RE: CMS-1656-P: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Acting Administrator Slavitt:

The American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE) welcome the opportunity to provide comments on CMS’ proposed rule (CMS-1656-P), published in the Federal Register on July 14, 2016, regarding changes to the hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system for calendar year (CY) 2017. Our three societies represent virtually all practicing gastroenterologists in the United States.

Our societies offer comments on the following areas of the proposed rule:

- Comprehensive Ambulatory Payment Classifications (C-APCs)
- APC Payment Issues Regarding Specific Codes
- Medicare Electronic Health Record Incentive Program (Meaningful Use) Proposals
- ASC Annual Update and Consumer Price Index for Urban Consumers (CPI-U)

Comprehensive Ambulatory Payment Classifications (C-APCs)

Our societies urge CMS to delay the creation of additional C-APCs for gastrointestinal (GI) procedures until stakeholders and the Agency have enough time to vet and review the impact of the CY 2016 changes for the C-APC GI stent procedures.

In CY 2016, CMS implemented a complete restructuring of APCs that included C-APC 5331 “Complex GI Procedures” for 12 GI endoscopy procedures involving stent procedures. The
effects of this transition have yet to be analyzed. In addition to this transition, GI endoscopy services recently underwent a major revision in the CPT codes to report services. For CY 2017, CMS proposes to add three additional C-APCs for GI procedures impacting a total of 79 GI endoscopy procedures. This constitutes a major change in the reporting structure for C-APCs. Such a massive movement of GI services and codes into C-APCs in the year immediately following implementation of a complete reconfiguration of APC families does not allow for analysis of the changes made in 2016. Sufficient time should be allowed for the Agency and stakeholders to analyze the impact of the APC restructuring and the stent C-APCs before another major change is implemented. Given that the procedure cost data used to develop proposed inputs for APCs are from the last 18 months, we are concerned that CMS does not have the appropriate inputs needed to further develop additional APCs at this time. Our societies urge CMS to delay development of additional APCs until more long-term cost data can be collected and analyzed.

We are also concerned that implementing additional APCs at this time will directly impact the costs captured to calculate future payments and may significantly impact the primary and adjunctive services over time. This impact is due to coding changes and individual hospital charge master changes in which facilities may not code for all elements of the service packaged in the C-APC. As a consequence of additional APCs, facilities may not realize that they have services which have gone unaccounted, and thereby result in inappropriately low payments. To alleviate this potential issue, we recommend that CMS delay finalizing C-APC 5302 and C-APC 5303 until CMS and stakeholders are able to assess the impact from C-APC 5331.

APC Payment Issues Regarding Specific Codes

HCPCS/CPT Codes G0105, G0121, 44388, 45378: A New Screening/Diagnostic Colonoscopy APC

Our societies urge CMS to correct what we believe is a mistake in this proposed rule in APC assignments involving screening and diagnostic colonoscopy procedures. CMS has proposed to move HCPCS codes G0105 (Colorectal cancer screening; colonoscopy on individual at high risk) and G0121 (Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk) into APC 5525 – Level 3 Diagnostic Radiology with Contrast. These services are not radiology services and have different cost centers and resources as well as clinical usage. CMS also proposes to move CPT codes 44388 (Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 45378 (Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) from APC 5312 (Level 2 Lower GI Procedures) to 5311 (Level 1 Lower GI Procedures). However, our societies are concerned that CMS did not provide a rationale in the proposed rule for the movement of these services to these different APCs. We are concerned that decreasing facility fees for colorectal cancer screening colonoscopy as well as the diagnostic colonoscopy subsequent to other colorectal cancer screening tests covered under Medicare sends the wrong message to beneficiaries and the public about CMS’ commitment to improve colorectal cancer screening rates and reduce the incidence of this devastating cancer, which has a five-year life expectancy of <5% if not detected early.
To reconcile this error, maintain clinical and resource homogeneity, and to support and enhance the public policy goal of colorectal cancer prevention by screening and diagnostic colonoscopy, our societies recommended that the Agency develop a new APC that includes screening colonoscopy procedures G0105 and G0121 as well as the necessary diagnostic colonoscopy procedures 44388 and 45378 subsequent to another colorectal cancer screening test as recommended by the U.S. Preventive Services Task Force and covered by CMS (i.e., fecal occult blood test (FOBT), fecal immunochemical test (FIT), or flexible sigmoidoscopy) to complete the continuum of care for colorectal cancer screening.1

Numerous stakeholders have divided the various screening modalities into “colorectal cancer prevention” versus “colorectal cancer detection.” The U.S. Multi Society Task Force (MSTF) on Colorectal Cancer Screening, together with the American Cancer Society and the American College of Radiology, concluded that colorectal cancer prevention is the preferred strategy and primary goal of colorectal cancer detection.2 The MSTF concluded that complete optical colonoscopy is required to confirm positive findings in all other colorectal cancer prevention and detection tests; this includes stool detection tests and flexible sigmoidoscopy.3 Coupled with recent cuts to the Medicare professional fees for diagnostic and screening colonoscopy procedures, these proposed reductions in the facility payment for colonoscopy services may have a significant impact on the availability of these services in the ASC setting, as ASCs are reimbursed by Medicare an average of 54 percent of the hospital outpatient rate. Our societies are concerned that the proposed assignment of diagnostic and screening colonoscopy procedures to APCs without resource and/or clinical coherence will shift the performance of these procedures from the ASC to the hospital setting if movement of these procedures to the proposed APCs is implemented, with a corresponding overall increase in costs to Medicare.

