



September 13, 2021

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
US Department of Health & Human Services  
200 Independence Avenue SW  
Washington, DC 20543

**Re: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to the Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements.**

Dear Administrator Brooks-LaSure,

On behalf of the American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE), we appreciate the opportunity to provide comments on the CY 2022 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1751-P). Together, our societies represent virtually all practicing gastroenterologists in the United States. We thank the Centers for Medicare & Medicaid Services (CMS) for its ongoing effort to engage with stakeholders to better understand the evolving healthcare environment and believe that the PFS comment solicitation on these issues is a positive step in this ongoing dialogue.

There are several provisions in the proposed rule impacting practicing gastroenterologists and Medicare beneficiaries. In this letter, we offer comments on the following provisions:

- Medicare Physician Fee Schedule
  - Valuation for Per-Oral Endoscopic Myotomy (POEM) (CPT Code 434XX)
  - Valuation of Colon Capsule Endoscopy (CPT Codes 91110, 91111, 9111X)
  - Proposal for the revision of Clinical Labor Relative Inputs
  - Telehealth and Other Services Involving Communications Technology
  - Split (or Shared) Visits

- Payment for the Services of Teaching Physician
- NCD 180.2 Enteral and Parenteral Nutritional Therapy
- Response to CMS' Coinsurance for Colorectal Cancer Screening Tests
- Request for Information – Resource Costs for Innovative Technologies
- Quality Payment Program
  - Merit-based Incentive Payment System (MIPS) Value Pathway
  - MIPS Performance Category Measures and Activities
  - MIPS Final Score Methodology
  - Calculating the Final Score
  - Final Score Performance Category Weighting
  - MIPS Payment Adjustments

### **Medicare Physician Fee Schedule**

#### **Proposed Valuation of Per-Oral Endoscopic Myotomy (POEM) (CPT code 434XX)**

CMS rejected the RUC recommended 15.50 physician work relative value units (RVUs) for CPT code 434XX (*Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])*) in the proposed rule, stating:

*We disagree with the RUC-recommended work RVU for CPT code 434XX and are proposing a work RVU of 13.29 based on a direct work RVU crosswalk from CPT code 36819 (Arteriovenous anastomosis, open; by upper arm basilic vein transposition). CPT code 36819 has the same 120 minutes of intra service time as CPT code 434XX, and has 283 minutes of total time, which is 2 minutes more than the 281 minutes of total time than for 434XX.*

We disagree with CMS' proposal for the following reasons which are detailed below:

- CMS did not provide a rationale explaining why it believes the survey data from 119 gastroenterologists, gastrointestinal surgeons and thoracic surgeons was flawed and required use of a crosswalk.
- Crosswalking the value of a procedure based on time alone is inappropriate.
- Crosswalking 434XX to 36819 based on time alone fails to consider the difference in intensity between the procedures.
- By setting the RVU of 434XX at 13.29, CMS creates a rank-order anomaly in the intensities of related procedures.

POEM is an axial procedure, which means it is performed with a single tool with a limited field of view looking down the same axis as the tool. During a laparoscopy, there are typically four separate ports physically distanced from each other which provide a much larger field of view and work area that is stable and consistent allowing for the procedures to be more controlled and well-defined. In addition, POEM is performed with a flexible endoscope which is harder to maneuver than the more rigid

laparoscope. Lastly, the consequence of an adverse event during POEM is severe in that a significant bleed or perforation could require emergency surgery. Vigilance with regards to precision and safety is of utmost importance. POEM is a procedure done within a much more limited field of view with a limited set of tools in which the consequence of a mistake can necessitate emergency surgery thus increasing the intensity of the procedure.

**We contend that crosswalking the value of a procedure based only on time is inappropriate.** CMS' rationale does not explain why it believes the survey data from 119 gastroenterologists, gastrointestinal surgeons and thoracic surgeons was so flawed as to require use of a crosswalk. Instead, CMS explains that it rejected the codes the RUC used to support the survey data (43279 and 43180) because they do not have identical times to POEM. However, the codes provided by the RUC were never meant to be crosswalk codes; they are bookends that demonstrate how the value of 434XX falls appropriately between them. They are also the top two key reference services (KRS) selected by the survey takers: 43279, *Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed*, (work RVU = 22.10; 150 minutes intra-service time) and 43180, *Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (eg, Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed*, (work RVU = 9.03; 60 minutes intra-service time). It is logical that the survey takers migrated towards the top two KRS codes based on their familiarity with these procedures and the disease states treated by these procedures. Codes 43279 and 43180 are bookends that demonstrate the validity of the 15.50 RVU recommendation for 434XX, which falls between the accepted RVU of 43279, the longer more intense procedure, and 43180, the shorter less intense procedure.

Additionally, the RUC provided Multi-specialty Points of Comparison (MPC) codes 19303, *Mastectomy, simple, complete* (work RVU = 15.00; 90-minutes intra-service time) and 60500, *Parathyroidectomy or exploration of parathyroid(s)* (work RVU = 15.60; 120 minutes intra-service time) to support its recommendation of 15.50 wRVUs.

Further, we provided the RUC with following tables (Table 1 and Table 2) containing additional comparison codes with similar time, intensity and post-operative visits which demonstrated the appropriateness of the 15.50 RVU for 434XX:

Table 1

CPT Code	Long Desc	Glob	Work RVU	Pre time	Intra Time	Post Time	Total Time	Time Source	Most Recent RUC Review	Top_Specialty	WPUT	MPC	2019 Util
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency	090	14.08	51	120	30	266	RUC	2016-01	OBSTETRICS/ GYNECOLOGY	0.0825		8
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g.	090	14.39	56	110	30	261	RUC	2014-04	OBSTETRICS/ GYNECOLOGY	0.0918		34
19303	Mastectomy, simple, complete	090	15.00	58	90	30	283	RUC	2016-04	GENERAL	0.1018	YES	24587
57265	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed; with enterocele repair	090	15.00	56	120	30	271	RUC	2017-01	OBSTETRICS/ GYNECOLOGY	0.0892		4370
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	090	15.00	56	90	30	241	RUC	2014-04	OBSTETRICS/ GYNECOLOGY	0.119		22432
434XX	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy)	090	15.50	47	120	30	261				0.095		
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	090	15.60	56	120	30	271	RUC	2014-04	OBSTETRICS/ GYNECOLOGY	0.0942		83
60500	Parathyroidectomy or exploration of parathyroid(s);	090	15.60	72	120	40	313	RUC - CMS Revised	2010-10	GENERAL SURGERY	0.086	YES	18399
15733	Muscle, myocutaneous, or fasciocutaneous flap; head and neck with named vascular pedicle (ie, buccinators, genioglossus, temporalis, masseter, sternocleidomastoid, levator scapulae)	090	15.68	58	120	30	305	RUC	2017-01	PLASTIC AND RECONSTRUCTIVE SURGERY	0.0865		5657
43279	Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed	090	22.10	80	150	30	404	RUC	2008-04	GENERAL SURGERY	0.097		829

Table 2

CPT Code	Long Desc	99204	99211	99212	99213	99214	99215	99231	99232	99233	99238	99239	99291	99292
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency				2						0.5			
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g.				2						0.5			
19303	Mastectomy, simple, complete				2	1					0.5			
57265	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed; with enterocele repair				2						0.5			
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)				2						0.5			
434XX	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy)				2						0.5			
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)				2						0.5			
60500	Parathyroidectomy or exploration of parathyroid(s);			1	2						0.5			
15733	Muscle, myocutaneous, or fasciocutaneous flap; head and neck with named vascular pedicle (ie, buccinators, genioglossus, temporalis, masseter, sternocleidomastoid, levator scapulae)			2	2						0.5			
43279	Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed				2			2	2		1			

Crosswalking 434XX to 36819 based only on time fails to take into consideration the difference in intensity between the procedures. CPT code 36819 is an open, three-dimensional procedure with a multi-person surgical team using a wide field of view, operating on an upper extremity with local

anesthesia from nerve block. It is not an endoscopic procedure, involves completely different work and has an IWPUT of 0.0755.

CPT code 434XX involves a high-risk dissection of the esophageal tissue layers using instruments limited to one forward viewing dimension performed under general anesthesia and can result in a catastrophic adverse event in the chest and mediastinum. The IWPUT of POEM is significantly higher at 0.091.

