December 28, 2016

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

Re: Medicare Program: Lung Cancer Screening Section of the 2017 Final 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 Nonexcepted Off-campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital

Dear Acting Administrator Slavitt:

The undersigned organizations, convened by the Lung Cancer Alliance (LCA), American College of Radiology (ACR), The Society of Thoracic Surgeons, and Medical Imaging and Technology Alliance (MITA), are pleased to follow up with comments on reimbursement rates for lung cancer screening G codes within the Calendar Year (CY) 2017 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule. We offer comments on specific areas of the Final Rule as follows:

Although we appreciate that the Agency provided a slight payment increase for G0296, low-dose CT lung cancer screening shared decision making session, in comparison to 2016 rates, we are deeply disappointed that CMS retained the steep reimbursement reductions for G0297, low-dose lung cancer screening. In addition, CMS primarily relied on limited data collected in 2015 when formulating these final reimbursement rates. This diverse coalition of patient advocacy organizations, hospitals, national medical specialty societies, and trade associations representing imaging manufacturers reiterates its underlying concern that reimbursement rates outlined in the Final Rule will negatively impact patient access to life-saving screening procedures, with a disproportionate impact on low income and rural areas, and undermine the overarching battle against lung cancer. The undersigned entities implore CMS to increase the reimbursement for the lung cancer screening G codes after utilizing more robust claims data in the CY 2018 HOPPS rulemaking cycle. In particular, we urge CMS to restore the 2016 reimbursement rates for G0297.

With respect to the shared decision making visit, the coalition agrees with and applauds the Agency's decision to place G0296 in Ambulatory Payment Classification (APC) 5822 (Level 2 Health and Behavior Services) because it leads to a slight increase in reimbursement in comparison to 2016 payment rates, however, we disagree with CMS' underlying methodology. In fact, we believe that the 2017 reimbursement rate for the shared decision making visit outlined in the Final Rule is not reflective of the service's actual geometric mean cost or clinical similarity.

As you recall, in CY 2016 CMS assigned G0296 to APC 5822 with a corresponding payment rate of $69.65. Yet, in the CY 2017 HOPPS Proposed Rule, CMS cited 2015 geometric cost data for the shared decision making visit to relegate this code to a Level 1 APC. More specifically, the 2017 Proposed Rule shifted G0296 to APC 5821 with a corresponding payment rate of $25.09, which is equivalent to a 64 percent cut in comparison to 2016 payment rates. Ultimately, CMS did not implement the reimbursement changes outlined in the Proposed Rule. Instead, the CY 2017 HOPPS Final Rule reassigned G0296 back to APC 5822 but with a slightly higher corresponding payment rate of $70.23. In the end, instead of a 64 percent payment decrease, the shared decision making visit received close to a 1 percent increase in reimbursement.

Upon closer review of the excel spreadsheet addendums within the CY 2017 HOPPS Final Rule, it is clear that CMS is utilizing arbitrary and capricious reasoning to assign G0296 to APC 5822. First and foremost, CMS acknowledges in the CY 2017 Final Rule that it *did not* utilize 2016 claims data when it initially assigned G0296 to APC 5822 in 2016. In fact, G0296 was initially placed into APC 5822 in 2016 because it reflected the Agency's best estimate at an appropriate APC assignment in the absence of cost information. Presumably in light of the absence of quality 2016 cost data, CMS states in the CY 2017 Final Rule that it did an analysis of 21 claims from 2015 and found that the final geometric mean cost for G0296 is $130.44. Per Addendum A (excel spreadsheet entitled 2017 Final Addendum A 11.01.16) via the CMS website, the geometric mean costs for APC 5821 (Level 1 Health and Behavior Services), APC 5822 (Level 2 Health and Behavior Services) and APC 5823 (Level 3 Health and Behavior Services) are $25.22, $70.23, and $125.96, respectively. It is unclear and concerning to the coalition why CMS ultimately assigned the shared decision making visit to APC 5822 when its corresponding $70.23 payment rate is woefully below the $130.44 geometric mean cost cited in the CY 2017 HOPPS Final Rule. While we can appreciate the challenges associated with placing G0296 within an APC that may have different clinical similarity; it did not go unnoticed that CMS's own shared decision making claims data for 2015 exceeds the geometric mean for a Level 3 APC. As a result, the undersigned members remain confused by CMS' attempt to correlate G0296 with a Level 2 APC. The coalition supports the text of the CY 2017 HOPPS Final Rule, which indicates that CMS will reevaluate the APC assignment for the shared decision making visit during the CY 2018 rulemaking cycle. As CMS undertakes this effort, we would welcome the opportunity to review the methodology to provide input and data to assist in developing accurate evaluations.