Our societies and over 1,000 public and private organizations, including the Centers for Disease Control and Prevention and many state departments of health, have joined together in the common goal of screening 80 percent of eligible Americans by 2018.4 While the Secretary has the authority to exclude from the OPPS certain services, including payment for screening and diagnostic mammography, it is important to note that more Americans (male and female) will die

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3 A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. Page 144.
from colorectal cancer in 2016 than any other cancer other than lung cancer, according the American Cancer Society. 5,6

Our societies believe that creation of a new APC category specific to colonoscopy for colorectal cancer screening and diagnosis after another Medicare-covered colorectal cancer screening procedure will help stakeholders to meet this public policy goal of “80% by 2018” while maintaining clinical and resource coherence within OPPS.

Proposed APC assignment for tube placement services and impact on APC 5301
We are concerned that CMS has moved several tube placement services which lack clinical and resource coherence into APC 5301 (Level 1 Upper GI Procedures). For example, CPT code 32561 (Installation of chest tube catheter; initial day) and 32562 (Installation of chest tube catheter; subsequent day) are services performed by pulmonologists and thoracic surgeons, not gastroenterologists and others who perform GI endoscopic procedures. CPT codes proposed for APC 5301 include:

- 32561 (Installation of chest tube catheter; initial day)
- 32562 (Installation of chest tube catheter; subsequent day)
- 32552 (Removal of indwelling tunneled pleural catheter with cuff)
- 32554 (Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance)
- 32555 (Thoracentesis, needle or catheter, aspiration of the pleural space; with imaging guidance)
- 32560 (Instillation, via chest tube/catheter, agent for pleurodesis (e.g., talc for recurrent or persistent pneumothorax))
- 32960 (Pneumothorax, therapeutic, intrapleural injection of air)
- 36575 (Repair of tunneled or non-tunneled central venous access catheter, without subcutaneous port or pump, central or peripheral insertion site)
- 36589 (Removal of tunneled central venous catheter, without subcutaneous port or pump)

The above services lack clinical and resource coherence with the other GI endoscopic procedures in this APC. They are in different cost centers within the hospital facility, require different staff, supplies, and equipment when compared to the services in APC 5301. Our societies seek guidance on why these vascular and thoracic services have been proposed for an APC which is clinically focused on upper GI procedures. Without rationale, we urge CMS not to finalize these proposed APC assignments.

5 Medicare Program: 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. CMS-1656-P. https://www.federalregister.gov/articles/2016/07/14/2016-16098/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment
APC Placement for 43240
Our societies request movement of CPT code 43240 (Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed) from C-APC 5303 (Level 3 Upper GI Procedures) to C-APC 5331 (Complex GI Procedures). Code 43240 includes the performance of the EGD and endoscopic ultrasound, endoscopic placement of stents and transmural drainage of the pancreatic pseudocyst. This procedure is a complex, multistep stent placement procedure which is similar in clinical coherence and resource utilization with all of the other GI endoscopic stent procedures currently placed in C-APC 5331. We urge CMS to recognize this discrepancy and to move code 43240 to C-APC 5331.

Medicare Electronic Health Record Incentive Program (Meaningful Use) Proposals
Our societies applaud CMS for proposing a change the Meaningful Use reporting period in 2016 from the full CY 2016 to any continuous 90-day period within CY 2016 for returning participants. We also applaud CMS proposing to allow all eligible professionals to apply for a significant hardship exception from the 2018 payment adjustment, for those eligible providers who have not successfully demonstrated Meaningful Use in a prior year but intend to attest to Meaningful Use for the 2017 reporting year (when MIPS starts).

These proposals will help ease the transition into the Merit-Based Incentive Payment System (MIPS). For example, the MIPS burden estimates for smaller practices are quite alarming. According to the data in the MIPS proposed rule, less than 50% of practices with 10-24 providers will receive a positive MIPS adjustment. These estimates are even more disturbing as the practice size gets smaller. Roughly 30% of practices with 2-9 eligible providers and merely 3% of solo-practitioners will receive a positive adjustment. As CMS is aware, these solo providers and small practices will also be required to participate in MIPS even if they want to enroll in any advanced alternative payment model in future years. Reviewing CMS’ burden and cost estimates also further highlight this dire predicament for small practices. The “Advancing Care Information” category will require an estimated 4 hours in time and $182 in costs per eligible MIPS clinician.

Our societies share the goal of reducing electronic health record reporting burdens among practicing gastroenterologists and other GI clinicians and believe these recommendations will advance this shared goal of lowering practice management burdens while increasing quality of patient care. Thus, we urge CMS to finalize these proposals.

