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CMS Rolls Out Revised Local Coverage Determination Process

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On October 3, 2018, the Centers for Medicare & Medicaid Services (CMS) announced a number of changes to the local coverage determination (LCD) process. The new guidelines are outlined in a revamped Chapter 13 – Local Coverage Determinations – of the Medicare Program Integrity Manual (PIM). This manual chapter had been the subject of criticism, with some stakeholders arguing that a lack of transparency potentially denies patient access to innovative treatments.

While CMS is responsible for developing national coverage determinations (NCDs), the vast majority of Medicare coverage decisions are made at the "local" levels by Medicare Administrative Contractors (MACs). Through this local process, CMS delegates significant authority to these contractors, who can develop coverage policies for any item or service for which there is no NCD, or when the NCD needs clarification for the local context.

According to CMS, the new manual provisions both respond to feedback from stakeholders, (e.g. during meetings and in correspondence from providers and healthcare associations), and fulfill the mandate of Section 4009 of the 21st Century Cures Act. Under Section 4009, the Secretary of the Department of Health and Human Services must require MACs to publish, for each LCD developed: (1) the determination, (2) where and when it was first made public, (3) links to the proposed LCD and responses to public comments, (4) a summary of the evidence and a list of sources, and (5) an explanation of the MAC's reasoning. This information is to be published at least 45 days prior to the effective date, on both the MAC's website and on the CMS website. As shown below, CMS has effectuated the revisions of the Cures Act, while also making some of its own process changes. According to the agency, Chapter 13 now reads in an accessible "roadmap" format, and the changes "will pave the way to expanded access to new medical technologies" by including more voices in the process. Further, CMS has announced its intention to consider more revisions based on stakeholder feedback.

It is yet to be seen whether the next changes will come from the agency, or from Congress. The Local Coverage Determination Clarification Act of 2018, passed the House in September and has been referred to the Senate Finance Committee. The Senate version of the bill is sponsored by Senator Johnny Isakson (R-GA), who desires to see more transparency in the LCD process.

With a January 8, 2019 implementation date, following are highlights of the LCD process under

revised PIM Chapter 13:

Informal Meetings: “Interested parties,” defined generally as “those that would be affected by the LCD, including providers, physicians, vendors, manufacturers, beneficiaries, caregivers, etc.,” may request informal meetings to discuss potential LCD requests. These meetings are not negotiations, but are intended to help requesters understand what evidence to submit with a formal request.

New LCD Requests: “Interested parties” may also request a new LCD. MACs must consider all requests from (1) beneficiaries who live, or receive care, in the jurisdiction, (2) health care professionals who do business in the jurisdiction, and (3) any interested party who does business in the jurisdiction.

Public Comment: Once a proposed LCD is published, MACs must allow a minimum of forty-five days for public comment. MACs are required to respond to all comments received by the deadline, though they may group similar comments and responses.

Contractor Advisory Committee (CAC): CACs are intended to promote communication between MACs and the healthcare community. They are a formal mechanism whereby healthcare professionals are informed of the evidence used in LCDs. Beneficiary representation is mandatory on CACs and non-physician healthcare professionals such as nurses and social workers can now participate. All meetings discussing evidence for a proposed LCD must be open to the public.

Open Meetings: MACs must hold open meetings to discuss both the evidence and the rationale behind proposed LCDs with jurisdiction stakeholders. Interested parties may make presentations.

Final Determinations: MACs must either finalize or retire all proposed LCDs within a year of publication. At least 45 days prior to the effective date, MACs must make available (1) the determination, (2) where and when it was first made public, (3) links to the proposed LCD and responses to public comments, (4) a summary of the evidence and a list of sources, and (5) an explanation of the MAC’s reasoning. This information must be included on both the MAC’s website and on the CMS website.

Reconsideration: This process now mirrors the NCD reconsideration process.

Challenge: While the old chapter contained a lengthy explanation of the challenge process, this has been omitted in the revised version because “42 CFR § 426 outlines all the requirements regarding the LCD Challenge process.” As before, only aggrieved parties may challenge LCDs. An “aggrieved party” is a “Medicare beneficiary, or the estate of a Medicare beneficiary, who is entitled to benefits under Part A, enrolled under Part B, or both . . . and is in need of coverage for an item or service that would be denied by an LCD, as documented by the beneficiary’s treating physician, regardless of whether the service has been received.”

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