Unfortunately, CMS utilized similar questionable principles when assigning G0297, LDCT screen, to a specific APC. In 2016, CMS placed G0297 into APC 5570 (Level 2 Imaging Without Contrast) with a corresponding payment rate of $112.49. Although this reimbursement rate did not accurately represent the additional time and effort associated with using structured reporting and contributing patient information into a data registry, the undersigned members largely supported this initial APC assignment because the payment level closely mirrored the HOPPS reimbursement rate for a diagnostic Chest CT without Contrast (HCPCS/CPT Code 71250), specifically $112.69. For comparison purposes, reimbursement for HCPCS/CPT Code 71250 in office setting, which is paid through the Medicare Physician Fee Schedule (MPFS), is $183.02.

The CY 2017 HOPPS Proposed Rule, however, proposed to reassign G0297 to APC 5521 (Level 1 Imaging Without Contrast), which has a lower associated payment rate of $63.33 and translates into a dramatic 44 percent reimbursement reduction in comparison to 2016 payment levels. Despite intense opposition from the undersigned members, CMS utilized the CY 2017 HOPPS Final Rule to further cut the actual LDCT screen. While the text of the Final Rule indicates that G0297 was reassigned to APC 5521 with a corresponding payment rate of $65.16, Addendums A and B (excel spreadsheet entitled 2017

Final Addendum B 11.01.16) posted on the CMS website reveals that APC 5521 is only reimbursed at $59.84.

Similar to the shared decision making visit, upon closer review of the Final Rule addendums, the Agency continues to make peculiar reimbursement decisions as it relates to the actual LDCT scan. Once again, CMS indicates in the CY 2017 Final Rule that it did not utilize 2016 claims data when it initially assigned G0297 to APC 5570 in 2016. Instead, the Agency elected to place G0297 in that particular APC because it represented their best pricing estimate in the absence of actual cost information. The Agency, however, did acknowledge that they utilized 2015 claims data when attempting to identify an appropriate APC for G0297 in CY 2017.

While CMS indicated in the Final Rule that the CY 2017 geometric mean cost for G0297 is $49.38, the text does not provide a total number of actual claims analyzed. The coalition is aware of an analysis on the Final Rule performed by The Moran Company for the American College of Radiology, which reveals that CMS used 35 single claims and initially came up with a geometric mean cost of $21 for G0297. In response, CMS analyzed an additional 3,940 claims which prompted the geometric mean cost to be increased to $49.38. Although we appreciate that the poor initial data prompted CMS to more thoroughly review the cost of the low-dose CT scan, the coalition strongly believes additional review is warranted. **Furthermore, the most surprising result of the Agency's final analysis is that the actual low-dose CT exam is now reimbursed at a lower rate than the shared decision making visit.** In addition, the coalition is aware that many submitted claims which utilized ICD-9 information due to the date of service occurring prior to the transition to ICD-10 were ultimately denied due to coding errors. It appears that CMS denied these claims without providing special accommodations surrounding the unusual circumstances characterizing the ICD-10 transition.

In general, our respective organizations remain deeply concerned that CMS is reluctant to follow stakeholder guidance and wait to alter the existing APC assignment for G0297 until hospitals can submit ample claims data gathered over a two year period. The coalition is displeased that CMS did not properly incorporate the principle of clinical similarity when assigning G0297 to APC 5521. Finally, the undersigned members are equally troubled that, unlike with the shared decision making visit, CMS did not include a similar comment that it would reevaluate the APC assignment for this procedure during the CY 2018 HOPPS rulemaking cycle. The coalition strongly urges CMS to utilize the upcoming HOPPS rules to review G0297 reimbursement rates.

The undersigned cosigners would like to reiterate our underlying concerns that inadequate reimbursement rates for the shared decision making visit and corresponding LDCT scan will make it cost prohibitive for hospital outpatient departments to offer these services. 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 and screening centers serving rural areas are just beginning to offer annual LDCT services to local patients.

Additionally, we urge CMS to recognize that finalizing 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, rural 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 cuts.

