



September 24, 2018

Seema Verma, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: [CMS-1695-P] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

The American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) welcome the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1695-P), published on July 31, 2018 in the *Federal Register*, regarding the proposed policy revisions to the CY 2019 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems. Together our societies represent virtually all practicing gastroenterologist in the United States.

There are number of provisions in the proposed rule that impact the practice of gastroenterology, particularly in the ASC setting, and the Medicare beneficiaries we serve. Below, we offer comments that address these areas.

ASC Inflationary Update

Our societies recognize that high quality gastrointestinal endoscopy can be safely performed in a variety of settings, including the physician office, the ASC and the hospital outpatient department (HOPD) based on the individual needs of the patient.

The ASC is an important part of the practice of gastroenterology, providing a safe, patient friendly and cost-effective environment for the provision of medical services. The majority of ASCs in which gastroenterologists practice are single specialty centers. However, ASCs across the country range in size and the specialty of care provided.

Our societies applaud CMS for its proposal to replace the Consumer Price Index for All Urban Consumers (CPI-U) with the Hospital Market Basket (HMB) as the annual inflationary update for ASC payments for calendar years 2019-2023. Using the same inflationary update factor for HOPDs and ASCs improves ASC payment predictability, lessens the payment gap between the two sites of service and allows ASCs to compete on a more leveled playing field with HOPDs for nursing and other health care professionals. **We support use of the HMB as the annual inflationary update for ASC payments and urge CMS to make this change permanent.**

Evaluation of Hospital Market Basket for ASCs

During the five-year period, CMS proposes to evaluate if the HMB is an appropriate proxy for ASC costs. The HMB is a better proxy for ASC costs than the CPI-U. As mentioned in our previous comments, ASCs must purchase the same equipment, devices and implants as hospitals to perform procedures. In fact, smaller ASCs often pay more, since they do not have the same purchasing power of a hospital or large health system. While there are other indices found in the CPI and Medicare Economic Index, the HMB is the most appropriate update factor for the ASC Payment System.

We recognize that ASC cost data may help the agency better understand ASC costs. However, implementing a cost reporting system for ASCs would add to already excessive administrative burdens facing ASCs. Keeping with CMS' initiative to put "Patients Over Paperwork," we urge the Agency to work with ASCs to develop alternate approaches for identifying ASC costs. We welcome the opportunity to work with CMS as it develops a solution for understanding ASC costs in the least burdensome manner.

Site-Neutrality

While ASCs are a more efficient and lower-cost alternative to the HOPD for a number of gastroenterology procedures, it does not mean, however, that reimbursement rates for services provided in both the ASC and the HOPD should be the same. Our societies support payment rates appropriate for each site of service and using appropriate policy and payment levers that result in patients receiving care in the most cost-efficient site of service.

Existing ASC payment structures do not adequately capture the costs of procedures that could otherwise be routinely performed in an ASC, such as endoscopic mucosal resection, endoscopic ultrasonography, variceal banding, endoscopic ablation, stenting, and gastrostomy tubes. The cost of providing these services exceeds current Medicare reimbursement in the ASC setting. Our societies look forward to further discussions with CMS on payment approaches that would allow these and other procedures to be routinely provided in the ASC, which will also serve to improve access for patients.

In the proposed rule, CMS states that it is moving ASCs to the HMB to help promote site-neutrality between HOPDs and ASCs and to encourage migration of services from the hospital back to the ASC. Payment for care provided in the HOPD, ASC and office should reflect the differential costs of providing care in each of these sites of service. Furthermore, reducing HOPD rates to ASC payment levels assumes current ASC payments are adequate. Inadequate ASC payment drives provider consolidation, discourages ASC expansion, and shifts patients from the ASC to the HOPD.

The HOPD may also be the preferred site of service for patients undergoing urgent endoscopic procedures or those with greater comorbidities undergoing elective procedures. Therefore, our societies consider it appropriate that procedures performed in the HOPD setting generate higher facility fees than procedures identified by the same Current Procedural Terminology (CPT) codes when performed in the ASC.

Applying the Hospital Adjustment to ASC Payment

CMS requested feedback on if it should apply the Affordable Care Act-mandated hospital adjustment of 0.75 to ASCs now that this site of service is being updated by the HMB. The ACA did not authorize the application of an additional adjustment to ASCs. Since, ASCs were specifically excluded from this adjustment, applying such adjustment to these facilities would be contrary to current law. **Thus, we agree with CMS that the adjustment should not be applied to ASCs.**

ASC Weight Scalar

We urge CMS eliminate the secondary scalar for ASCs and to apply the OPPS relative weights to services provided in the ASC.

