



September 13, 2022

Submitted electronically via: <https://www.regulations.gov>

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1772-P  
P.O. Box 8016  
Baltimore, MD 21244-8013

**RE: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (CMS-1172-P)**

Dear Administrator Brooks-LaSure:

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-1772-P), regarding the proposed policy revisions to the CY 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems. Together, our three societies represent virtually all practicing gastroenterologists who provide preventive, consultative and therapeutic care for the U.S. population.

There are several provisions in the proposed rule that adversely impact Medicare beneficiaries and the practicing gastroenterologists who treat them. Below, we offer comments that address these areas:

- Proposed changes to APC 5371 impacting lower GI motility codes
- Endoscopic submucosal dissection (ESD) HCPCS Code C9779
- Proposed OPPS Payment for Devices – Transitional Pass-Through Payment
- Calculation of OPPS Scaled Payment Weights
- OPPS MIPS Value Pathway (MVP)
- OPPS Payment for Software as a Service (SaaS)

Proposed changes to APC 5371 impacting lower GI motility codes

In 2021, CMS finalized a reorganization of the Urology and Related Services Ambulatory Payment Classifications (APCs) and expanded the APCs from seven to eight levels, making changes to the codes within each APC to adhere to program rules. For 2023, CMS is proposing refinements to the CPT codes in each Urology APC level based on claims data. We noticed that lower GI motility codes 91117 and 91122 are part of APC 5371 (Level 1 Urology and Related Services) for which changes have been proposed. Upon further investigation, we noted that GI motility codes, which all have similar clinical intensity, resource utilization and cost, are divided between two APCs:

- APC 5371 – Level 1 Urology and Related Services
  - 91117 (Colon motility 6 hr study)
  - 91122 (Anal pressure record)
- APC 5722 – Level 2 Diagnostic Tests and Related Services
  - 91037 (Esoph imped function test)
  - 91120 (Rectal sensation test)
  - 91132 (Electrogastrography)

We reviewed the “Costs for Hospital Outpatient Services, by HCPCS code for CY 2023” CMS file and confirmed that the mean costs for GI motility procedures are similar. Code 91117 is not listed in the file because its volume is low.

Costs for Hospital Outpatient Services, by HCPCS code for CY 2023								
HCPCS	SI	APC	Payment Rate	Single Frequency	Total Frequency	Geometric Mean Cost	CV	Deleted Code Used in APC Costs
91037	S	5722	\$285.63	2130	5386	\$206.62	70.657	
91120	S	5722	\$285.63	1802	2624	\$213.32	68.266	
91122	T	5371	\$224.14	3557	5147	\$324.49	74.080	
91132	S	5722	\$285.63	4	12	\$326.40	0.000	

**Because GI motility tests have similar clinical intensity, resource utilization and costs, we ask CMS to remove codes 91117 and 91122 from APC 5371 (Level 1 Urology and Related Services) and place them into APC 5722 (Level 2 Diagnostic Tests and Related Services) with codes 91037, 91120 and 92232 so that all motility codes are in the same APC.**

Endoscopic submucosal dissection (ESD) HCPCS Code C9779

On October 1, 2021, a new HCPCS level II code (C9779) was announced for Medicare facility payment of endoscopic submucosal dissection (ESD) procedures. ESD is an advanced procedure that allows for en bloc removal of pre-malignant and early-stage malignant lesions in the GI tract. The technique involves marking a safety margin with coagulation points around the lesion, injection of a solution under the targeted lesion to act as a cushion, incision, cutting around the perimeter of the lesion, and dissection of the lesion from the submucosal space parallel to the deep muscle layer with a specialized knife, and finally, cauterization and hemostasis of active bleeding as required and mucosal closure. ESD is performed either in the upper GI tract typically in either the esophagus or gastric location, or in the lower GI tract via a colonoscopy.

The C9779 code descriptor (Endoscopic submucosal dissection (ESD), including endoscopy or colonoscopy, mucosal closure, when performed) combines both upper and lower gastroenterology procedures. This descriptor combines both upper and lower endoscopy which is problematic due to the different resources required for access of either the upper or lower procedure. No other procedure in the gastroenterology family combines both upper and lower access for this reason.