CMS does not explain how POEM, an endoscopic surgical procedure, is similar to vein transposition except that the procedures have identical intra-service times. A search of the RUC database for 90-day global codes with 120 minutes of intra-service time yields 235 CPT codes with IWPUTs ranging from - 0.036 to 0.1983. This demonstrates that CMS does not set the same intensity for each minute regardless of procedure. Instead, CMS recognizes that value is based on multiple factors including procedure time, technical skill required, physical effort involved, mental effort and judgment, and stress due to the potential risks to the patient. By rejecting the robust and valid survey data for 434XX and using a crosswalk based only on time, CMS is ignoring the assessment of expert physicians as well as the RUC process.

**By setting the RVU of 434XX at 13.29, CMS creates a rank-order anomaly in the intensities of related procedures (Table 3).** The RUC noted in its recommendation to CMS that CPT code 43180 requires much less physician time, work, and intensity than CPT code 434XX. Additionally, 74% of the survey respondents who selected key reference code 43180 indicated overall, 434XX was more intense and complex to perform than 43180. However, the IWPUT of 43180 is 0.0855, which is *higher* than the 0.073 IWPUT resulting from CMS' recommended RVU of 13.29 for 434XX.

Table 3

						RVW					Total	Pre	PRE-TIME				INTRA-TIME					IMM
Source	CPT	Global	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	Pkg	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST	
1st REF	43279	090	Laparoscopy, surgical, esophagomyot		0.097			22.10			404	4	40	20	20			150			30	
RUC Rec	434XX	090	Lower esophageal myotomy, transoral		0.091			15.50			281	3	33	3	10			120			50	
2nd REF	43180	090	Esophagoscopy, rigid, transoral with c		0.086			9.03			201	4	40	10	10			60			20	
CMS Rec	434XX	090	Lower esophageal myotomy, transoral		0.073			13.29			281	3	33	3	10			120			50	

**For these reasons, we urge CMS to accept the RUC recommended RVU of 15.50 for 434XX to prevent a rank order anomaly in the intensities of related procedures. The survey data the RUC accepted was robust and clearly support this value.**

## Colon Capsule Endoscopy (CPT codes 91110, 91111, and 9111X)

### 91111 work RVU

For CPT code 91111, CMS disagreed with the RUC-recommended work RVU of 1.00 and proposed a work RVU of 0.90 based on a crosswalk to CPT code 95923 (*Testing of autonomic nervous system function; sudomotor, including 1 or more of the following: quantitative sudomotor axon reflex test (QSART), silastic sweat imprint, thermoregulatory sweat test, and changes in sympathetic skin potential*).

CMS correctly noted that the surveyed intra-service work time for 91111 had decreased by three minutes, from 18 minutes to 15 minutes. While there was a minor reduction in intra-service time, the total time

reported by the survey takers was seven minutes greater than the current total time even though this time was ultimately not added to pre- and post-service time. **Therefore, in practice 91111 does not take less total time than in the past. This supports the RUC's decision to maintain the current work RVU.**

We support CMS' statement that the decrease in time as reflected in survey values should not automatically equate to a one-to-one or linear decrease in the valuation of work RVUs. There was no evidence in the survey data that there has been a reduction in the intensity of the procedure or in the total amount of work involved. **CPT code 91111 was previously reviewed by the RUC in 2016. No changes in technology or technique have made this procedure less intense or appreciably faster since then.**

For a code that was performed only 146 times in the Medicare population in 2019, we had an extremely robust survey response of 56. The 25<sup>th</sup> percentile RVU was 1.11 RVUs. However, the RUC operates with the initial presumption that the current values assigned to the codes under review are correct and, therefore, recommended the current value of 1.00 RVUs. We do not believe CMS should disregard the RUC recommendations in favor of a crosswalk. **We urge CMS to adopt the RUC recommendation of 1.00 RVU.**

#### 91111 PE input CA016

CMS proposed to refine the clinical labor time for the "Prepare, set-up and start IV, initial positioning and monitoring of patient" (CA016) activity from the RUC-recommended 9 minutes to 6 minutes for CPT code 91111. CMS does not agree that it would be typical for CPT code 91111 to require an additional 3 minutes for positioning as compared with the other codes in the family, particularly in light of the clinical similarities between these services.

We provided a detailed account of time for clinical labor activities in the PE Summary of Recommendations (SOR) form to the RUC (Attachment A). Additionally, during the RUC meeting a member of the PE Subcommittee asked for additional information on patient positioning for 91111. We explained why positioning the patient for capsule endoscopy of the esophagus is different from other capsule endoscopy procedures in the code family. For capsule endoscopy of the esophagus, clinical staff position the patient on the bed with a small pillow about 2.5 inches high under the head to facilitate drinking and ingestion of the capsule. The film is removed, and the patient is assisted in rolling over from supine to their left side on the narrow procedure table. This left lateral position increases the angle between the gastroesophageal junction (GE) junction and stomach to promote longer esophageal dwell times. Staff assists in keeping the patient stable (without rolling back and forth) in this position on the narrow procedure cart to delay capsule transit across the GE junction and then into a sitting position after the capsule is swallowed. **Capsule endoscopy of the gastrointestinal tract (91110) and colon (9111X) do not require these additional steps for positioning, as noted in the PE SOR; therefore, the RUC-recommended time for 91111 is accurate. For these reasons, we recommend 9 minutes for CA016 for code 91111.**

#### 91111 PE inputs EQ148 and EF023

CMS also proposed to refine the equipment time for the capsule endoscopy recorder kit (EQ146) from 64 minutes to 61 minutes and the exam table (EF023) from 44 minutes to 41 minutes to match their proposed 3-minute reduction of patient positioning time (CA016) in clinical labor time for CPT code 91111. **In asking CMS to restore the three minutes of patient positioning time to CA016 for 91111, we also request restoration of those minutes to the equipment time for EQ146 and EF023.**

### **Clinical Labor Pricing Update**

For CY 2022, CMS proposes to update the clinical labor wage rates according to data from the United States Bureau of Labor Statistics (BLS). We agree that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS.

As the clinical labor pricing has not been updated since 2002, we agree that CMS should update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. However, it is unfair that the real increase in clinical labor costs is not recognized through an update to the conversion factor. We recognize that CMS is limited when it comes to addressing the broader challenges of the PFS; however, **we urge CMS to delay for one year the implementation of the updated clinical labor inputs.** This additional year would give the agency time to work with Congress on a longer-term solution.

Since it has been 20 years since the last update, the impact of the update should occur through a transition period. **We agree with CMS' proposal for a four-year transition to the new clinical labor cost data. We also urge CMS to regularly update the clinical labor cost data, and all inputs, to avoid the volatility caused by the current update occurring in services with high-cost supplies and equipment which are disproportionately impacted by the budget neutrality component within the practice expense relative values.**

#### **Revised Time Frame for Consideration of Services Added to the Telehealth List on a Temporary Basis**

We thank CMS for proposing to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. We agree that this will allow CMS time to collect more information regarding utilization of these services during the pandemic and provide stakeholders the opportunity to continue to develop support for the permanent addition of appropriate services to the telehealth list through CMS' regular consideration process, including notice-and-comment rulemaking.

Currently, telephone E/M codes 99441-99443 are included in the Category 3 telehealth list. However, CMS has proposed to delete these codes and replace them with G2252 (*Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*). **Our societies recommend that CMS keep telephone E/M (either 99441-99443 or G2252) on the telehealth list on a permanent basis after the expiration of the public health emergency. If one code must be selected, we prefer E/M codes 9941-99443 be maintained on the list.**

Telephone E/M is identical to office visits that are currently on the list of telehealth services. The only difference between telehealth office visits and telephone E/M is the absence of real-time video. The physician time, intensity and level of medical decision making for telephone E/M and office visits are identical. The interactions among the beneficiary and physician (or other practitioner) that take place during a telephone E/M visit are similar to telehealth office visits. In both cases, the physician can assess the patient's condition, make a medical decision, and communicate that decision to the patient equally well via telephone only or a real-time audio/visual telehealth platform. The absence of video does not change or diminish the time, intensity, or level of medical decision making. For these reasons, **we believe telephone E/M (either 99441-99443 or G2252) meets all Category 1 criteria.**

During the COVID-19 pandemic, studies have been conducted that affirm the widespread anecdotal reports from physicians that many Medicare beneficiaries have difficulty with video visits and report satisfaction with the quality of E/M services provided via telephone. We present the following studies to support the addition of telephone E/M (99441-99443 or G2252) to the Medicare telehealth services list on a permanent basis.

