

September 29, 2017

Dear Representative:

As leading organizations representing the interests of patients, providers, and manufacturers, we write to ask that you cosponsor H.R. 3635, the *Local Coverage Determination Clarification Act of 2017*, introduced by Representatives Jenkins and Kind.

Medicare coverage policy decisions are made nationally and locally. National coverage decisions (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 decisions.

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 that you cosponsor H.R. 3635. H.R. 3635 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 and finalizing a coverage determination. Additionally, H.R. 3635 would require MACs seeking to adopt another MAC's proposal to independently evaluate and consider the evidence needed to make a coverage determination. Further, H.R. 3635 would provide physicians and suppliers with a meaningful reconsideration process outside of the self-interested review of a MAC that finalized the LCD being objected to. Finally, nothing in H.R. 3635 would prevent an eligible aggrieved party from availing themselves of an administrative law judge.

We urge you to cosponsor H.R. 3635. It will improve Medicare's coverage process and ensure that patients can benefit from medical innovation. To cosponsor, please contact Elizabeth Stower in Rep. Kind's office at elizabeth.stower@mail.house.gov or Colin Brainard in Rep. Jenkins' office at colin.brainard@mail.house.gov.

Sincerely,

Advanced Medical Technology Association
American Academy of Neurology
American Academy of Allergy Asthma and Immunology
American Association of Clinical Urologists
American Association of Neurological Surgeons and Congress of Neurological Surgeons
American Association of Oral and Maxillofacial Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Mohs Surgery
American College of Rheumatology
American Congress of Obstetricians and Gynecologists
American Pathology Foundation
American Society for Plastic Surgeons
American Society for Radiation Oncology
American Society of Clinical Oncology
American Society of Clinical Pathology
American Society of Cytopathology
American Urological Association
Amputee Coalition
Association of Molecular Pathology
Association of Pathology Chairs
Coalition of State Rheumatology Organizations
College of American Pathologists
National Association of Spine Specialists
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
US Oncology Network

Arizona Society of Pathologists
California Society of Pathologists
Colorado Society of Pathologists
Connecticut Society of Pathologists
Delaware Society of Pathologists
Florida Society of Pathologists
Hawaii Society of Pathologists
Idaho Society of Pathologists
Illinois Society of Pathologists
Indiana Association of Pathologists
Iowa Association of Pathologists
Kansas Society of Pathologists
Louisiana Society of Pathologists
Maryland Society of Pathologists
Massachusetts Society of Pathologists
Minnesota Society of Pathologists
Mississippi Association of Pathologists
Nevada Society of Pathologists
New Hampshire Society of Pathologists
New Jersey Society of Pathologists
New Mexico Society of Pathologists
New York State Society of Pathologists
North Carolina Society of Pathologists
Oklahoma State Association of Pathologists
Oregon Pathology Association
Pennsylvania Association of Pathologists
South Carolina Society of Pathologists
South Dakota Society of Pathologists
Tennessee Society of Pathologists
Utah Society of Pathologists
Vermont State Pathology Society
Virginia Society for Pathology
Washington State Society for Pathologists
West Virginia Association of Pathologists
Wisconsin Society of Pathologists