

CMS's New Process for Issuing Local Coverage Determinations

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In October 2018, the Centers for Medicare & Medicaid Services (“CMS”) announced that it made significant changes to the process by which local coverage determinations (“LCDs”) are developed and issued. These changes were published in Chapter 13 of the Medicare Program Integrity Manual (“Manual”) and were made in response to requirements of the 21st Century Cures Act, which mandated that CMS increase the transparency of the LCD process to ultimately improve patient access to services.¹ Indeed, CMS describes the changes as intended to “help increase transparency, clarity, consistency, reduce provider burden and enhance public relations while retaining the ability to be responsive to local clinical and coverage policy concerns.”²

An LCD is a decision made by a Medicare Administrative Contractor (“MAC”) to apply or deny Medicare coverage within that MAC’s jurisdiction. Because an LCD only applies within the states (or portions of states) where the MAC has an agreement with CMS, different MACs may issue conflicting LCDs for a particular item or service. Since the evidence supporting coverage may develop over time, LCDs may also be leveraged for reconsideration—a process through which stakeholders may request that a MAC take a second look at an existing LCD to determine whether a change is warranted. This new LCD transparency is beneficial to stakeholders—physicians and other clinicians, providers, manufacturers, and suppliers billing Medicare for services—as they determine what services to provide their clients and whether reconsideration of certain LCDs is worth requesting.

Stakeholders criticized the previous LCD process as lacking in transparency due to limited communication when either new LCDs were issued or existing LCDs were revised, since many meetings discussing the implementation of LCDs were closed to the public. The new process addresses these concerns. Briefly, the 21st Century Cures Act requires each MAC that develops an LCD to make available the following

¹ Pub. Law. No. 114-255 § 4009 (2016).

² CMS, MLN Matters MM 10901, Local Coverage Determinations (LCDs) (2018), *available at*: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10901.pdf>.

information on its Medicare website, at least 45 days before the effective date of an LCD:

- the determination in its entirety,
- where and when the proposed determination was first made public,
- hyperlinks to the proposed determination and a response to comments submitted to the MAC with respect to such proposed determination,
- a summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence, and
- an explanation of the rationale that supports such determination.³

Based on these requirements, CMS has revamped Chapter 13 to serve as a roadmap for stakeholders to engage in the LCD process and understand the steps in developing both new and reconsidered LCDs. Additionally, the Manual sets forth specific requirements for communicating information to stakeholders to ensure that they are involved in all steps of the LCD development process.

New LCD Process

This Chapter 13 roadmap outlines nine steps that must be followed when a MAC plans to issue a new LCD:

1. **Informal Meetings.** The new LCD process may begin with informal meetings, set up for educational purposes only, in which stakeholders in the MAC's jurisdiction can informally discuss potential subjects for an LCD. Although these meetings will not be considered pre-decisional negotiations, they allow prospective requestors to communicate via conference call or in person before submitting a formal request for review to assure that all relevant evidence needed for review to determine coverage is submitted. These meetings are discretionary and are not a prerequisite to a new LCD. Nonetheless, MACs are instructed to publish on their contractor websites how a stakeholder may contact them to request an informal meeting.
2. **New LCD Requests from Interested Stakeholders.** The new LCD request process is a mechanism through which stakeholders within a MAC's jurisdiction can request a new LCD. MACs are instructed to consider all new LCD requests from stakeholders, including those from beneficiaries receiving care, health care professionals delivering services, and any interested party conducting business in a MAC's jurisdiction.

³ Pub. Law. No. 114-255 § 4009 (2016).

New LCD Request Requirements. MACs will review new LCD request materials within 60 calendar days of receipt; during this review period, a MAC will also determine whether or not the request is complete. If the MAC determines a request to be incomplete, the MAC will notify the requestor, in writing, as to why, so that the requestor may resubmit a complete request.

A new LCD request is formal and complete if it:

- is in writing submitted to the MAC via e-mail, fax, or written letter;
 - clearly identifies the statutorily defined Medicare benefit category to which the requestor believes the item or service fits, and provides a rationale justifying the assignment;
 - includes language that the requestor wants contained in the LCD;
 - includes a justification for the new LCD request that is supported by peer-reviewed evidence (full copies of published evidence to be considered must be included);
 - contains information addressing the relevance, usefulness, clinical health outcomes, or medical benefits of the item or service; and
 - includes information that fully explains the design, purpose, and/or method of using the item or service for which the new LCD request is made.
3. **Clinical Guidelines, Consensus Documents, and Consultation.** During the development of an LCD, MACs must supplement their research with clinical guidelines, consensus documents (such as practice guidelines issued by professional organizations), and consultation by experts, medical associations, or other health care professionals, if available and applicable. Any experts consulted by MACs must sign consent forms indicating that their opinions may be used, disclosed publicly, and clearly identified as such within the proposed or final LCD.
4. **Requirements for the Proposed LCD.** All proposed LCDs must be drafted in consultation, published on the Medicare Coverage Database (“MCD”),⁴ and be available for public comment, in writing, for a minimum of 45 days before the LCD becomes effective. A MAC may decide to extend the public comment period as needed. These processes must be used for all LCDs except in the following situations:
- An LCD is revised for compelling reasons;

⁴ The Medicare Coverage Database may be accessed here: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.