“Positive Early Patient and Clinician Experience with Telemedicine in an Academic Gastroenterology Practice during the COVID-19 Pandemic”<sup>1</sup>, published in *Gastroenterology* describes a ‘real-world’ experience of patient and clinician-rated acceptability of telephone and video outpatient visits during the initial four weeks of the COVID-19 emergency at a large, diverse gastroenterology (GI/hepatology) practice in an academic health system. During the study period, a total of 1,718 patients had GI/hepatology visits; 104 (6%) were in person and 1614 (94%) were via telemedicine. Mean patient age was 60 (SD=16); 59% were female, 20% were Black, 64% White, and 16% Other/Unknown. In this early period, 27% of visits were conducted via video and 72% via telephone. In week 1, 7% of telemedicine visits were via video; this increased to 47% by week 4. After adjusting for study week and demographics, Black race (OR 2.6, 95% CI 1.6-4.2) and age 60+ (OR 1.9, 95% 1.4-2.7), were independently associated with having telephone versus video visits. There were notable racial and age differences in online portal use; 87% portal use among Whites versus 39% of Blacks; 77% among age <60 versus 48% among age 60+; P<.0001. A conclusion of the study was that practices should continue to work to mitigate disparities in access to technology and low digital literacy. *The study highlights the importance of continued access to telephone E/M for patients age 60+ and Black patients who, according to the study, were less likely to be able to use video visit technology. It is important to maintain access to telephone E/M for these populations; failure to do so will further increase the racial disparities we have seen regarding both COVID-19 and colorectal cancer screening and uptake.*

The study, “Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic”<sup>2</sup>, published in the *Journal of the American Medical Association* describes a cross-sectional study of community-dwelling adults (N = 4525) using 2018 data from the National Health and Aging Trends Study, which is nationally representative of Medicare beneficiaries aged 65 or older, to assess the prevalence of telemedicine unreadiness. *The study estimates that 13 million older adults may have trouble accessing telemedical services; a disproportionate number of those may be among the already disadvantaged. Its conclusion was telephone visits may improve access for the estimated 6.3 million older adults who are inexperienced with technology or have visual impairment.*

A narrative review on "Telemedicine, the Current COVID-19 Pandemic, and the Future"<sup>3</sup> in *Family Medicine and Community Health* describes how telemedicine may also facilitate access to care, especially among rural and underserved populations, and reduce healthcare costs by decreasing emergency room visits and hospital admissions among patients with chronic illnesses. *The study finds that having more frequent communication with a patient who has a chronic condition can help them avoid readmissions to the hospital and emergency department, lowering the overall cost of chronic disease management.*

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<sup>1</sup> Serper M, Nunes F, Ahmad N, Roberts D, Metz DC, Mehta SJ, Positive Early Patient and Clinician Experience with Telemedicine in an Academic Gastroenterology Practice during the COVID-19 Pandemic, *Gastroenterology* (2020), doi: <https://doi.org/10.1053/j.gastro.2020.06.034>.

<sup>2</sup> Lam K, Lu AD, Shi Y, Covinsky KE. Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic. *JAMA Intern Med*. Published online August 03, 2020. doi:10.1001/jamainternmed.2020.2671

<sup>3</sup> Kichloo A, Albosta M, Dettloff K, et al. Telemedicine, the current COVID-19 pandemic and the future: a narrative review and perspectives moving forward in the USA. *Fam Med Community Health*. 2020;8(3):e000530. doi:10.1136/fmch-2020-000530

## Other Non-Face-to-Face Services Involving Communications Technology under the PFS

### Interim Final Provisions in the CY 2021 PFS Final Rule

CMS proposes to permanently implement HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*). CMS proposes to crosswalk the relative value units for G2252 (RVUs) to CPT code 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion*). **We disagree with CMS’ decision to permanently implement G2252 and its proposed RVU.**

**We disagree that G2252 for “Brief communication technology-based service” is equivalent to E/M provided over the telephone.** In its “Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019”<sup>4</sup> fact sheet released November 1, 2018, CMS describes virtual check-in as a “brief communication technology-based service when the patient checks in with the practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed.” Virtual check-ins of any duration are completely different from audio-only (telephone) E/M.

The E/M care provided via telephone is much more than a “*virtual check-in service*.” Physicians are providing E/M care over the telephone including assessing the patient’s condition, medical decision making, and communicating with the patient as they would for a telehealth visit using a real-time audio/visual telehealth platform. **The absence of video does not change or diminish the time, intensity, or level of medical decision making of telephone E/M. For these reasons, we urge CMS not to permanently implement G2252.**

While CPT codes 99441-99443 were valued by the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) in 2007, the value established by the RUC at that time represents a much different service than that which has been provided during the COVID-19 pandemic and afterward. Additionally, in the 2021 MPFS proposed rule, CMS indicated concern that the practice expense of telephone visits is different from E/M visits. While we do not believe there is a difference in practice expense between telephone and video E/M visits (staff must still interface with patients prior to the telephone or video visit and must perform additional activities, such as preparing patients for the call or video and reviewing medication, etc.), these issues can be addressed if CMS works with the CPT Editorial Panel to update 99441-99443 and they are revalued, including practice expense, by the RUC. **We urge CMS to continue to cover and reimburse telephone E/M codes 99441-99443 at the rate established in the March 31, 2020, COVID-19 IFC (99441, 0.48 wRVU; 99442, 0.97 wRVU; 99443, 1.50 wRVU) and work with the CPT Editorial Panel to update them so they can be appropriately revalued by the RUC.**

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<sup>4</sup> <https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year>

For the above reasons, **we urge CMS not to permanently implement G2252 and, instead, continue to cover 99441-99443 while working with the CPT Editorial Panel to update them so they can be appropriately revalued by the RUC.**

### **Split (or Shared) Visits**

Our societies thank the agency for addressing and aligning shared or “split” visits for physicians and non-physician practitioners (NPPs). As noted in the proposed rule, for visits in the non-facility setting (e.g., a physician’s office), the physician can bill for the visit rather than the NPP as long as the services are furnished “incident to” a physician’s professional services. However, for visits furnished under similar circumstances in facility settings (e.g., hospital setting), current regulations provide for payment only to either the physician or NPP who personally performs all elements of the service, and no payment is made for services furnished “incident to” the billing professional’s services. With respect to split visits in certain facility settings, CMS’ long standing split billing policy allows a physician to bill for a visit when both the billing physician and an NPP in the same group each perform portions of the visit. However, the physician must perform a substantive portion of the visit.

CMS proposes to define a split (or shared) visit as an E/M visit in the facility setting, for which “incident to” payment is not available, and that is performed in part by both a physician and an NPP. Only the physician or NPP who performs the substantive portion of the split (or shared) visit would bill for the visit. CMS also proposes to allow physicians and NPPs to bill for split visits for both new and established patients and for initial and subsequent visits. **We thank CMS for expanding the availability of shared services in Medicare.**

#### Definition of “substantive portion”

CMS proposes to define “substantive portion” as more than half of the total time spent by the physician and NPP. This proposed change of “substantive portion” on time could have significant implications for our members if portions of split (or shared) services that are used to qualify for billing at the physician rate no longer qualify as a result of this change. CMS notes that medical decision-making is not easily attributed or quantifiable to a single physician or NPP when the work is shared, and that time is more precise. However, this proposed change requires monitoring and tracking of physician and NPP time spent on every visit, including when it is spent simultaneously. **We believe CMS underestimates the potential burden of tracking time, as well as the perverse incentive for team-based and/or coordinated care if time determines which provider bills for the service.** For example, CMS proposes nine specific activities that could count toward total time, meaning physicians and NPPs will have to document time spent for each of these categories to determine who provided the substantive portion and therefore bills for the service provided.