We greatly appreciate the opportunity to express our concerns with the lung cancer screening reimbursement cuts within the CY 2017 HOPPS Final Rule. The coalition stands ready to work with CMS to implement changes and improve these outcomes. In addition, the coalition will be closely monitoring CMS' decisions pertaining to G0296 and G0297 in the CY 2018 rulemaking cycle. 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,

Academy of Radiology Research (ARR)
Affiliated Community Medical Center (MN)
Aiken Regional Medical Center (SC)
American Association of Physicists in Medicine (AAPM)
American College of Radiology (ACR)
American College of Surgeons' Commission on Cancer
American Healthcare Radiology Administrators (AHRA)
American Roentgen Ray Society (ARRS)
American Society for Radiation Oncology (ASTRO)
American Society of Clinical Oncology (ASCO)
Angel Medical Center (NC)
Anne Arundel Medical Center (MD)
Associated Radiologists of Flint (MI)
Association for Quality Imaging (AQI)
Association of Community Cancer Centers (ACCC)
Association of University Radiologists (AUR)
Baptist Health (FL)
Baptist Memorial Hospital (TN)
Berger Health System (OH)
Beth Israel Deaconesses Medical Center, Harvard Medical School (MA)
Beverly Hospital (MA)
Blanchard Valley Health System (OH)
Blue Ridge Regional Hospital (NC)
Boulder Community Health (CO)
Bradford Regional Medical Center (PA)
Carle Foundation Hospital (IL)
Carteret Healthcare Department of Radiology (NC)
Catholic Health Initiatives (National)
Center for Cancer Prevention and Treatment at St. Joseph Hospital (CA)
Central Oregon Radiology Associates, P.C. (OR)
Central Peninsula Hospital (AK)
Centrastate Medical Center (NJ)

Christiana Care Health System (DE)
Cone Health Lung Cancer Screening Program (NC)
Cullman Primary Care, PC (AL)
Dartmouth-Hitchcock (NH)
Delaware Diagnostic Imaging (DE)
Diagnostic Radiology Center of the Treasure Coast, Inc. (FL)
Dignity Health St. Joseph's Hospital (AZ)
DLP Conemaugh Memorial Medical Center (PA)
Doctors Imaging Services, LLC. (LA)
DuPage Medical Group (IL)
East Coast Florida Outpatient Imaging (FL)
Edward-Elmhurst Healthcare (IL)
Elmhurst Memorial Hospital (SC)
Fairfax Radiological Consultants, P.C. (VA)
Florida Hospital and Memorial Medical Center
Florida Hospital Fish Memorial
Florida Hospital—Deland (FL)
Florida Hospital—Flager (FL)
Florida Medical Clinic
Fox Chase Cancer Center (PA)
Georgia Radiology Associates (GA)
Good Samaritan Hospital (IN)
Great Lakes Medical Imaging (NY)
Greenville Health System Outpatient Radiology (SC)
Grove City Medical Center (PA)
Hallmark Health System (MA)
Haywood Regional Medical Center a Duke LifePoint Hospital (NC)
Henry Ford Health System (MI)
Hills and Dales General Hospital (MI)
Hollings Cancer Center, Medical University of South Carolina
Holmdel Imaging (NJ)
Jennie Edmundson Hospital (IA)
John Muir Health (CA)
John T. Mather Memorial Hospital (NY)
Kalispell Regional Healthcare (MT)
Karmanos Cancer Institute (MI)
Keck Medical Center of USC (CA)
Kennedy Health (NJ)
KentuckyOne Health (KY)
Lahey Hospital and Medical Center (MA)
Lake Radiology, Inc. (FL)
Lake Regional Imaging Center (MO)
Lehigh Valley health Network (PA)
Lung Cancer Alliance (LCA)
Maimonides Medical Center (NY)
Mainline Health (PA)
Massachusetts General Hospital
Maui Medical Group (HI)
Mayo Clinic Florida

