



The Society
of Thoracic
Surgeons



September 6, 2016

Mr. Andrew M. Slavitt
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Lung Cancer Screening Section of the [2017 Proposed Rule](#) - Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

Dear Acting Administrator Slavitt:

The undersigned organizations, convened by the Lung Cancer Alliance (LCA), American College of Radiology, The Society of Thoracic Surgeons, and Medical Imaging and Technology Alliance (MITA), are pleased to provide comments on the impact of severe reductions in reimbursement to lung cancer screening G codes within the Calendar Year (CY) 2017 Hospital Outpatient Prospective Payment System Proposed Rule. If implemented, reimbursement for Codes G0296, low-dose CT lung cancer screening shared decision making session, and G0297 low-dose CT (LDCT) lung cancer screening, will be reduced by 64 and 44 percent, respectively, in comparison to 2016 payment rates. This diverse collection of patient advocacy groups, hospitals, national medical specialty societies, and trade associations representing imaging manufacturers, are deeply concerned about the impact of these reimbursement changes on patient access to lung cancer screening. **As a result, we urge the Centers for Medicare and Medicaid Services (CMS) to rescind these damaging cuts by retaining the current structure of the various Ambulatory Payment Classifications as established in the CY 2016 HOPPS Final Rule.**

More than 220,000 Americans are diagnosed with lung cancer each year resulting in more than 157,000 annual deaths from this disease. In fact, lung cancer remains the most deadly form of cancer in the United States, killing more people than breast, colon, and prostate cancer combined. Lung cancer is also the leading cause of cancer death in every racial and ethnic subgroup, as well as the leading cancer killer of women.

Despite these alarming statistics, lung cancer can often be successfully treated if caught early. Unfortunately, patients don't typically display symptoms of this deadly disease until the cancer is in its most advanced stages which are largely incurable and far more costly to treat than at an earlier stage. As a result, adoption of federal policies to promote widespread screening of at-risk populations using LDCTs is viewed as a critical way to combat lung cancer deaths in America.

Thankfully, over the past three years the effort to improve access to annual LDCT scans for patients at high risk of developing lung cancer received two major boosts. First, in December 2013, the United States Preventive Services Task Force (USPSTF) assigned a new, higher grade of "B" to annual LDCTs administered to asymptomatic patients who are at high risk of developing lung cancer.



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More specifically, the Task Force recommended that patients between the ages of 55 and 80 with at least 30-pack years (e.g. smoking one pack a day for 30 years; smoking two packs a day for 15 years, etc.) of smoking history should receive annual LDCTs to screen for suspicious lung nodules. Patients with a 30-pack year history of tobacco use who have quit smoking within the last 15 years were also deemed eligible to receive annual LDCTs.

Per the provisions of the Patient Protection and Affordable Care Act (PPACA), annual LDCTs for the patient populations outlined by the USPSTF would now be deemed an Essential Health Benefit. As a result, effective January 2014, private insurance companies selling non-grandfathered policies through the health insurance exchanges are required to cover annual LDCTs without copays, coinsurance, or deductibles.

The results of the National Lung Screening Trial (NLST), a randomized control trial of more than 53,000 high-risk patients between the ages of 55 and 74 conducted by the American College of Radiology Imaging Network (ACRIN) in conjunction with the National Cancer Institute (NCI), provided indisputable empirical evidence to the USPSTF regarding the benefits of screening patients with this advanced imaging modality. NLST started in 2002 and ultimately stopped in November 2010 when the LDCT arm achieved a 20 percent mortality benefit (the endpoint of the trial) over the standard x-ray arm. In addition to the overwhelmingly positive NLST data, subsequent detailed analyses by Milliman Inc. demonstrate that annual LDCT scans are more or equally cost effective than other accepted cancer screening interventions, including breast, cervical, and colorectal screenings. Additional studies have also indicated that the incorporation of tobacco cessation for those individuals still smoking— which is called for in all comprehensive guidelines— can further increase the cost effectiveness of lung cancer screening with cost benefits to CMS in treating other diseases, as well.

Given the decision by the USPSTF to assign a new, higher “B” grade to annual LDCTs for lung cancer screening, the LCA, ACR, and STS sought full coverage for the Medicare population, as well. Rather than automatically adopting the Task Force’s recommendation and granting immediate access to these services for qualifying beneficiaries, CMS elected to convene a National Coverage Determination (NCD) process for LDCTs. NCDs are a lengthy, time intensive effort by the agency to both solicit stakeholder feedback and review published scientific evidence regarding a particular procedure before issuing a final decision on whether the service will be offered to Medicare beneficiaries.

