Congress of the United States
Washington, DC 20515

October 1, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar and Administrator Verma:

The undersigned bipartisan Members of Congress write to express concerns about Medicare Administrative Contractors (MACs) denying patients' access to annual low dose Computed Tomography (LDCT) screens for early detection of lung cancer administered in Independent Diagnostic Testing Facilities (IDTF). Lung cancer remains the most deadly form of cancer in the United States, killing approximately 157,000 Americans annually. We are concerned that MACs are incorrectly interpreting provisions within the Centers for Medicare and Medicaid Services (CMS) issued National Coverage Determination (NCD) that governs access to LDCT lung cancer screens. Furthermore, the undersigned members fear these additional barriers will further exacerbate this troubling mortality trend.

CMS concluded in a February 2015 NCD that there was sufficient evidence for select Medicare beneficiaries at high risk of developing lung cancer to receive annual LDCT scans without any form of patient cost sharing, including copayments, coinsurance, or deductibles. In an unprecedented move ultimately supported by all affected stakeholders, the Agency also mandated that qualifying patients must undergo a one-time shared decision making visit with their treating physician, typically a primary care physician, prior to receiving their first LDCT lung cancer scan. Along with educating patients about the requirements associated with LDCT screens, such as the importance of adhering to annual screening schedule and the benefits and drawbacks of CT scans, the shared decision making visit includes intensive smoking cessation interventions.

One of the many mandates the NCD placed on qualifying radiology imaging facilities is the requirement to make "available smoking cessation interventions for current smokers." As a result, all imaging facilities offering LDCTs, including physician offices, hospital outpatient departments and IDTFs, provide written smoking cessation guidance for qualifying patients to review, if they choose.

Despite the seemingly straightforward NCD requirements for radiology imaging facilities, the underlying reasoning behind the MAC denials is a cause for confusion. At first, MACs stated that IDTFs are unable to perform LDCTs due to perceived prohibitions on any screening service being offered in this type of care setting. It appears the MACs ultimately withdrew denials based on this rationale due to the fact that IDTFs offer screening mammograms. Subsequent CMS communication clarified that patients are permitted to receive LDCTs in all care settings, as well. Nevertheless, MACs continue to deny patient access to LDCTs in IDTFs because they believe "making available smoking cessation interventions," which are distinct from the shared decision making visit, constitutes a therapeutic intervention. Since IDTFs are prohibited from offering therapeutic interventions, patients are forced to pay out-of-pocket for Medicare covered LDCTs received in this setting.

We are concerned that CMS is insisting that the only way to clarify the requirements for LDCT lung cancer screens in the IDTF setting is by reopening the existing NCD. In lieu of this burdensome, time

consuming approach, we urge CMS to issue a "Change Request Transmittal" clarifying that LDCT lung cancer screens, including requirements that smoking cessation interventions be made available to patients, do not constitute therapeutic interventions. Written materials to encourage smokers to stop tobacco use are utilized by physician offices, hospital outpatient departments, and IDTFs to meet the NCD requirements pertaining to "makes available smoking cessation interventions." The NCD as written is acceptable, but CMS does need to clarify what is meant by "makes available smoking cessation interventions" and that distribution of literature to patients is not a "therapeutic activity" that disqualifies IDTFs from performing these services. Since IDTFs are a byproduct of CMS regulations, issuing what essentially constitutes a technical clarification via a Change Request Transmittal will ensure patients can receive LDCT lung cancer screens in all accepted settings.

The unfortunate reality is that smokers at high risk of developing lung cancer are not receiving LDCTs. In 2016, fewer than 2 percent of the more than 7.6 million eligible patients were screened for lung cancer.[1] Further, the Centers for Disease Control and Prevention (CDC) found that "nonmetropolitan rural counties had higher incidence of and death from several cancers related to tobacco use and cancers that can be prevented by screening,"[2] indicating that this screening is needed most in rural areas. Continued access issues within the IDTF setting will only exacerbate these troubling trends.

Numerous bipartisan Members of Congress have closely monitored issues surrounding adequate availability of LDCTs and remain committed to ensuring that this life saving cancer screen remains fully accessible. For example, Congressional letters sent in September 2016 and June 2017, respectively, urged the Administration to balance access to care issues prior to implementing draconian reimbursement cuts to LDCTs via the Hospital Outpatient Prospective Payment System rulemaking process. In addition, in June 2014, more than 140 bipartisan Members of Congress signed a letter to the Department of Health and Human Services (HHS) urging prompt completion of the lung cancer screening NCD.

Expeditiously fixing access to care issues surrounding LDCTs remains our principal goal. We appreciate your consideration of our concerns and look forward to your response.

Sincerely,

JIM RENACCI
Member of Congress

BILL PASCRELL, JR.
Member of Congress

LARRY BUCSHON, M.D.
Member of Congress

JOHN B. LARSON
Member of Congress

[1] J Clinical Oncol 36, 2018 (suppl; abstr 6504). Accessed via: http://abstracts.asco.org/214/AbstView_214_221571.html
[2] Henley SJ, Anderson RN, Thomas CC, Massetti GM, Peaker B, Richardson LC. Invasive Cancer Incidence, 2004–2013, and Deaths, 2006–2015, in Nonmetropolitan and Metropolitan Counties — United States. MMWR Surveill Summ 2017;66(No. SS-14):1–13. DOI: http://dx.doi.org/10.15585/mmwr.ss6614a1.

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