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7 CMS-5517-P: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models
8 CMS-5517-P: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models
ASC Annual Update and Consumer Price Index for Urban Consumers (CPI-U)

Our societies urge CMS to replace the CPI-U with the hospital market basket as the update mechanism for ASC payments.

The OPPS update is based on the Inpatient Hospital Market Basket (HMB), which is comprised of data that reflects the cost of items and services necessary to furnish an outpatient surgical procedure and has historically been higher than the CPI-U, the update factor used for ASCs. As our societies have previously noted, CPI-U is not a suitable inflation index to update ASC payments because it does not accurately represent the costs borne by facilities to furnish surgical procedures. The CPI is an index that measures the average change over time in the price of consumer goods – “goods and services that people buy for day-to-day living.” The CPI-U represents the buying habits of the residents of the urban or metropolitan areas in the United States, not the ever-increasing costs of operating a health care facility. In addition to not being representative of the inflationary costs ASCs face, the CPI-U can fluctuate greatly up or down throughout the year, so CMS cannot provide a reliable sense of how ASC final payments will be impacted for the coming year.

CMS acknowledges year after year in the OPPS/ASC payment rule that they are not statutorily required to adopt any particular update mechanism, so they continually default to the CPI-U, since the CPI–U must be used in the absence of any update implemented by the Secretary. According to the Medicare Payment Advisory Commission (MedPAC), growth in ASCs since 2009 has been relatively slow with roughly 100 centers merging or closing per year.9 This slower growth in the number of ASCs for CY 2009-2014 may be due in part to, according to MedPAC, the substantially higher rates that Medicare pays for ambulatory surgical services in the hospital outpatient departments than in ASCs. Since upper and lower endoscopy are among the most common procedure performed in the ASC setting, our societies fear that the consequences of CMS’s inaction have led to increased migration of GI endoscopic services to the hospital setting, resulting in higher costs for the Medicare program and its beneficiaries. Therefore, we urge CMS to replace the CPI-U with the hospital market basket as the update mechanism for ASC payments.

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9 MedPAC; Medicare and Health Care Spending, June 2016
SUMMARY OF RECOMMENDATIONS

Comprehensive Ambulatory Payment Classifications (C-APCs)
- Delay the creation of additional C-APCs for gastrointestinal (GI) procedures until stakeholders and the Agency have enough time to vet and review the impact of the CY 2016 changes for the C-APC GI stent procedures.
- Delay development of additional APCs until more long-term cost data can be collected and analyzed.
- Delay finalizing C-APCs 5302 and 5203 until CMS and stakeholders are able to assess the impact from C-APC 5331.

APC Payment Issues Regarding Specific Codes
- Correct CMS’ proposed APC assignment involving screening and diagnostic colonoscopy procedures G0105 and G0121 by removing them from APC 5525 (Level 3 Diagnostic Radiology with Contrast).
- Develop a new APC that includes screening colonoscopy procedures G0105 and G0121 as well as the necessary diagnostic colonoscopy procedures 44388 and 45378 subsequent to another colorectal cancer screening test to complete the continuum of care for colorectal cancer screening.

Proposed APC Assignment for Tube Placement Services and Impact on APC 5301
- Remove tube placement services 32960, 32552, 32554, 32555, 32560, 32561, 32562, 36575, and 36589 from APC 5301 (Level 1 Upper GI Procedures) as these are services performed by pulmonologists and thoracic surgeons, not gastroenterologists and others who perform gastrointestinal endoscopic procedures, and they lack clinical and resource coherence with other codes in the APC.

APC Placement for 43240
- Move 43240 from C-APC 5303 (Level 3 Upper GI Procedures) to C-APC 5331 (Complex GI Procedures) as this is a complex, multistep stent placement procedure which is similar in clinical coherence and resource utilization with all of the other GI endoscopic stent procedures currently placed in C-APC 5311.

Medicare Electronic Health Record Incentive Program (Meaningful Use) Proposals
- Finalize CMS’ proposals for changes to the Meaningful Use reporting period in 2016 for returning participants from the full CY 2016 to any continuous 90-day period within CY 2016 and for allowing all eligible professionals to apply for a significant hardship exception from the 2018 payment adjustment, for those eligible providers who have not successfully demonstrated Meaningful Use in a prior year but intend to attest to Meaningful Use for the 2017 reporting year (when MIPS starts).

ASC Annual Update and Consumer Price Index for Urban Consumers (CPI-U)
- Replace the CPI-U with the hospital market basket as the update mechanism for ASC payments.
CONCLUSION

If we may provide any additional information, please contact Brad Conway, Vice President of Public Policy, Coverage & Reimbursement, ACG, at 301-263-9000 or bconway@gi.org; Leslie Narramore, Director of Reimbursement, AGA, at 410-349-7455 or lnarramore@gastro.org; or Lakitia Mayo, Director of Health Policy and Quality, ASGE, at 630-570-5641 or lmayo@asge.org.

Sincerely,

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