In light of the decision to conduct an NCD, in September 2014 LCA, ACR, and STS, convened many of the same cosigners of this document and worked diligently with CMS to develop and outline the key components of an effective lung cancer screening program. The lung cancer screening coalition was extremely pleased that CMS followed many of the recommendations outlined by our organizations and Medicare ultimately elected to cover annual LDCTs effective February 2015.

More specifically, CMS’ final NCD stipulated that asymptomatic patients (no signs or symptoms of lung cancer) between the ages of 55 and 77 could receive annual LDCT scans performed by qualifying radiologists. The final NCD also incorporated our organizations’ recommendation that physicians report lung cancer screening patient outcome data to a data registry, as well as utilize a structured reporting system to assist physicians with proper follow-up care if a suspicious nodule is detected. We also supported the requirement that patients with the necessary clinical characteristics undergo a shared decision making visit conducted by a primary care giver/treating physician in order to discuss the importance of smoking cessation, as well as the benefits and potential weaknesses of annual lung cancer screens, prior to receiving their initial scan.



Despite the recent policy victories focused on expanding access to annual LDCTs for patients covered either through private insurance or Medicare, the coalition is gravely concerned that the payment cuts included in the CY 2017 HOPPS Proposed Rule will effectively undermine these important accomplishments. Our collective organizations are perplexed and indeed quite astonished that these cuts came so quickly on the heels of the revised USPSTF grade and positive CMS NCD.

Quite simply, if the reimbursement rates for the shared decision making visit and corresponding LDCT scan are too low, it will be cost prohibitive for hospital outpatient departments and many will not be able to afford to offer these services at all. Furthermore, if the services are unavailable in the outpatient setting, qualifying patients will be unable to receive annual screens and the battle to combat lung cancer mortality will be severely undermined. This reality is especially troubling considering that numerous community based hospitals are just beginning to offer annual LDCT services to local patients.

Additionally, we urge CMS to recognize that these cuts will undoubtedly have the greatest negative impact on the underserved poor and minority patients due to their reliance on hospital outpatient departments located in inner cities or large geographic areas. In addition, the underserved poor and minority patients are some of the most vulnerable populations with the highest rates of lung cancer mortality. While undoubtedly unintended, CMS cannot ignore the inherent inequitable impact of these proposed cuts which are outlined in the chart below:

HCPCS Code	Descriptor	2016 APC	2016 Payment	2017 APC	2017 Payment	Dollar Difference	% Change
G0296	LDCT-LCS Shared Decision-making Session	5822	\$ 69.65	5821	\$ 25.09	-44.56	-64%
G0297	Low-dose Lung Cancer Screening	5570	\$ 112.49	5521	\$ 63.33	-49.16	-44%

We are very concerned that these steep cuts in reimbursement will prompt numerous hospital outpatient departments to either eliminate existing LDCT lung cancer screening services or discourage other facilities from taking the appropriate steps to offer this screening benefit to their local patient population in the future. By proposing these lower payment rates, CMS fails to recognize the additional time and effort involved in the shared decision making session, such as evaluating the patient and advising them of the screening process and smoking cessation options. The cuts also illustrate CMS's lack of recognition regarding elevated levels of time and work associated with administering an LDCT screen, including utilizing structured reporting materials and reporting clinical practice and patient information to data registries.

Based on information released through the CY 2017 HOPPS Proposed Rule, CMS cited 2015 geometric cost data for both the shared decision making visit and LDCT screen which, in turn, relegated these two codes to a Level 1 Ambulatory Payment Classification (APC). Prior to the release of this most recent regulation, both G0296 and G0297 were classified as Level 2 APCs and, as a result, grouped with other services that have a geometric mean cost of \$110. In comparison, services grouped within a Level 1 APC have a geometric mean cost of \$63. Our organizations request that CMS explain their rationale for the proposed APC restructure and why these codes fall into lower APCs which produce such devastating cuts.

The undersigned organizations strongly oppose the effort to group both the shared decision making and LDCT lung cancer screen codes as Level 1 APCs. We believe that CMS should maintain the current APC structure as it was finalized in the CY 2016 HOPPS Final Rule and maintain G0296 and G0297 in their current Level II APC assignments of 5582 and 5570, respectively. The agency's



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efforts to further restructure APCs causes instability throughout the HOPPS and CMS provides little to no explanation as to the rationale behind these changes, as well as whether these severe cuts are justified.

Finally, our collective organizations hope that CMS did not make these reimbursement reductions due to any lingering concerns about the large population of patients who would potentially qualify for this screening benefit. Although the United States has a large population of current and former smokers, the narrow age bracket (asymptomatic patients ages 55-77) and stringent clinical characteristics (30 pack-year smoking history or former smoker who quit within 15 years) issued by CMS through the NCD ensure that only the most vulnerable Medicare beneficiaries will ultimately receive annual LDCTs without cost-sharing. We urge the agency to rescind these reimbursement reductions by retaining the current structure of the various Ambulatory Payment Classifications as established in the CY 2016 HOPPS Final Rule. Implementation of these cuts will undoubtedly serve as a disincentive for hospital outpatient departments to offer this life saving screening benefit.