While changing the inflationary update used for the ASC will decrease the gap in payment between the ASC and hospital setting, the secondary scaling of ASC weights will continue to cause a divergence in payment between the two sites of service. CMS updates the ASC relative payment weights each year using the national OPPS relative payment weights. CMS had adopted a policy whereby the ASC relative payment weights are scaled to achieve year-to-year budget neutrality in the ASC payment system. In contrast, the OPPS relative weights reflect real growth in the relative cost of services performed in the HOPD. Conceptually, the annual change in relative weights should move in the same direction in both the ASC and HOPD settings. However, the secondary rescaling process applied in the ASC payment system is not working appropriately and is causing an ongoing divergence in the ASC weights. Since the inception of the rescalar in 2009, there has never been an increase ASC relative weights. For CY 2019, CMS is proposing an ASC weight rescalar of 0.8854, which is lower than the 2018 final ASC weight rescalar of 0.8995. If finalized, ASCs will have experienced a 11.5 percent reduction in the scalar since 2009. Based on past trends, we only foresee the secondary rescalar further eroding the relationship of HOPD and ASC payments for the same set of services.

ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2019

Our societies support CMS' proposal to lower the device offset percentage threshold from 40 percent to 30 percent for CY 2019 and subsequent years and we urge the Agency to finalize this proposal.

ASC Covered Ancillary Services

Under the ASC Payment System certain diagnostic tests within the medicine range of CPT codes (90000 to 99999) for which separate payment is allowed under the OPPS are ASC covered ancillary services when they are integral to an ASC covered surgical procedure.

As such, we request that CMS add CPT code 91040 (*Esophageal balloon distension study, diagnostic, with provocation when performed*) to the list of ASC covered ancillary services. This diagnostic procedure falls within the allowed CPT range, separate payment is allowed under the OPPS and it is integral to a number of procedures that are performed in the ASC, including several esophagogastroduodenoscopy services (CPT codes 43235, 43236 and 43239).

Definition of ASC Covered Surgical Procedures

Since 2008, CMS has defined ASC covered surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that CMS has determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and are separately paid under the OPSS.

For CY 2019, CMS is proposing to revise its definition of surgery to include certain “surgery-like” procedures that are assigned codes outside the CPT surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range that have been determined to not pose a significant safety risk and would not require an overnight stay when performed in an ASC. Our societies support this proposal. However, as we stated in our comments last year, **our societies recommend that CMS further revise the definition of an ASC covered surgical procedure to include invasive procedures that do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and are separately paid under the OPSS.** Expanding the definition to include other invasive procedures would better accommodate not only existing procedures, but also future procedures made available through technical advances. **Moreover, broadening the definition to allow invasive procedures to be performed in an ASC (in addition to a HOPD), would permit these services to be performed in the more efficient, lower cost ASC setting, which may reduce Medicare spending and lower beneficiary out-of-pocket costs for these services.**

Annual Update to the ASC List

As CMS undertakes its annual update to the ASC list of covered surgical procedures and covered ancillary services and considering the interest in expanding the scope of covered services, we again request that CMS include on the list of ASC codes that are eligible for separate payment the 15 codes shown in Table 1.

Table 1

CPT Code	Descriptor	Rationale
91010	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report;	Invasive procedure involving placement of probes or catheters into a body cavity
91013	Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with stimulation or perfusion (eg, stimulant, acid, or alkali perfusion)	Invasive procedure involving placement of probes or catheters into a body cavity
91020	Gastric motility (manometric) studies	Invasive procedure involving placement of probes or catheters into a body cavity

CPT Code	Descriptor	Rationale
91022	Duodenal motility (manometric) study	Invasive procedure involving placement of probes or catheters into a body cavity
91030	Esophagus, acid perfusion (Bernstein) test for esophagitis	Invasive procedure involving placement of catheter into a body cavity; performed in conjunction with other invasive procedures
91034	Esophagus, gastroesophageal reflux test; with nasal catheter pH electrode(s) placement, recording, analysis and interpretation	Invasive procedure involving placement of probes or catheters into a body cavity
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation	Invasive procedure involving placement of probes or catheters into a body cavity
91037	Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation;	Invasive procedure involving placement of probes or catheters into a body cavity
91038	Esophageal function test, gastroesophageal reflux test with nasal catheter intraluminal impedance electrode(s) placement, recording, analysis and interpretation; prolonged (greater than 1 hour, up to 24 hours)	Invasive procedure involving placement of probes or catheters into a body cavity
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report	Invasive procedure involving introduction of instrument through a natural body orifice
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report	Invasive procedure involving introduction of instrument through a natural body orifice

CPT Code	Descriptor	Rationale
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report	Invasive procedure involving introduction of instrument through a natural body orifice
91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report	Invasive procedure involving placement of probes or catheters into a body cavity
91120	Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)	Invasive procedures involving placement of probes or catheters into a body cavity
91122	Anorectal manometry	Invasive procedures involving placement of probes or catheters into a body cavity

The services we propose are diagnostic procedures currently covered when delivered in the hospital outpatient department, but not in the ASC.

