

September 12, 2016

Dear Representative:

As leading organizations representing the interests of patients, providers, and manufacturers, we write to ask that you cosponsor H.R. 5721, the *Local Coverage Determination Clarification Act*.

Medicare coverage policy decisions are made nationally and locally. National coverage determinations (NCDs) are made by the Centers for Medicare and Medicaid Services (CMS) to describe the circumstances under which Medicare will cover an item or service on a nationwide basis. Local Coverage Determinations (LCDs) are developed by Medicare Administrative Contractors (MACs) on whether, and under what circumstances, to cover a particular item or service on a contractor-wide basis.

Most coverage policy is determined on a local level by MACs. MACs may make coverage decisions where CMS has not made a national coverage determination or where the rules are too vague regarding a specific procedure. LCD policy may not, however, conflict with a NCD. Although CMS' Program Integrity Manual instructs MACs on how to develop LCDs, the current process lacks transparency and sufficient stakeholder involvement to ensure that decisions are in the best interests of patients.

As a result of contractor reforms that have taken place over the past several years, local MACs are now responsible for much larger jurisdictions, and there are fewer opportunities for stakeholders to interact with the contractor medical directors who make local medical policies. As an example, a decision by one MAC could impact beneficiaries in ten states.

Moreover, contractors are allowed to adopt another MAC's draft LCDs. This ability to coordinate decisions effectively transforms a local coverage determination into a national one without having followed the more rigorous national coverage determination requirements. Basic procedural fairness for patients, providers, manufacturers, and other stakeholders is often lacking in local coverage determinations.

In light of these challenges, it is imperative that improvements are made to the LCD process to enhance openness and transparency and enhance accountability. Therefore, we ask you to cosponsor H.R. 5721. H.R. 5721 would require Medicare contractors to establish a timely and open process for developing LCDs that includes open public meetings, meetings with stakeholders, an open comment period in the development of draft policies, and posting of responses to comments received, as well as a description of all evidence relied upon and considered when drafting a coverage determination. Furthermore, H.R. 5721 would require MACs seeking to adopt another MAC's proposal to independently evaluate and consider the evidence needed to make a coverage determination. Finally, H.R. 5721 would provide physicians and suppliers a meaningful reconsideration process outside of the self-interested review of the MAC that finalized the LCD being objected to.

We urge you to cosponsor H.R. 5721. It will improve Medicare's coverage process and ensure that patients can benefit from medical innovation.

Sincerely,

Advanced Medical Technology Association (AdvaMed)

American Society of Clinical Oncology (ASCO)

American Society for Radiation Oncology (ASTRO)

Amputee Coalition

College of American Pathologists

US Oncology Network