Meadville Medical Center (PA)
Medical College of Wisconsin (WI)
Medical Imaging and Technology Alliance (MITA)
Memorial Hermann Health System (TX)
Mercy Fairfield Hospital (OH)
Mercy Health- Youngstown (OH)
Mercy Medical Center (MA)
Meridian Imaging (NJ)
Methodist Diagnostic Center-Midtown (TN)
Mission Imaging Services-534 (NC)
Mission Imaging Services—MPHC (NC)
Mohawk Glen Radiology Associates (NY)
National Hispanic Medical Association
National Jewish Health
National Rural Health Association
Naugatuck Valley Radiology (CT)
Nebraska Methodist Health System
Neuroskeletal Imaging and Central Florida Imaging Specialists (FL)
NJIN of Edison, Cranford, and Menlo Park (NJ)
North Country Hospital (VT)
Northwell Health (NY)
Northwest Community Hospital (IL)
Northwest Hospital and Medical Center (WA)
Oakland University William Beaumont School of Medicine (MI)
Open MRI of Longview (TX)
Penn Highlands DuBois (PA)
Penn Medicine (PA)
Pennsauken Diagnostic Center (NJ)
Phelps Hospital (NY)
Premier Radiology (TN)
Prevent Cancer Foundation
Providence Health and Services (CA)
Punxsutawney Area Hospital (PA)
Quantum Radiology (GA)
Radiological Society of North American (RSNA)
Radiologist Specialists of Florida (FL)
Radiology and Imaging of South Texas
Radiology Associates of Ridgewood, P.A. (NJ)
Radiology Associates of Tallahassee (FL)
Radiology Associates of Wausau, S.C. (WI)
Radiology Associates of West Pasco (FL)
Radiology Associates, LLP (TX)
Radiology Business Management Association (RBMA)
Radiology Group, PC, SC (IA)
Radiology Specialists of the Northwest (OR)
Red River Valley Radiology Associates (TX)
Riddle Hospital (PA)
Rush Oak Park Hospital (IL)
Rush University Medical Center (IL)

Saint Francis Hospital (WV)
Saint Joseph Health System- Plymouth Medical Center (IN)
Salem Radiology Consultants, PC (OR)
Seattle Cancer Care Alliance (WA)
Seattle Radiologists (WA)
Sentara Belleharbour Ambulatory Imaging Center (VA)
Sentara Obici Hospital (VA)
SMG Compass Imaging (MA)
Society of Computed Body Tomography and Magnetic Resonance (SCBT-MR)
Society of Thoracic Radiology (STR)
SouthCoast Health Imaging (GA)
Southeast Radiology, LTD. (PA)
Southern Ohio Medical Center (OH)
Southwest X-Ray, LP (TX)
SSM Health: St. Joseph Hospitals- St. Charles and Lake St. Louis (MO)
St. Cloud Hospital, CentraCare Health (MN)
St. Elizabeth Healthcare (KY)
St. Francis Health (KS)
St. Rita's Medical Center (OH)
St. Tammany Parish Hospital (LA)
St. Vincent's Health System (AL)
Stillwater Medical Center (OK)
Suburban Radiologic Consultants (MN)
Susquehanna Valley Diagnostic Imaging (PA)
The Imaging Institute (RI)
The Jewish Hospital Mercy Health (OH)
The McDowell Hospital (NC)
The Ohio State University Wexner Medical Center
The Society of Thoracic Surgeons (STS)
The Valley Hospital (NJ)
Thomas Imaging Center (WV)
Thomas Jefferson University Department of Radiology (PA)
Thomas Memorial Hospital (WV)
Tidelands Health (SC)
Toll Gate Radiology II, LLC (RI)
Trident Medical Center (SC)
UCLA, Department of Radiological Sciences
Union Hospital of Cecil County (MD)
Unity Point, Trinity Medical Center (IL)
University Hospitals Seidman Cancer Center (OH)
University of Alabama at Birmingham
University of Arizona Cancer Center
University of Chicago Medicine
University of Illinois at Chicago
University of Illinois Hospital and Health Science System
University of Miami Hospital and Clinics
University of Minnesota Health Lung Cancer Screening Program
University of Vermont Health Network, Champlain Valley Physicians Hospital
University of Virginia Health System

University of Washington Medical Center
University of Wisconsin School of Medicine and Public Health
Upstate Medical University (NY)
VCU Health Community Memorial Hospital (VA)
VCU Health Early Detection Lung Cancer Screening Program (VA)
Virginia Mason Medical Center
Wadley Advanced Imaging (TX)
Wake Radiology Associates (NC)
Watertown Regional Medical Center (WI)
WellSpan Good Samaritan Hospital (PA)
WellStar Health System (GA)
Westmed Medical Group (NY)
Windber Hospital, Inc. (PA)