Our societies further recommend that CMS revise the definition of an ASC covered surgical procedure to include infusion services. Today, infusion services are predominantly provided in the HOPD setting, because physician offices cannot support the level of nursing required to supervise these services. However, providing infusion services in the HOPD is not cost-effective. ASCs employ the appropriate nursing staff and could deliver these services at a lower cost, but they are not permitted to do so. We request that CMS also include on the list of ASC codes that are eligible for separate payment the two codes shown in Table 2.

Table 2

CPT Code	Descriptor	Rationale
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	Requires supervision of specialty trained nurses not available in typical physician office, but are available in an ASC
96415	Chemotherapy administration, intravenous infusion technique; each additional hour	Requires supervision of specialty trained nurses not available in typical physician office, but are available in an ASC

We strongly encourage CMS to move forward as quickly as possible with an expanded definition for ASC covered surgical procedures to make these services available to Medicare beneficiaries in a lower cost, more convenient, and highly preferred site of service.

Quality Reporting Program

Our societies support quality measures that are both actionable and meaningful to endoscopy ASCs. We appreciate CMS' new Meaningful Measures Initiative geared toward improving patient outcomes and reducing regulatory burden.

Specifically, we thank CMS for recognizing that measures ASC-9/OP-29 Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients and ASC-10/OP-30 Colonoscopy Interval for Patients with History of Adenomatous Polyps are not appropriate measures for a facility-based quality reporting program. As we have stated in previous comments, these measures were developed by our societies to assess physician performance for endoscopy services, not as facility-level measures.

We also support the continued delay of implementing the mandated Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey until further analysis of the cost and administrative burden impacts on ASCs.

Request for Information on Price Transparency

As part of the proposed rule, CMS is seeking feedback on what changes are needed to support greater transparency around patient obligations for their out-of-pocket costs. Transparency is a huge problem for Medicare beneficiaries receiving screening colonoscopies. Medicare beneficiaries expect no cost sharing for a screening colonoscopy as it is a Medicare covered preventive service, but nearly half of all Medicare beneficiaries receiving a screening colonoscopy will face out-of-pocket costs.

If during a screening colonoscopy a potentially precancerous polyp is removed, the screening service is "reclassified" as a diagnostic service for Medicare billing purposes. Thus, beneficiary coinsurance is no longer waived for the service. However, there is no way of knowing in advance whether a polyp will be removed during a screening colonoscopy. Moreover, polyp removal occurs in nearly half of all screening colonoscopies

in patients who are at average risk of developing colorectal cancer. Therefore, a significant number of Medicare beneficiaries are surprised to find out after their screening that they must pay a coinsurance. Medicare beneficiary cost-sharing should be waived for screening colonoscopies reclassified as diagnostic because polyps are removed. A colonoscopy performed in the absence of signs or symptoms is a screening colonoscopy regardless of what is identified and removed during the procedure.

CMS may implement this change by directing providers to use the Medicare screening colonoscopy codes “G0105” or “G0121” for these procedures or by waiving cost-sharing for procedures billed with the PT modifier.

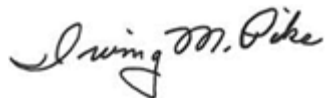
Request for Information on Part B Competitive Acquisition Program

Our societies are concerned that CMS may be considering adding medical reviews and utilization management as part of a new Part B Competitive Acquisition Program (CAP). **ACG, AGA and ASGE strongly opposes any future Part B CAP that includes vendors or Medicare Administrative Contractors (MACs) conducting medical reviews or utilization management.** Utilization management undermines shared decision-making between physician and patients, increases physician burden and often puts patients at risk by delaying access to necessary care.

CONCLUSION

The ACG, AGA and ASGE appreciate the opportunity to offer these comments. If we may provide any additional information, please contact Brad Conway, Vice President of Public Policy, ACG, at 301-263-9000, or bconway@acg.gi.org; Jessica Roth, Director of Regulatory Affairs, AGA, at 240-482-3230, or jroth@gastro.org; or Lakitia Mayo, Senior Director of Health Policy and Education, at 630-570-5641, or lmayo@asge.org.

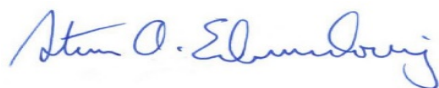
Sincerely,



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