**We also disagree that medical decision-making is not attributable or measurable.** The provider’s individual documentation and notes would reflect the elements of medical decision-making. This documentation is already required, thus making it less burdensome than dissecting and allocating the time spent with a patient for a shared service. We urge CMS to define “substantive portion” to include either more than 50 percent of the medical decision making by the physician or NPP or more than 50 percent of the time spent by the physician or NPP.

Defining “substantive portion” to consist of over 50 percent of medical decision-making also would be consistent with how physicians are held accountable for the care provided to patients under the Quality Payment Program (QPP). Regardless of who spends over 50 percent of time, patients will be attributed to our physicians for purposes of the QPP’s Quality and Cost performance categories. Thus, **if the physician**

**is held accountable for the cost and quality of care delivered, CMS should expand the definition of “substantive portion” to include medical decision-making.** This would also be consistent with CMS’ proposal to append the Modifier 52 for such shared/split services. According to the CPT 2021 Coding Manual, the 52 (Reduced Services) modifier signifies that the service is partially reduced *at the discretion of the physician or NPP*. This determination *or discretion* would obviously include medical decision-making.

Our societies also note that CMS’ reference to the CPT 2021 language on shared visits is partially correct, “when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).” The complete language is:

A shared or split visit is defined as a visit in which a physician and other qualified healthcare professional(s) jointly provide the face-to-face and non-face-to-face work related to the visit. When time is being used to select the appropriate level of services for which time-based reporting of shared or split visits is allowed, the time personally spent by the physician and other qualified healthcare professional(s) assessing and managing the patient on the date of the encounter is summed to define total time. Only distinct time should be summed for shared or split visits (i.e., when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).

The CPT 2021 manual specifically notes that “[w]hen time is being used to select the appropriate level of services for which time-based reporting of shared or split visits is allowed,” which does not preclude medical decision-making from being used to select the appropriate level of service. Also, CMS should not use this language to demonstrate that time should be the only determinative factor in defining “substantive portion.” Thus, **we urge CMS to include medical decision-making when determining the “substantive portion” of the shared visit.**

#### Request for comment on the definition of “same group”

CMS has proposed to continue to permit billing for split (or shared) services only where the practitioners are in “the same group.” The proposed rule does not define “same group,” however, CMS seeks comments on this definition. Our societies believe that **the definition should include tax identification number but also professional service agreements that the physician has with the institution, or other care-coordination models under the Quality Payment Program that could include multiple TINs.** CMS’ proposal states that it will not pay for partial E/M visits; thus, practitioners that perform part but not a complete E/M service may only bill if they are in the same group. This is important since Medicare does not pay for partial E/M visits.

#### New and Established Patients

Our societies agree and thank CMS for proposing to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients. We agree that there is no reason to preclude the physician or NPP from billing for split (or shared) visits for a new patient, in addition to an established patient, or for initial and subsequent split (or shared) visits.

#### **Payment for the Services of Teaching Physicians**

Our societies appreciate CMS addressing and clarifying how teaching physicians should consider time spent by the resident in selecting the office/outpatient E/M visit level. Current regulations restrict payment for such services unless the teaching physician renders sufficient control over the management

of the patient. According to CMS, absent a public health emergency, if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service.

For residency training sites that are located outside a metropolitan statistical area, however, payment may also be made if a teaching physician is present through audio/video real-time communications technology (that is, “virtual presence”).

Our societies agree that it is appropriate to include only the time of the teaching physician because the Medicare program makes separate payment for the program’s share of the resident’s graduate medical training program. However, **we urge CMS to allow a “virtual presence” in training sites located within the metropolitan statistical area as well.** Telemedicine and digital health technology are already becoming an established part of medical practice. This is very likely to persist after the COVID-19 pandemic. As CMS considers expanding the use of telehealth service for the elderly and Medicare beneficiaries in other areas of the Medicare Part B program, our societies urge CMS to consider removing this prohibition on virtual presence for teaching physicians in a metropolitan statistical area.

We also appreciate CMS’ acknowledgement that time is an accurate indicator of the complexity of an evaluation and management visit, despite the fact that currently medical decision-making is the only way to determine the evaluation and management level. **We reiterate our comment above that CMS should take a similar approach when determining the substantial portion of split (or shared) visits.**

#### **NCD 180.2 Enteral and Parenteral Nutritional Therapy**

Our societies thank CMS and agree with the proposal to allow greater access and safety to enteral nutrition. Enteral nutrition is provided through a nasogastric, jejunostomy, or gastrostomy tube. Parenteral nutrition is provided intravenously to the patient with pathology of the alimentary tract severe enough that it does not allow for absorption of sufficient nutrients. CMS believes the current national coverage determination (NCD) does not provide for pharmacy-prepared parental solutions, which would increase patient safety. It also unnecessarily adds to patient and provider burden as it requires repeated reviews of medical necessity for those individuals who need enteral or parenteral nutrition services as a result of chronic diseases that affect the ability to eat or to digest/absorb nutrition. Local contractors have proposed local coverage determinations (LCDs) that, if finalized, would provide parenteral and enteral nutrition coverage for certain Medicare beneficiaries. We agree that removing this NCD would better serve the needs of the Medicare program and its beneficiaries. We urge CMS to finalize this proposal.

#### **Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests**

We are grateful that CMS is finally able to gradually eliminate the Medicare’s beneficiary’s coinsurance when a polyp(s) is removed during a screening colonoscopy beginning CY 2022 through CY 2030, when coinsurance is completely waived. This change is pursuant to legislation passed as part of Consolidated Appropriations Act of 2021. Our societies advocated for this legislation on behalf of our members and patients. We believe this important policy change will help increase colorectal cancer screening rates in the Medicare population, thus, we commend CMS and Congress for this change.

Colorectal cancer is largely preventable but too few people are getting screened. The American Cancer Society also estimates that when detected and treated early, the 5-year survival rate for colorectal cancer

is 90%. Unfortunately, early detection occurs in less than 40% of colorectal cancer cases. Routine screening and colonoscopy with polypectomy are powerful tools for prevention. Like most types of cancer, according to the American Cancer Society, the risk of colorectal cancer increases with age. For every subsequent 5-year age group, the incidence rate approximately doubles until age 50, and thereafter increases by about 30%. Colorectal cancer remains the second leading cause of cancer death in the U.S. among men and women combined. Our societies remain committed to raising awareness for colorectal cancer screening and prevention through colonoscopy. We must do more to increase screening rates in the Medicare population, especially due to the COVID-19 pandemic.

The National Cancer Institute recently estimated a 1% increase in deaths from breast and colorectal cancer over the next 10 years - *the equivalent of approximately 10,000 excess deaths* - due to the pandemic's impact on screening and treatment. This is likely an underestimate because models assumed a 6-month disruption in care followed by the return to routine care, which has since proven too optimistic.

We thank CMS for implementing this legislation and look forward to working with the agency in the future to reduce colorectal cancer incidence rates and deaths. This includes removing Medicare beneficiary cost-sharing when the patient is referred to our members for the necessary colonoscopy subsequent to positive result in a non-invasive, colorectal cancer screening test (e.g., fecal immunochemical test (FIT) or Cologuard). Our societies believe this scenario is part of the colorectal cancer screening continuum, as there can be no diagnosis without further assessment (i.e., the follow-up colonoscopy). Ideally, a screening program should guarantee full coverage of the cascade of screening events in the target population. Participation in colorectal cancer screening programs is influenced by organizational (e.g., modality of invitation and test delivery, interventions at system and provider level) and individual factors (e.g., gender, race, socioeconomic status, subject attitude towards screening). Studies demonstrate that there is a wide variation and low adherence to a diagnostic colonoscopy after a positive screening test.<sup>5 6 7 8 9 10 11 12 13</sup> Yet, one study concluded that patients who did not have a colonoscopy after receiving a positive fecal occult blood test had a 103% higher risk of death, compared with those who had a colonoscopy.<sup>14</sup>

<sup>5</sup> Eckmann, Jason D. MD1; Ebner, Derek W. MD1; Bering, Jamie MD2; Kahn, Allon MD3; Rodriguez, Eduardo MD3; Devens, Mary E. CCRP4; Lowrie, Kari L. ACRC4; Doering, Karen CCRP4; Then, Sara ACRC4; Burger, Kelli N. BS5; Mahoney, Douglas W. MS5; Prichard, David O. MD4,6; Wallace, Michael B. MD7; Gurudu, Suryakanth R. MD3; Finney, Lila J. PhD, MPH8; Limburg, Paul MD4; Berger, Barry MD4,9; Ahlquist, David A. MD4; Kisiel, John B. MD4 Multitarget Stool DNA Screening in Clinical Practice: High Positive Predictive Value for Colorectal Neoplasia Regardless of Exposure to Previous Colonoscopy, The American Journal of Gastroenterology: 1 2020 - Volume 115 - Issue 4 - p 608-615 doi: 10.14309/ajg.0000000000000546.