- An LCD is revised to make non-substantive corrections, such as grammatical errors that do not substantially change the LCD;
 - An LCD is revised based on a non-discretionary coverage update to reflect changes statutes, federal regulations, National Coverage Determinations (“NCDs”), CMS rulings, etc.; or
 - An LCD is revised to effectuate an administrative law judge’s decision to nullify an existing LCD due to an LCD challenge.
5. **The Contractor Advisory Committee (“CAC”).** A CAC is a formal entity established by a MAC in each state in which the MAC operates. CACs are composed of health care professionals and representatives of beneficiaries and medical organizations and are intended to supplement the MAC’s internal expertise to ensure unbiased consideration regarding the coverage of services. The purpose of the CAC is to provide a formal mechanism for health care professionals to be informed of the evidence used in developing LCDs and to promote communications between the MAC and the health care community.

All CAC meetings will be open to the public. MACs will also record the public meetings, and the video or audio recordings will become part of the LCD record and posted on the MACs’ website.

6. **Open Meeting.** After a proposed LCD is made public, MACs will hold an open meeting to discuss the review of the evidence and the rationale for the proposed LCD with stakeholders in their jurisdiction. Interested parties, generally those that would be affected by the LCD (such as providers, physicians, manufacturers, vendors, or beneficiaries), may make presentations related to the proposed LCD. MACs must notify the public about the dates, times, and location for an open meeting, and must post the planned agenda for an open meeting a minimum of two weeks prior to the event on their website. Open meetings will be recorded, will become part of the LCD record, and will be posted on the MACs’ website.
7. **Response to Public Comments.** MACs will respond to all comments received during the comment period of the proposed LCD by using the Response to Comment (“RTC”) Article associated with the LCD, which is published on the start date of the notice period. The RTC Article will remain publicly available indefinitely on the MCD or the MCD Archive.
8. **Publication of the Final Determination.** After the close of the comment period and the required meetings and consultation, the final LCD and the RTC Article will be published on the MCD.
9. **Notice Period and Effective Date.** The LCD will become effective a minimum of 45 days after the final LCD is published on the MCD. Unless extended by the

MAC issuing the LCD, the effective date of the LCD is the 46th calendar day after the notice period began.

LCD Reconsideration Process

The LCD reconsideration process allows for beneficiaries or stakeholders in a MAC's jurisdiction to request that a current LCD be revised. MACs are required to post information to their website regarding the LCD reconsideration process, including:

- a description of the LCD reconsideration process, and
- instructions for submitting LCD reconsideration requests, including postal, e-mail, and fax addresses to where such requests may be submitted.

In order for an LCD to be reconsidered, the requestor must submit a valid LCD reconsideration request to the appropriate MAC. The MAC will determine whether the request is valid or invalid within 60 calendar days of receiving the request. If the request is valid, the MAC will follow the new LCD process outlined above or include the LCD on the MAC's waiting list. The MAC will notify the requestor, in writing, if the request has been accepted or placed on the waiting list.

Evaluating the Changes Made by CMS

Despite the new regulations that require increased transparency in the LCD process, there are still some criticisms of this process that should be noted. For instance, the new rules do not permit MACs to consider unpublished proprietary data as evidence to support a new or revised LCD. This may hamper the efforts of some smaller stakeholders to inform CMS of new items or services, especially when a smaller stakeholder has conducted a well-designed study but is reluctant to publish due to competitive concerns. In addition, the publication requirement may delay the availability of new technologies. Indeed, in the past, CMS has been known to consider proprietary data as support for the issuance of NCDs. Nonetheless, the changes to the LCD process as reflected in the revised Chapter 13 of the Manual indicate CMS's commitment to improving access to services among Medicare beneficiaries.

The official instruction, CR10901, issued to all MACs regarding this change is available [here](#).

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*This Client Alert was authored by **Arthur J. Fried, Robert E. Wanerman, and Elena M. Quattrone**. For additional information about the issues discussed in this Client Alert or for assistance in evaluating or submitting any LCD requests, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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