We greatly appreciate the opportunity to express our concerns with the lung cancer screening reimbursement cuts within the CY 2017 HOPPS Proposed Rule. Our organizations are confident that CMS will rectify this situation in the Final Rule and continue to demonstrate its strong commitment to expanded patient access to annual LDCT lung cancer screens. Should you have any questions or comments, please do not hesitate to contact Laurie Fenton Ambrose (lfenton@lungcanceralliance.org), President and Chief Executive Officer, Lung Cancer Alliance, Cynthia Moran (cmoran@acr.org), Executive Vice President, Government Relations, Economics, and Health Policy, American College of Radiology, Courtney Yohe (cyohe@sts.org), Director of Government Relations, The Society of Thoracic Surgeons, or Patrick Hope (phope@medicalimaging.org), Executive Director, Medical Imaging and Technology Alliance.

Sincerely,

ACMH Hospital (PA)
Academy of Radiology Research
Addison Gilbert Hospital (MA)
American Association of Physicists in Medicine
American College of Radiology
American College of Surgeons' Commission on Cancer
American Medical Association
American Roentgen Ray Society
American Society of Clinical Oncology
American Society for Radiation Oncology
Association for Quality Imaging
Association of University Radiologists
Blanchard Valley Health System
Brigham and Womens Health Care (MA)
Clark Memorial Hospital (IN)
Community Memorial Hospital (VA)
Cone Health Lung Cancer Screening Program (NC)
Dartmouth Hitchcock (NH)



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DeCesaris Cancer Institute at Anne Arundel Medical Center (MD)
 Diagnostic Imaging, NW (WA)
 Dignity Health--Central Coast Region (CA)
 Edward Cancer Center (IL)
 Excelsa Advanced Lung Cancer (PA)
 Franciscan St. Francis Health (IN)
 Greenville Health System Cancer Institute (SC)
 Grove City Medical Center (PA)
 Helen G. Nassif Community Center at St. Luke's Hospital (IA)
 Henry Ford Allegiance Health (MI)
 Henry Ford Health System
 Houston Methodist Hospital
 Kennedy Health (NJ)
 KentuckyOne Health
 John T. Mather Memorial Hospital (NY)
 John Muir Health (CA)
 Lahey Hospital and Medical Center (MA)
 Lahey Outpatient Center (MA)
 Legacy Health (OR)
 Long Beach Memorial Medical Center (CA)
 Lung Cancer Alliance
 Lung Cancer Screening Program at St. Joseph Hospital (CA)
 Massachusetts General Hospital
 Maimonides Medical Center (NY)
 Medical Imaging and Technology Alliance
 Medical University of South Carolina, Hollings Cancer Center
 Mercy Health Toledo Region (OH)
 Mercy Health Youngstown (OH)
 Mercy Fairfield Hospital (OH)
 National Comprehensive Cancer Network
 National Jewish Health
 Nebraska Methodist Hospital (NE)
 Northwell Health (NY)
 NYU College of Global Health
 Oakland University William Beaumont School of Medicine
 OhioHealth
 Our Lady of Lourdes Memorial Hospital (NY)
 Penn Medicine (PA)
 Penn Highlands Healthcare (PA)
 Phelps Memorial Hospital (NY)
 Pinnacle Health System (PA)
 Prevent Cancer Foundation
 Radiology Business Management Association
 Radiological Society of North America
 Roy and Patricia Disney Family Cancer Center at Providence St. Joseph Hospital Center (CA)
 Rush University Medical Center (IL)
 Rush Oak Park Hospital (IL)
 Saint Barnabas Lung Cancer Institute (NJ)
 St. Tammany Parish Hospital (LA)
 Salem Health (OR)



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Sarasota Memorial Health Care System (FL)

Sentara Cancer Network (VA)

Society of Thoracic Imaging

Society of Thoracic Radiology

Spectrum Health (MI)

SUNY at Stony Brook Medicine (NY)

The Society of Thoracic Surgeons

UC Davis Comprehensive Lung Cancer Screening Program (CA)

UC Health (OH)

UI Health Center at University of Illinois at Chicago (IL)

University Hospitals Seidman Cancer Center (OH)

University of Chicago

University of Virginia Emily Couric Clinical Cancer Center

Upstate Medical University

UT Health Northeast—Pulmonology Clinic (TX)

VCU Health Lung Cancer Screening Program (VA)

Windsong Radiology Group (NY)

Winthrop University Hospital (NY)



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