<sup>6</sup> Kapidzic A, Grobbee EJ, Hol L, van Roon AH, van Vuuren AJ, Spijker W, et al. . Attendance and yield over three rounds of population-based fecal immunochemical test screening. Am J Gastroenterol 2014; 109: 1257–64.

<sup>7</sup> Zorzi M, Fedato C, Grazzini G, Sassoli de' Bianchi P, Naldoni C, Pendenza M, et al. . Screening for colorectal cancer in Italy, 2010 survey. Epidemiol Prev 2012; 36: 55–77.

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<sup>9</sup> Levin TR, Corley DA, Jensen CD, et al. Effects of Organized Colorectal Cancer Screening on Cancer Incidence and Mortality in a Large Community-Based Population. Gastroenterology. 2018;155(5):1383-1391.

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<sup>11</sup> Sali L, Mascalchi M, Falchini M, Ventura L, Carozzi F, Castiglione G, et al. ; SAVE study investigators. Reduced and full-preparation CT colonography, fecal immunochemical test, and colonoscopy for population screening of colorectal cancer: a randomized trial. J Natl Cancer Inst 2015; 108: 319.

<sup>12</sup> Zavoral M, Suchanek S, Zavada F, Dusek L, Muzik J, Seifert B, et al. . Colorectal cancer screening in Europe. World J Gastroenterol 2009; 15: 5907–15.

<sup>13</sup> Schreuders EH, Ruco A, Rabeneck L, Schoen RE, Sung JJ, Young GP, et al. . Colorectal cancer screening: a global overview of existing programmes. Gut 2015; 64: 1637–49.

<sup>14</sup> Zorzi, Manuel, Battagello, Jessica, Rita Fiore, Memo, Laura, Senore, Carlo, Rugge, Massimo. Colorectal cancer incidence and mortality after negative fecal immunochemical tests by age 70: A prospective observational study. International Journal of Cancer 2021; Sep 15;149(6):1257-1265.

## **Algorithm Software/AI Language Request for Information – Resource Costs for Innovative Technologies**

CMS outlines a number of questions concerning resource costs and reimbursement for healthcare Artificial Intelligence (AI) in the proposed rule, as well as issues of bias, health equity, program integrity, and care quality. We support CMS' efforts to better understand the multitude of healthcare AI systems and services available to practitioners and patients and appreciate the opportunity to provide our input on these topics.

***Q1: To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work?***

Like other digital health technologies that physicians and non-physician practitioners have adopted, healthcare AI is a tool for clinicians to deploy to enhance the impact of good patient care. The sophistication of AI technologies varies widely across medical specialties. In GI, AI 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 is currently in use in GI is for the detection of polyps, bleeding, and reflux events.

AI for polyp detection during colonoscopy is designed to have a high sensitivity and false positive rate. This means that physicians will have to take the time to reject false positive polyps that they otherwise would have correctly ignored with their own visual inspection. On the flip side, if the software is able to detect polyps that might have gone unnoticed, again, this would increase procedure time as those polyps will now need to be removed. Ultimately while the latter may increase procedure time, it may also have the benefit of increasing polyp detection. In this space, the physician work may actually increase, and it ultimately will depend on the cost versus benefit curve to decide whether that increased work and expense is justified by improved polyp detection.

Similar to AI for polyp detection, AI for bleeding detection during capsule endoscopy is designed to enhance the image review process by highlighting images that may have evidence of bleeding. Unfortunately, as with polyp detection, the technology is not accurate enough to rely on as there are both false positives and negatives. False negatives are especially problematic as the consequence of a missed polyp or bleeding lesion can come with significant morbidity. Ultimately, liability rests with the physician and cannot be passed on to the AI software company. While this technology may help to inform or confirm a physician's analysis, it is not a substitute for comprehensive physician image review.

Perhaps the least accurate of the three AI technologies is AI used to detect reflux events during impedance pH monitoring. Unfortunately, the software is in its infancy and the false positive rates are high enough that many physicians choose to turn this optional feature off during study analysis as it takes more time to remove the AI detected events than to start with a blank study. In the end, while there is potential for AI to improve the quality of image analysis be that in real-time during colonoscopy or image review during capsule endoscopy, it is far from replacing physician work and in its current state may actually increase physician work in some settings.

***Q2: How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries?***

Because the AI technologies 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 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 the AI 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.

For bleeding detection, the software again is not accurate enough to be relied upon. While the AI analysis may suggest a series of images that may show evidence of bleeding, this serves more as a confirmatory check on the physician image review. If the physician were just to review the AI-suggested images and not review the entire video, they would be liable for missed lesions or bleeding sources that certainly could have been missed. Again, because the consequence of a missed polyp or missed source of bleeding is significant, the AI would need to reach almost 100% sensitivity to truly supplement physician work. Unfortunately, in order to reach 100% sensitivity, the false positive rate would then negate any possible time saved.

***Q3: How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs?***

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. Physician practices and hospitals that want to use AI must absorb the cost, which is another barrier to adoption. CMS should consider requiring companies to include AI in the software and licensing costs instead of on a subscription basis.

Another barrier to adoption is the cost of the AI 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 would need to be very inexpensive and incredibly accurate before large scale adoption would be likely.

***Q4: Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?***

We do not believe that, as compared with other services paid under the PFS, healthcare AI services in GI are more subject to fraud, waste, or abuse. Overutilization may be a concern but related more to inappropriate reliance on AI technologies that are still inaccurate. For example, because the currently available AI technologies in GI are for image analysis, they are likely to be always on when available. If physicians over utilize the AI suggestions in their work the quality may decrease. Even when using AI,

physicians must deliver the standard of care required and described by the CPT code. AI is not yet at a place where it can deliver this care autonomously and we must be careful to ensure that each AI technology is clearly categorized and utilized respective to its state of development. We urge CMS to investigate development of standards for AI.

***Q5: Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?***

AI models in GI and otherwise are susceptible to biases in training data; in addition, their accuracy is dependent on the circumstances in which they are tested. It is imperative that AI technologies are trained on data coming from a diverse population (gender, race, demographics) and that there is transparency about this training set. In addition, when considering reported AI outcomes, acknowledging the possible differences between ideal testing scenarios and the real-world is critical. For example, what happens if the AI polyp detection or bleeding detection software is applied to patients with altered anatomy, or suboptimal bowel cleanse, or risk factors for disease. CMS should thoroughly understand these factors when considering coverage and reimbursement of software algorithms and AI.

## **Quality Payment Program**

Our societies support a value-based payment system that balances cost and quality of care. As such, members of our societies have been highly engaged in the development of episode-based cost measures and have actively engaged the Administration regarding the development of a Merit-based Payment System (MIPS) Value Pathway (MVP) for gastroenterologists. Our societies have viewed the MVP concept as a glide path to physician participation in alternative payment models (APMs), although opportunities for gastroenterologists remain limited.

A complaint we hear frequently from our members is the Quality Payment Program (QPP), and MIPS specifically, is complex and confusing with minimal upside reward for the significant investment physician practices make for successful participation. While we support the idea of a MVP pathway, our assessment is that the MVP pathway as proposed is a re-arrangement of the current MIPS requirements that lacks significant incentive for participation and adds another layer of complexity to the overall understanding of the program.

