CMS REVAMPS LCD PROCESS VIA MEDICARE PROGRAM INTEGRITY MANUAL

CMS recently unveiled several changes to the local coverage determination (LCD) process, including a way to request such a determination, repurposed public meetings and a reconsideration process that is consistent with that used for national coverage determinations. CMS Administrator Seema Verma said the reforms will "pave the way to expanded access to new medical technologies," and she signaled more changes may be coming.

Scott Whitaker, the president and CEO of the Advanced Medical Technology Association, tweeted that CMS' changes are a "solid step toward addressing concerns from the MedTech industry" about the LCD process. He also tweeted that the medical technology community hopes to work with CMS on additional changes. AdvaMed has been pushing for changes to the LCD process, as has the College of American Pathologists, and the House recently passed an LCD reform bill.

Verma says the reforms will make local coverage decisions more transparent and increase stakeholder input. The changes respond to Congress' requirement in the 21st Century Cures Act for more transparency in the LCD process, CMS says in a press release. The manual revisions are the first since August 2015, CMS says.

Verma suggests in a blog post that there may be unnecessary gaps between FDA approving a technology and Medicare paying for it. She notes the payment policies haven't been updated in decades, and suggests more changes are under consideration.

The revisions to the Medicare Program Integrity Manual include a step-by-step description of the LCD process, and offer an option for stakeholders to request an informal meeting with Medicare Administrative Contractors (MACs) that determine local coverage decisions. The reforms also include a new process for stakeholders within a MAC's jurisdiction to request a new LCD.

CMS will also require a standardized summary of clinical evidence supporting LCD decisions and MAC coverage determination rationale, according to an agency fact sheet. Proposed coverage decisions that are not finalized within a year of when they are posted will be retired, CMS says. Under the new process, the agency says, MACs will notify the public when they publish a final decision and provide a web link to it. MAC responses to public comments will be linked to in a final LCD and remain in the Medicare Coverage Database archives indefinitely. The manual revisions make the LCD reconsideration process consistent with the NCD reconsideration process, and MACs must follow the full process for valid requests, CMS says.

The agency also is changing how certain LCD-related meetings are conducted. The Contractor Advisory Committee, which includes members that review the quality of evidence used in the development of an LCD, now can include other health care professionals like nurses and social workers in addition to physicians. CMS also says the committee must include beneficiary representatives. Meetings will be open to the public, and MACs will determine how frequently they occur, CMS says.

Open public meetings, which are separate from the CAC meetings, can be held virtually to allow for broader participation, a CMS release says, and MACs will need to clearly identify the location, dates and how a conference will be held.

CMS says the changes to the manual reflect feedback from requests for information on how to reduce administrative burden. The agency has set up an email inbox to collect feedback on how the revisions work, and CMS says it will consider additional changes based on that feedback.

AdvaMed Executive Vice President for Payment and Health Care Delivery Policy Don May commended CMS for making changes to the LCD process. "Having a more open LCD meeting process for MACs and requiring them to provide rationales for their decisions will help allow for greater stakeholder engagement and a fairer process, and ensure that no Medicare beneficiaries are denied access to life-changing innovations because of bureaucratic impediments," May said.

Verma said the changes respond to concerns by those working on new medical technologies. "The changes announced today to the local coverage determination process mean that coverage decisions will be more transparent and more responsive to innovators bringing new medical technologies to our Medicare beneficiaries," Verma says in a blog post. "In this way, the new process will pave the way for expanded access to these technologies."

Verma echoed White House Office of Management and Budget Associate Director for Health Programs Joe Grogan's recent comments that CMS' treatment of medical devices is hard to understand, and that there are gaps in Medicare payment policies. "We recognize that confusion exists around some of Medicare's policies in this area, and that certain products may not have a clear pathway to coverage and payment today. Beyond the changes we're announcing today, we are considering a series of additional clarifications and improvements to our current policies and processes," Verma says in the blog. Grogan last month said the administration was looking at changes to device coverage, and that the process could stretch over years.