**Our societies urge CMS to create two HCPCS codes one for upper ESD (including esophagus and gastric) and one for lower ESD.** Due to the complex nature of these procedures a single HCPCS code does not accurately reflect the different clinical intensity and resource utilization for these services. Two separate HCPCS codes would allow proper tracking of the costs associated with performance of ESD in each target area.

CMS' cost files indicate that there were 26 claims available for CY2023 rulemaking reflecting a geometric mean of \$3,961.06. When reviewing what we believe are the 26 claims used, it appears those claims can be split into upper and lower reflecting different cost inputs. Our proposal is based on the data currently available and accounting for the supplemental disposable supplies utilized in the in the lower GI tract such as additional stabilization and traction devices. The addition of these disposables results in higher facility costs for ESD in the colon. **The proposed new Upper GI ESD C code should be assigned to APC 5303 Level 3 Upper GI procedures; the lower GI ESD C code assigned to APC 5331 – Complex GI procedures.**

#### Proposed OPSS Payment for Devices – Transitional Pass-Through Payment (TPT)

The Public Health Emergency (PHE) continues to have a major and ongoing impact on hospitals' abilities to use TPT technologies, and these impacts are not reflected in metrics such as procedure volume and case mix. We would request a one-year extension of add-on payments for TPT eligible technologies as elective procedure volumes have not stabilized. Due to COVID burdens and staffing shortages, many hospitals canceled or significantly reduced scheduled procedures. Furthermore, companies' ability to train hospitals in the use of new technologies has been limited which in turn stunts the adoption of new technology.

We appreciate CMS' decision to use its equitable adjustment authority under 1833(t)(2)(E) of the Act to provide a four-quarter extension of TPT payments for device categories whose eligibility would be discontinued beginning CY 2022 because the technology would no longer be considered new. We don't believe that the full costs of TPTs will be fully reflected in the 2021 claims data that CMS proposes to use for rate setting, even if other COVID impacts have had less impact on claims data in 2021 than in 2020. Therefore, consistent with its policy for 2022, we urge CMS to again use its equitable adjustment authority under Section 1833(t)(2)(E) of the ACT to extend for four quarters TPT eligibility for C1748 (Endoscope, single-use (i.e. disposable), upper gi, imaging/illumination device (insertable)).

#### Calculation of OPSS Scaled Payment Weights

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

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. Since the payment systems were aligned, CMS has taken the relative weights in the OPSS, which have already been scaled, and then applies a secondary weight scalar, known as the ASC weight scalar, before arriving at the ASC payment weights. CMS updates the ASC relative payment weights each year using the national OPSS 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 OPSS 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 continued application of the ASC weight scalar exacerbates the growing divergence in ASC and HOPD rates, especially for GI procedures which are among the highest-volume procedures in the ASC setting. **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 in ASC relative weights.**

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

#### OPSS MIPS Value Pathway (MVP)

Our societies generally support the concept of allowing ASCs to tailor their quality measurement and improvement efforts to those procedures more frequently treated at the facility. However, we believe that much work on the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) is still needed before it is adapted for other quality programs. We believe that the current design is not geared toward improving patient outcomes around an episode, condition, or other public health priority and requires significant redesign before it is implemented even in MIPS.

It is our understanding that MVPs are intended to more broadly represent value with cost and quality captured within a clinical concept or procedure. The questions that CMS poses for the ASC Quality Reporting Program appear to have a greater focus on creating sets of related measures similar to the MIPS specialty sets which enable the selection of more appropriate quality measures. If so, this would be a more appropriate direction although would need further thoughtful consideration.

Regardless of the Agency's intended direction on a new pathway for facility reporting, CMS must stop the practice of adopting measures from one program into another without communication with the measure stewards. The absence of robust testing to ensure that it is feasible for ASCs to implement each measure as specified with reliable and valid scores produced at the facility level increases burden on healthcare teams while simultaneously setting them up for poor performance with no immediate actionable feedback. We already experienced this with facilities where colonoscopies are performed and the reporting of ASC-10 (Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use), which was developed as a provider measure and is QID185 in MIPS. To our knowledge the vast majority, if not all, of the measures included in Tables 73-75 have not been tested for use by ASCs. **It is imperative that CMS work in close collaboration with the measure stewards if any measure from one program is to be considered for another.** Measure stewards are charged with the maintenance of their measures, so they remain true to their intent, are specified to produce valid results, and are tested consistent with their original intent, which includes assessment at the provider or facility levels.