While we appreciate that CMS proposes a gradual implementation timeline for MVPs such that they would first become an option in 2023, we do not support CMS' proposal to make MVP participation mandatory beginning in 2028. We understand the flexibility of the Agency to pursue more innovative approaches to an MVP pathway is limited by the statute. However, until CMS can truly streamline reporting across performance categories in a manner that is new and innovative and make MVP participation more meaningful, less burdensome and a true glide path to APM participation, the MVPs should be voluntary when formally incorporated into the program and should remain that way, allowing physicians, group practices, and subgroups the option to participate in traditional MIPS.

This flexibility is important as there remain several outstanding questions and issues that CMS must get right in order to attract participation in MVPs. The ongoing changes to MIPS, including this move to MVP reporting, increases in data requirements such as data completeness, and the future shift to digital quality measures present challenges. CMS must also consider whether the requirements to register when reporting an MVP and/or as a subgroup places additional undue burden on eligible clinicians and practices with little-to-no added value.

MVPs should not carry forward the flaws and problems of MIPS but should instead be an alternative that is grounded in improving patient care around an episode of care, clinical condition, or other public health priority.

Our societies appreciate CMS' recognition that there is not a "one size fits all" MVP structure that is suitable for all specialties. CMS states MVP development could be approached in various ways including in a manner that is broad, as well as in a more granular manner. Our societies appreciate being included in the development of a well-constructed and well-defined colorectal cancer prevention MVP which would center on screening colonoscopy, and we desire to work with CMS in that regard.

CMS has shown interest in a broader "colon health" MVP, but, as our societies have previously communicated to CMS, including in a February 2021 letter, a singular clinical problem, like colorectal cancer prevention through screening colonoscopy, offers the granularity needed for the MVP to be meaningful to both patients and clinicians. A granular MVP is also more likely to enhance comparative reporting. A broad gastroenterology MVP with unrelated quality measures would be disjointed rather than cohesive. Our societies are trying to guide CMS in the direction of a gastroenterology MVP that is feasible, given availability of quality measures, and meaningful for our physician members. We have been perplexed at the types of quality measures that have been suggested by CMS staff for a gastroenterology MVP, including surgical measures that would not be attributable to our members. CMS

seems to be reaching for more measures to include in a broad gastroenterology MVP rather than focusing its efforts on constructing a more granular MVP based on the availability of measures upon which CMS and the GI societies could build on in the future. As CMS introduces this new pathway, it should aim to test simple and focused conditions, procedures, and patient populations. In the future, as more quality and cost measures are developed, and data submission is potentially more automated, CMS can then work with stakeholders to consider MVPs that encompass more integrated episodes of care.

## **Merit-based Incentive Payment System**

At this time, and until there are more opportunities for gastroenterologists to participate in APMs, our priority is to ensure gastroenterologists who participate in MIPS can do so with minimal administrative burden and without putting their practice at risk for payment penalties. The COVID-19 pandemic has led to widespread and significant health care staffing shortages, with practices re-assigning staff to all but essential responsibilities. Our organizations therefore ask CMS to keep program changes to a minimum and to automatically apply the Extreme and Uncontrollable Circumstances Hardship Exception for the 2021 MIPS Performance Period.

## **MIPS Performance Category Measures and Activities**

### ***Quality***

#### Automatic Calculation of Outcome-based Administrative Claims Quality Measure

Our societies do not support automatic calculation of administrative claims measures, even as more outcome-based administrative claims quality measures get added to MIPS. Because CMS has struggled with adequate risk adjustment for administrative claims measures and to preserve choice of quality measures — a hallmark of MIPS — physicians must have the choice to elect an administrative claims measure as one of their six required quality measures.

#### Data Completeness Criteria

We appreciate the proposal to continue the data completeness criteria at 70 percent for the 2022 performance period and oppose the increase to 80 percent beginning with the 2023 MIPS performance period. Over time, we urge CMS to adopt requirements that are based on a set number of eligible patients or case minimums per measure, rather than an arbitrary percentage, which will make it easier for physicians and practices to track while also ensuring reliability of the performance scores used for MIPS benchmarking. For example, the current 20 patient case minimum does not produce adequate reliability for most measures gastroenterologists currently have available to report.

Percentage requirements of 70 percent or higher do not account for physicians who provide care beyond a single site and wrongly assume that data is fluid between sites. Some specialties, including gastroenterology, provide services across multiple sites using the same NPI/TIN; however, not all sites (including across sites of service) may: (1) participate in MIPS; or (2) use the same registry or EHR that the physician uses for MIPS reporting. Until physicians and other eligible clinicians can work within an environment where data and care are integrated seamlessly across settings and providers, it is premature to continue to increase the MIPS data completeness requirement.

### Selection of MIPS Quality Measures

We oppose removal of measure QPP425 *Photodocumentation of Cecal Intubation* from claims-based reporting; although we thank CMS for proposing to retain this measure for registry reporting as it is recognized by our societies as an important quality indicator for colonoscopy. Removing this measure from claims-based reporting disadvantages gastroenterologists in small practices who do not participate in registry reporting from having a meaningful, specialty-specific measure to report. If this measure is removed the only other GI measure available for claims-based reporting would be QPP320 *Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*, which is considered topped out with a seven-point cap.

### Substantive Changes to Measures

Our societies support the intent and draft criteria for determining whether a substantive change has been made to a quality measure. We also encourage CMS to consider a substantive change to be any modification to a measure that impacts performance scores that may likely be due to the changes in the measure construct or coding and not actual performance. For example, if year-over-year comparisons could not be attributed to actual changes in performance, it should be considered a substantive change.

### Request for Information: COVID-19 Vaccination by Clinicians Measure

Our societies support the intent of this measure, particularly given the importance of patients with inflammatory bowel disease being up to date with vaccinations. However, this measure should be voluntary given the evolving nature of the COVID-19 pandemic and strategies for vaccination, including frequency by which boosters will be necessary. We also suggest that data obtained from this measure will be of minimal value unless patient self-reported COVID-19 vaccination can be verified. Further, if CMS attempts to use this measure to capture provision of effective care, there will be enormous consequences for clinicians who practice in areas where there is significant vaccine hesitancy and refusal. Instead, CMS could consider the addition of an Improvement Activity that involves the dissemination of factually correct information to patients about the COVID-19 vaccine.

### ***Cost***

#### Substantive Changes Criteria for Cost Measures

Our societies support the intent and draft criteria for determining whether a substantive change has been made to a quality measure. We also encourage CMS to consider a substantive change to be any modification to a measure that impacts performance scores that may likely be due to the changes in the measure construct or coding and not actual performance. For example, if year-over-year comparisons could not be attributed to actual changes in performance, it should be considered a substantive change.

### ***Improvement Activities***

#### Group Reporting

We support CMS' position of allowing subgroups to perform and attest to their improvement activities separate from the parent group, as well as CMS' proposal to apply the 50 percent improvement activity

participation threshold within subgroups. As our societies have previously commented, the 50 percent requirement, in absence of subgroup reporting, discouraged the use of specialty-oriented improvement activities within multi-specialty practices.

### ***Promoting Interoperability***

#### **Query of Prescription Drug Monitoring Program (PDMP) Measure**

Our societies support CMS' proposal to maintain the Electronic Prescribing Objective's Query of the PDMP measure as optional, especially as many physicians and health systems remain incapable of interconnecting their health information technology with a PDMP system, and to assign it 10 bonus points for the CY 2022 performance period/2024 MIPS payment year.

#### **Provide Patients Electronic Access to Their Health Information Measure**

Our societies echo the comments of the American Medical Association (AMA) that expanding to an encounter start date of Jan. 1, 2016, does not take into consideration the limitations of EHR technology to support physicians and health systems' compliance with this proposed policy. If old medical records are digitized using digital imaging or PDF-style formats, these formats will make it challenging to search for or protect specific information in EHRs. We concur with the AMA that CMS should create flexibility that allows physicians to provide most of the information requested but still allows leeway for health information management personnel or a physician's professional judgment to determine when it is impractical for certain information to be made available in a "timely" manner.

#### **Public Health and Clinical Data Exchange Objective and Scoring**

CMS is proposing a MIPS eligible clinician may earn 5 bonus points if they report a "yes" response for either the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure. We support bonus points for this measure which demonstrates the value of participation in clinical data registries.

