

701 Pennsylvania Ave., NW, Suite 800  
Washington, DC 20004-2654  
Tel: 202 783 8700  
Fax: 202 783 8750  
www.AdvaMed.org



**AdvaMed**  
Advanced Medical Technology Association

September 6, 2017

**Via Electronic Mail Only**

Tamara Syrek Jensen  
Director, Coverage and Analysis Group  
Centers for Medicare & Medicaid Services  
U.S. Department of Health & Human Services  
Mail stop: S3-02-01  
7500 Security Boulevard  
Baltimore, Maryland 21244

**Re: Local Coverage Process Concerns**

Dear Ms. Syrek Jensen:

I am writing on behalf of the Advanced Medical Technology Association (AdvaMed) to seek your assistance in ensuring that Medicare's local coverage process remains transparent and participative. AdvaMed has been in regular contact with members of the Coverage and Analysis Group regarding a host of concerns that our members have experienced related to the local coverage process. This letter addresses our ongoing concerns regarding the transparency of the LCD revision and development process. Unfortunately, these concerns persist and are having a significant impact on beneficiary access to life altering medical technologies. This letter identifies several irregularities related to the LCD process.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming patient health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

AdvaMed supports Medicare's local coverage process as a very important means to provide prompt decisions on the items and services that benefit Medicare's beneficiaries. Local coverage decisions (LCDs) ensure beneficiary access to life saving and medically necessary products and procedures. These local coverage processes serve to help generate knowledge about new technologies and procedures and can better inform long-term decisions on effectiveness and value. AdvaMed appreciates the level of flexibility that the LCD process can provide in addressing local circumstances and needs, and its ability to provide timely decision-making for important medical breakthroughs. Notwithstanding, our members continue to raise concerns related to the transparency of the local coverage process.

AdvaMed members continue to have concerns regarding the process for notifying stakeholders of proposed revisions to, and drafting of, new LCDs. For example, it is difficult to locate and monitor the development of local coverage policies. Consequently, stakeholders frequently miss the opportunity to comment on draft and revised LCDs because there is no standardized process for announcing the issuance of a draft or proposed LCD. The lack of a standardized process for notification also forces stakeholders to check the websites of the various MACs on an almost daily basis for any changes. Checking websites is made even more difficult because contractor web sites are often poorly organized or designed. AdvaMed members also note that, although contractors have list serves, key policy changes are often not mentioned in list serve e-mails. This process is highly ineffective and deprives stakeholders of the opportunity to actively engage in the comment development process for these critical coverage documents.

- ***AdvaMed asks CMS to work with local MACs to develop a system, similar to the one used by the Coverage and Analysis Group, that posts proposed/draft and revised LCDs on the CMS website and that simultaneously provides notice to stakeholders.***

Chapter 13 of the Medicare Program Integrity Manual provides specific procedural requirements for the development of LCDs. Contractors are required to provide notice and comment periods for all new LCDs, revised LCDs that restrict existing LCDs, and revised LCDs that make substantive policy corrections.<sup>1</sup> Contractors are also required to solicit comments from state Carrier Advisory Committees,<sup>2</sup> and to provide open public meetings for the purpose of discussing draft LCDs.<sup>3</sup>

The requirements to solicit and provide feedback to stakeholders on information solicited during public meetings are not working effectively. In too many instances our members have been confronted with the reality of having MACs host open public meetings, followed by lengthy lags in publication and feedback on public comment, only to be followed by publication of a final LCD that does not reflect any of the information discussed during the public meeting. One example of this is a recent LCD on Surgical Dressings (L33831) that was finalized by CGS and Noridian effective July 24, 2017. The draft of this LCD was originally published on August 6, 2015. Following publication of the draft, the MACs hosted an open public meeting on August 26, 2015 during which many stakeholders presented their perspectives on the impact of the proposed changes. AdvaMed worked with our members to submit written comments for that meeting. The comment period on the proposed/draft LCD closed on September 21, 2015.

