDMA appreciates that CMS has clarified in the CED Draft Guidance when CED for an item or service will end. This guidance, however, leaves unaddressed the critical issue of how the agency will define the endpoints for the CED study itself. In cases in which CMS does not specify the length of time for data collection, a burdensome reporting requirement may continue indefinitely. Such uncertainty is unfair to those that are shouldering the burden and the cost of the data collection and inserts unnecessary unpredictability into the CED process. CMS should address in the final guidance document that it will be clear about the endpoint for data collection at the outset of CED.
CMS also should provide additional guidance regarding the pathway for coverage after the end of CED. CMS acknowledges that there may be a gap between the end of a CED study and a decision regarding coverage of an item or service based on that study, but provides no guidance about the process the agency intends to use to evaluate the CED study data and make a coverage determination. CMS should elaborate on this process, including establishing timeframes for decisions and opportunities for public input, in the final guidance document.

CMS does address the issue of patient access to an item or service subject to CED in the time between the end of the CED study and a coverage determination by saying that it “may address the issue of ongoing coverage by working with investigators to develop integrated research strategies during the planning of CED studies,” by, for example, using “practical observational studies to close outstanding evidence gaps and allow coverage after a [randomized controlled trial] ends where appropriate.” MDMA appreciates that CMS has at least addressed the issue of patient access after the end of CED, but is very concerned that CMS’s proposed approach could result in multiple, overlapping, and duplicative studies that unnecessarily impose additional, burdensome requirements on manufacturers, providers, and patients. MDMA urges CMS to find a less burdensome means to ensure coverage between the end of the CED study that provides the data necessary to make a coverage determination and the issuance of the coverage determination itself that would preserve scarce resources for more productive activities.

**Role of AHRQ**

As noted above, MDMA’s primary concern is that the use of CED does not restrict access to innovative medical technology. The costs associated with data collection and analysis under CED are not insignificant and are not wholly funded by CMS. These costs include the non-clinical research costs of clinical trials, as well as registry development and maintenance. MDMA members devote considerable resources to clinical research on new and innovative medical devices. The additional costs of CED, borne in part by manufacturers, must not be so burdensome that they force manufacturers to limit the resources available for innovation. This is a particular concern for small companies who must invest a significant percentage of their

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3 CED Draft Guidance at 8.
resources to get a new technology through the approval or clearance process and typically have few resources left to collect data beyond that required by the Food and Drug Administration (FDA).

In the CED Draft Guidance, CMS indicates that the authority for the application of CED is the provision of the Social Security Act that authorizes Medicare coverage in the context of research conducted and supported by AHRQ. One of the roles of AHRQ with regard to CED, according to CMS, is its “capacity to establish public/private partnerships to financially support CED studies.”4 Because the statutory authority for CED is premised on AHRQ’s research activities, it is important for CMS to clarify AHRQ’s role in CED process generally, particularly because AHRQ’s mission is different from CMS’s. In particular, to address concerns regarding the costs of CED studies and the effect of those costs on medical innovation, MDMA urges CMS to more clearly articulate the types of partnerships that ARHQ may establish and the public funding that will be available for evidence collection and analysis.

**Formal Evidentiary Criteria**

Before it released the CED Draft Guidance, CMS convened a meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC).5 Among the topics the MEDCAC addressed was the use of formal evidentiary criteria in the application of CED. CMS describes the conclusions of the MEDCAC in the CED Draft Guidance, but does not provide any of its own guidance on the use of evidentiary criteria for CED. MDMA believes it is important for CMS to define these thresholds in general terms in a guidance document that will help improve the predictability and transparency of CMS’s coverage decisions. CMS also should seek comments on any changes to the thresholds defined in the guidance as it gains more experience with CED.

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4 Id. at 9.
With regard to each individual application of CED, the evidentiary threshold will vary based on a number of circumstances, including but not limited to whether the item or service is diagnostic or therapeutic in nature, the severity of the disease, the safety profile of the technology, etc. The specific evidentiary threshold necessary to invoke CED for a particular item or service must be identified through extensive input from stakeholders, such as physicians, researchers, and manufacturers who are deeply familiar with the technology, the existing evidence, and the opportunities and challenges associated with collecting additional data. Only with appropriate input from the manufacturer and other stakeholders can CMS identify an appropriate evidentiary threshold for invoking CED for any item or service. CMS should make clear in the final guidance document that it will do so.

In general, MDMA believes that the thresholds for invoking CED should be established at levels that ensure that CED continues to be used infrequently and not when other forms of coverage are justified by the available evidence, consistent with the principles established in CMS’s 2006 guidance document on CED. MDMA is confident that the appropriate use of CED can improve health outcomes for Medicare beneficiaries. We also recognize, however, that CED involves considerable investment of time and resources by CMS and stakeholders, and therefore only should be applied when necessary. This should be reflected in the final guidance document to avoid any uncertainty that might have a chilling effect on ongoing medical innovation.

**Existing National Non-Coverage Decisions**

MDMA has previously asked CMS to review its existing national non-coverage decisions and remove any provisions that deny coverage to new technologies that CMS has not specifically reviewed. This will help ensure that Medicare’s coverage decisions do not inhibit innovation and access to improvements in care. Some NCDs specify that only the listed items or services are covered and all other technologies are non-covered, regardless of whether CMS has reviewed those technologies. These policies discourage innovation by shutting the door to new technologies until CMS completes a coverage analysis on each technology. They also create an administrative burden for CMS by requiring these technologies to be reviewed through a national coverage analysis, rather than allowing local contractors to decide whether to cover them.
Rather than establishing blanket non-coverage policies for unspecified technologies, CMS should identify the exact items and services that are covered or are not covered, and provide local contractors discretion to determine whether to cover any remaining technologies. CMS did not address this issue in its CED Draft Guidance, but MDMA continues to believe that it is an area of vital importance to continued medical innovation and urges CMS to respond accordingly.

**Conclusion**

In conclusion, MDMA supports CMS’s efforts to revise its CED process to reduce barriers to innovation and improve health outcomes for Medicare beneficiaries. We ask you to take our comments into account when finalizing the CED Guidance and look forward to working with you in the future on this important issue. Thank you.

Sincerely,

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