Our societies oppose "all-or-nothing" scoring approaches such as being proposed for situations in which the MIPS eligible clinician fails to report on any one of the two measures required for this objective or reports a "no" response for one or more of these measures. In such cases, CMS is proposing the clinician would receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Promoting Interoperability (PI) performance category. It is likely that most gastroenterologists will be exempt from both measures for this objective. In such cases, CMS proposes the 10 points would get redistributed to the objective "Provider to Patient Exchange." We recommend that CMS not shift more points to the Provider to Patient Exchange objective but continue to score the other promoting interoperability objectives as it would normally do.

#### **Safety Assurance Factors for EHR Resilience (SAFER) Guides Measure**

Although our societies appreciate the importance of practices being prepared for planned or unplanned EHR unavailability, we agree with the AMA's position that CMS should not finalize its proposal to require physicians to attest to having completed an annual assessment of the nine SAFER Guides on the basis the measure is out of scope for the PI category and the guides have not been recently updated. Instead, CMS should consider including the SAFER Guides as an option under the Improvement

Activities category and should work with the Office of the National Coordinator to engage in an update of the guides and undertake an education and awareness campaign to disseminate information to the field, including information tailored to small and medium-sized physician practices.

#### Reweighting the PI Category for MIPS Eligible Clinicians in Small Practices

We support CMS' proposal that beginning with the CY 2022 performance period clinicians and small practices seeking to qualify for the PI hardship exception and reweighting will no longer be required to submit an application. Instead, CMS is proposing to automatically assign a weight of zero percent to the PI category and redistribute its weight to another performance category if no data is submitted to the PI category by or on behalf of a MIPS eligible clinician in a small practice. If 84 percent of the 49,278 clinicians in small practices who were scored as an individual for MIPS did not submit Promoting Interoperability performance category data and did not apply for a small practice hardship exception, it points to a clear communication and education problem. As such, we are equally concerned that small practices will not know the automatic hardship exception applies and will submit PI data when they would have otherwise benefitted from the hardship exception. We ask CMS to broaden its communication efforts to clearly communicate to physicians this exception and other program changes.

### **MIPS Final Score Methodology**

#### ***Quality***

##### Quality Measure Benchmarks

Consistent with the position of our societies last year, we support CMS' proposal to set benchmarks for the CY 2022 performance period based on the actual data submitted during the CY 2022 performance period. Because of the flexibilities CMS instituted regarding submission of 2020 data, there may not be a representative sample of historic data for benchmarking. CMS should also explore the impact the use of 2019, 2020, and 2021 data will have on setting benchmarks and risk-adjustment models and consider scoring based on pay-for-performance.

We do not support the proposal to expand the definition of the baseline period to calculate a benchmark. Expanding from two to three performance periods when a measure is suppressed creates instances where the underlying data are too retrospective and not reflective of current performance. This approach does not address the concerns of using a representative sample of historic data since many of the baseline periods would include data from 2019, 2020, and 2021 data – all of which are impacted by the COVID-19 pandemic. We encourage CMS to avoid the use of these data for benchmarking purposes.

##### Assigning Quality Measure Achievement Points

Our societies oppose removing the 3-point floor for measures that can be reliably scored against a benchmark for the 2022 performance period at this time. As stated in the proposed rule, CMS had previously discussed waiting to remove the 3-point floor until there was further development of the MVP framework. We recommend the 3-point floor should not be removed until the 2023 performance year when MVPs are introduced into the program. During the pandemic, clinicians have been limited in their abilities to gain the experience otherwise expected that would allow for raising the bar around all scoring elements.

##### Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We support maintaining for small practices the three-point floor policy for measures that do not have a benchmark or fail to meet the case minimum requirement. We appreciate CMS does not want the removal of the three-point floor for all other practices to discourage the reporting of new measures in the program because they may lack a benchmark or do not meet the case minimum. We support raising the floor for new measures in the program for all collection types for their first two years in the program. In comments previously shared by our societies, the achievement point cap of three points creates a disincentive for clinicians to report new measures, and, consequently, makes it more difficult for a measure to meet the requirements for establishing benchmarks. Gastroenterology has few measures. Efforts to add more gastroenterology measures must be met with incentives for reporting those measures. We agree with the AMA that the floor for reporting a new measure should be raised to a minimum of 7 points to provide sufficient incentive for practices to take on the risk of reporting on a new measure and the associated investments in new protocols and workflow, which often require IT and practice redesign costs.

#### Assigning Measure Achievement Points for Topped Out Measures

We share the AMA’s concern with CMS’ continued efforts to remove quality measures from MIPS regardless of whether the measure is truly topped out and not just representative of top performers or one data source. The GI societies substantively updated the measure specification for QPP425 Photodocumentation of Cecal Intubation beginning with the 2019 performance year. Historical benchmarks became available for the measure beginning with the 2021 performance year, and the measure is already marked as topped out for both claims-based and registry reporting. Data from GIQuIC, the largest national clinical registry of gastroenterology-specific quality data, including more than 13 million colonoscopy cases, demonstrates QCDR reporters of QPP425 show higher performance than the average registry participant as illustrated in the tables below. The GI societies recognize there continues to be opportunity for improvement on this measure and offer educational programming and direction to support ongoing monitoring of this priority quality indicator for colonoscopy.

#### **2019**

	<b>All participants</b>	<b>GIQuIC 2019 QCDR individual reporters</b>
Provider n	4,154	269
Mean performance	84.1%	92.34%
SD performance	27.1%	16.26%
Minimum performance	0%	3.17%
Maximum performance	100%	100%
Mean denominator count	376.1	452.3

#### **2020**

	All participants	GIQuIC 2020 QCDR individual reporters
Provider n	4,002	167
Mean performance	87.1%	94.37%
SD performance	24.4%	14.86%
Minimum performance	0%	0%
Maximum performance	100%	100%
Mean denominator count	276.1	319.3

Our societies appreciate CMS' proposal to maintain QPP425 for registry reporting for 2022. We oppose removal of this priority measure from claims-based reporting given its importance and because the measure's removal would disadvantage gastroenterologists in small and rural practices who are providing screening colonoscopy services, and who would be left with one gastroenterology-specific, claims-based measure for reporting. QPP425 illustrates our concern with removal of quality measures from MIPS regardless of whether the measure is truly topped out and not just representative of top performers or one data source. Gastroenterologists have been challenged over the years in being able to meaningfully report across a broad array of QPP and QCDR specialty-specific quality measures with available measures changing each performance year. Most notable was the removal of the only outcome measure broadly available to gastroenterologists, QPP343 Screening Colonoscopy Adenoma Detection Rate, beginning with the 2020 performance year.

Clinical experts from the GI societies invested a tremendous amount of time in working with CMS and Acumen to develop the episode-based cost measure Screening/Surveillance Colonoscopy, recognizing the linkage between quality and cost measures to measure value. With the surprising removal of QPP343 and the topped-out status assigned to many of the few remaining gastroenterology-specific quality measures available for reporting, our societies are consequently challenged and deeply concerned with moving forward with an MVP concept.

#### Case Minimum Requirements

We urge CMS to evolve its benchmark methodology to better distinguish care and ensure it meets scientific evidence. We appreciate CMS' recognition that adequate reliability may not always be achieved using a case minimum of 20 patients across all quality measures and support including some flexibility to enable larger case minimum requirements on a measure-by-measure basis. We urge CMS to ensure that all MIPS measures have high reliability, and this reliability standard should be higher than 0.7 not 0.4. While the 20-patient case minimum has been used since the beginning of this program, it remains unclear how CMS determined that this number produced adequate reliability across all the quality measures. In fact, if the current case minimum is based on assumptions and not actual measure score reliability testing, we urge CMS to revisit the current approach and modify the requirements to enable the proposed flexibility on a measure-by-measure basis for not just to new measures but to existing MIPS measures.

Measure scores that are used for quality category scoring and public reporting must demonstrate sufficient reliability; otherwise, the scores will likely be misrepresentative of the actual quality of care provided.

#### Incentives to Report High-Priority Measures Incentives and to Use CEHRT to Support Quality Performance Category Submissions

CMS should continue to incentivize through bonus points high-priority measures and end-to-end electronic reporting until the 2023 performance year when MVPs are introduced into the program.