Following the close of the comment period there was no additional feedback or comment from the MACs until an updated version of the LCD was published on June 2, 2017, with a July 24, 2017 effective date. Additionally, the comments and meeting response summary from the MACs

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<sup>1</sup> Medicare Program Integrity Manual, 13.7.2. We note that certain revisions to LCDs are not subject to notice and comment periods. However, these tend to be minor revisions to LCDs or those that do not restrict coverage. See Medicare Program Integrity Manual, 13.7.3

<sup>2</sup> Medicare Program Integrity Manual, 13.7.4.

<sup>3</sup> Medicare Program Integrity Manual, 13.7.4.1.D.

for the August 2015 open public meeting were not published until June 8, 2017 almost two years later **and** following the publication of the final LCD language.

While the Program Integrity Manual specifically addresses the timeline for other aspects of the LCD development process, it does not include any parameters regarding the time period during which contractors must address concerns raised by the public during open meetings. The absence of a definitive timeframe for responding to these comments, as illustrated by the nearly two year lag in the preceding example, makes the process highly ineffective in addressing stakeholder concerns and needs.

Furthermore, the lack of detail contained in the meeting summaries, compounded by the lag in time between the meeting and their publication, makes it very difficult for stakeholders to intelligently respond to the contractor's concerns if they choose to request a reconsideration of the policy. An additional complicating factor is the seeming failure of the MACs to consider public and other comments presented by interested stakeholders. MACs are inconsistent with regard to the process for accepting stakeholder comments—with some requiring that all comments be submitted in writing thereby negating the purpose of allowing in-person comments during public meetings.

- ***AdvaMed recommends that MACs be required to provide a detailed summary of the comments received during the open public meeting on the draft LCD no later than 90 days following the close of the comment period.***
- ***AdvaMed recommends that the MACs also provide, no later than 90 days following the public meeting, a transcribed copy of comments and statements delivered during the public meetings to assist stakeholders in developing additional comments.***
- ***AdvaMed recommends that the MACs be required to accept and to consider oral and/or written comments presented by stakeholders during CAC and open public meetings.***

In no case should contractors be allowed to post their response to comments after the LCD has been posted for finalization as was the case with the Noridian and CGS Surgical dressing policy.

The effectiveness of the open public meeting process is further compromised by difficulty in locating meeting information on the various contractor websites and by allowing MACs to scheduled meetings on related LCDs on the same date-- interfering with stakeholders' ability to attend and present relevant comments and to hear feedback from other stakeholders.

- ***AdvaMed recommends that MACs more prominently place information regarding open public meetings on their websites.***
- ***AdvaMed recommends that MACs coordinate on the scheduling of open public meetings to avoid conflicts with meetings being hosted in other jurisdictions.***

Openness and transparency in developing LCDs benefits patients, providers, and other stakeholders. In order to resolve some of the issues identified above, AdvaMed requests that CMS instruct its various contractors to ensure that all LCD developments are promptly posted on the CMS web site, and that contractor web sites are developed with clear navigation aids, so that

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LCD information is readily accessible. Additionally, Advamed asks that CMS work with MACs to improve the process for responding to open/public meeting feedback.

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Advamed and its members are strongly supportive of the local coverage process and the way in which it confers patient access to important therapies. The concerns that we have highlighted in this letter, as well as other letters, are important matters that impact beneficiary access. We hope that we can work closely with you and your staff to discuss how they can be resolved. Should you or your staff have any questions, please contact DeChane Dorsey ([ddorsey@Advamed.org](mailto:ddorsey@Advamed.org) or 202-434-7218) or Chandra Branham ([cbranham@Advamed.org](mailto:cbranham@Advamed.org) or 202-434-7219).

Sincerely,

A handwritten signature in black ink that reads "Donald May". The signature is written in a cursive style with a long, sweeping underline.

Donald May  
Executive Vice President,  
Payment and Health Care Delivery

cc: Laurence Wilson

Enclosures