#### OPSS Payment for Software as a Service (SaaS)

CMS refers to algorithm-driven services that help make clinical assessments (e.g., clinical decision support software, clinical risk modeling, and computer aided detection) as "software as a service (SaaS)." CMS seeks comment on the specific payment approach for these services under the OPSS as SaaS technologies becomes more widespread.

Like other digital health technologies that physicians and non-physician practitioners have adopted, healthcare artificial intelligence (AI) and other SaaS tools are used for clinicians to deploy to enhance the impact of good patient care. The sophistication of AI technologies varies widely across medical specialties. In GI, these solutions are still in the early stages and while some may have the potential to inform physician work, they are far from augmenting or replacing physician work. The main areas in which AI and SaaS are currently in use in GI is for the detection of polyps, bleeding, and reflux events.

Because the AI and SaaS in GI are still in the early stages and not accurate enough to be relied upon, they do not decrease intensity. For example, during colonoscopy, the AI and SaaS image review software can still miss polyps so the physician must still do the work of a comprehensive visual inspection as they do in the current state. Physicians are also still liable if a polyp is missed, and an interval cancer develops – having these tools present does not remove that liability. In addition, if the software does detect an overlooked polyp, the procedure time will actually increase as the physician will now take the time to remove the polyp identified by the software.

Healthcare providers recognize the value of healthcare AI tools and have made significant investments to integrate these innovative technologies into patient care. In GI, technologies currently in use commonly require a one-time cost to purchase the equipment and a subscription model to use the software. Hospitals that want to use these technologies must absorb the cost, which is another barrier to adoption. CMS should consider requiring companies to include AI and SaaS in the software and licensing costs instead of on a subscription basis. Another barrier to adoption is the cost of this technology in comparison to its benefit to gastroenterologists and patients. For example, if the cost of AI technology is very high and it yields only a small improvement in quality the benefit will not justify the cost. Because physicians are quite good at detecting polyps, bleeding lesions, and reflux events, AI and SaaS would need to be very inexpensive and incredibly accurate before large scale adoption would be likely.

The Tri-Societies appreciate the agency's exploration of this growing area in the healthcare marketplace. We look forward to further discussions and potential proposals in future rulemaking.

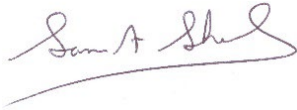
### Conclusion

Our societies urge CMS to:

- Remove codes 91117 and 91122 from APC 5371 (Level 1 Urology and Related Services) and place them into APC 5722 (Level 2 Diagnostic Tests and Related Services) with codes 91037, 91120 and 92232 so that all motility codes are in the same APC.
- Create two HCPCS codes one for upper ESD (including esophagus and gastric) and one for lower ESD.
- Extend for four quarters TPT eligibility for C1748- Endoscope, single-use (i.e. disposable), upper gi, imaging/illumination device (insertable).
- Eliminate the secondary scalar for ASCs and apply the OPPS relative weights to services provided in the ASC.
- Work in close collaboration with the measure stewards if any measure from one program is to be considered for an OPPS MVP.
- Looks forward to working with CMS on a specific payment approach under the OPPS as SaaS technologies becomes more widespread.

Thank you for the opportunity to comment on this proposed rule and issues concerning gastroenterology. We appreciate the ongoing dialogue concerning these important issues, as well as CMS' significant effort in the proposed rule. If you have any questions about our request or if we may provide any additional information, please contact Brad Conway, ACG, at 301-263-9000 or [bconway@gi.org](mailto:bconway@gi.org); Leslie Narramore, AGA, at 410-349-7455 or [Lnarramore@gastro.org](mailto:Lnarramore@gastro.org); or Lakitia Mayo, ASGE, at 630-570-5641 or [lmayo@asge.org](mailto:lmayo@asge.org).

Sincerely,

A handwritten signature in blue ink that reads "Samir A. Shah". The signature is fluid and cursive, with a long horizontal stroke at the bottom.

Samir A. Shah, MD, FACC  
President, American College of Gastroenterology

A handwritten signature in blue ink that reads "John M. Carethers". The signature is cursive and somewhat stylized.

John M. Carethers, MD, AGAF  
President, American Gastroenterological Association

A handwritten signature in blue ink that reads "Bret T. Petersen". The signature is cursive and clearly legible.

Bret T. Petersen, MD, MASGE  
President, American Society for Gastrointestinal Endoscopy