### **Calculating the Final Score**

#### Complex Patient Bonus

Our societies defer to the thoughtful analysis the AMA has conducted regarding CMS' proposed revision of the methodology to calculate the complex patient bonus. There appears to be too many outstanding questions and concerns regarding the proposed methodology, and, as such, the proposal should not be finalized. Instead, we support the AMA's recommendation to increase the cap on the complex patient bonus to at least 20 points and scale the formula so that individual clinicians in the upper quintile can receive at least a 15-point bonus. We also encourage CMS to consider the AMA's comments regarding standardizing risk indicators, including using the median instead of the mean and using a more robust measure of variation than the standard deviation to ensure real differences in the complexity of a physician's patients relative to most other physicians is appropriately reflected.

In addition to the complex patient bonus, our societies appreciate CMS' interest in stakeholder input about how the Agency can close the health equity gap, including through the QPP. In this regard, the proposed new and modified Improvement Activities to address racism and health equity are good steps. We believe the collection of better demographic data that will allow for stratification of measures and addressing gaps in health equity is worthy of a separate RFI which will allow our societies to respond more thoughtfully to the important questions that have been preliminarily raised in this proposed rule.

### **Final Score Performance Category Weights**

#### Re-weighting the Cost Performance Category

Because CMS determined it cannot reliably calculate scores for the cost measures that adequately capture and reflect the performance of MIPS eligible clinicians, the agency announced via email communication on May 20, 2021, it will assign a weight of 0 percent to the cost performance category for the CY 2020 MIPS performance period and redistribute the cost category weight to another performance category or categories. Our societies supported that decision and encouraged CMS to assign a weight of 0 percent to the cost category of the CY 2021 performance year as well because of the lingering impact COVID-19 is having on patient care. We request CMS to make this decision in the final rule in an effort to minimize confusion among physicians.

#### Redistributing Performance Category Weight for Small Practices

We agree that given infrastructure and resource limitations within small practices, it is appropriate to place more emphasis on a performance category, such as Improvement Activities, that pose a reduced reporting burden. We support CMS' proposal in this regard and encourage CMS to host provider

educational sessions specifically on the requirements of the Improvements Activities category, which we believe is too often an overlooked category.

## **MIPS Payment Adjustments**

### Establishing the Performance Threshold

We are grateful for the flexibilities and hardship exemptions and accommodations that have been afforded to physicians during the ongoing public health emergency. We are also aware CMS is under statutory obligation beginning with the 2024 payment year to set the performance threshold at the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. However, we ask CMS to use any and all authorities granted to it, including under its Extreme and Uncontrollable Circumstances hardship exception policy, to lower the performance threshold from the proposed 75 points. At a minimum, the performance threshold should remain at 60 points. As the AMA has aptly pointed out in its letter, the COVID-19 pandemic has interrupted MIPS participation across three performance years so far. Prior to the start of the public health emergency, the performance threshold was 30 points. Jumping from 30 to 75 points during a period of significant health care delivery disruption is unreasonable. Not only has the pandemic disrupted the health care system, but it has been exacerbated by extreme weather disasters in large swaths of our country. With every anticipation that the pandemic will extend into 2022, we urge CMS to not increase the performance threshold next year.

### Conclusion

Thank you for the opportunity to comment on the CY 2022 PFS 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).

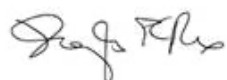
Sincerely



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John M. Inadomi, MD, AGAF  
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President, American Society for Gastrointestinal Endoscopy



September 17, 2021

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

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1715-P  
P.O. Box 8016  
Baltimore, MD 21244-8013

RE: [CMS–1753–P] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

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-1753-P), regarding the proposed policy revisions to the CY 2022 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:

- Calculation of OPPS Scaled Payment Weights
- Expiration of Transitional Pass-Through Payments for Certain Devices – Use of Equitable Adjustment Authority
- Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Test
- Additions to the List of ASC Covered Surgical Procedures

A summary of our recommendations can be found on page 5.

### Calculation of OPPS 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. 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 rescaler in 2009, there has never been an increase in ASC relative weights.**

The proposed scalar weight for CY 2022 is 0.8591, which is the same as the 2021 final ASC weight scalar. If finalized, ASCs will again experience a negative impact from the scalar. This continues to be detrimental to practices that are already struggling to withstand the challenges of practice during the ongoing COVID-19 pandemic. Based on past trends, we only foresee the secondary rescaler further eroding the relationship of HOPD and ASC payments for the same set of services. **We, therefore, urge CMS eliminate the secondary scalar for ASCs and to apply the OPPS relative weights to services provided in the ASC.**

### Expiration of Transitional Pass-Through Payments for Certain Devices – Use of Equitable Adjustment Authority

**We support CMS' proposal to use CY 2019 claims data instead of CY 2020 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in final rule 2021 OPPS rate setting caused by the effects of the COVID-19 public health emergency (PHE).** We agree that the COVID-19 pandemic has significantly impacted utilization of services and cost patterns and that CY 2019 data are the most recent complete calendar year of data prior to the COVID-19 PHE and are a better approximation of expected CY 2022 hospital outpatient services.

We support the proposed payment extension for technologies for which transitional pass-through payment would otherwise be discontinued in 2022. However, we recommend all pass-through devices that experienced a disruption due to the COVID-19 PHE have a full three years of data collection. This includes extensions for transitional pass-through payments for drugs, biologics, and device categories, set to expire in 2023, including C1748 (Endoscope, single-use (that is, disposable), upper GI, imaging/illumination device (insertable)). Due to the rise of the COVID-19 Delta variant and resulting increase in hospitalizations, many states are, again, halting all non-emergency procedures. Therefore, as the COVID-19 PHE is ongoing, CY 2023 OPPS rate-setting will also be impacted. For these reasons, **we ask CMS to allow a 1-year**

**payment extension for new device categories for which transitional pass-through payment would otherwise expire in 2022 and 2023.**

Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

We are grateful that CMS is finally able to gradually eliminate the Medicare's beneficiary's coinsurance when a polyp(s) is removed during a screening colonoscopy beginning CY 2022 through CY 2030, when coinsurance is completely waived. This change is pursuant to legislation passed as part of Consolidated Appropriations Act of 2021. Our societies advocated for this legislation on behalf of our members and patients. We believe this important policy change will help increase colorectal cancer screening rates in the Medicare population, thus, we commend CMS and Congress for this change.

Colorectal cancer is largely preventable but too few people are getting screened. The American Cancer Society also estimates that when detected and treated early, the 5-year survival rate for colorectal cancer is 90%. Unfortunately, early detection occurs in less than 40% of colorectal cancer cases. Routine screening and colonoscopy with polypectomy are powerful tools for prevention. Like most types of cancer, according to the American Cancer Society, the risk of colorectal cancer increases with age. For every subsequent 5-year age group, the incidence rate approximately doubles until age 50, and thereafter increases by about 30%. Colorectal cancer remains the second leading cause of cancer death in the U.S. among men and women combined. Our societies remain committed to raising awareness for colorectal cancer screening and prevention through colonoscopy. We must do more to increase screening rates in the Medicare population, especially due to the COVID-19 pandemic.

The National Cancer Institute recently estimated a 1% increase in deaths from breast and colorectal cancer over the next 10 years - *the equivalent of approximately 10,000 excess deaths* - due to the pandemic's impact on screening and treatment. This is likely an underestimate because models assumed a 6-month disruption in care followed by the return to routine care, which has since proven too optimistic.

We thank CMS for implementing this legislation and look forward to working with the agency in the future to reduce colorectal cancer incidence rates and deaths. This includes removing Medicare beneficiary cost-sharing when the patient is referred to our members for the necessary colonoscopy subsequent to positive result in a non-colonoscopy, colorectal cancer screening test (e.g., fecal immunochemical test (FIT), multi-target stool DNA test (Cologuard), flexible sigmoidoscopy, etc.). Our societies believe this scenario is part of the colorectal cancer screening continuum, as there can be no diagnosis without further assessment (i.e., the follow-up colonoscopy). Ideally, a screening program should guarantee full coverage of the cascade of screening events in the target population. Participation in colorectal cancer screening programs is influenced by organizational (e.g., modality of invitation and test delivery, interventions at system and provider level) and individual factors (e.g., gender, race, socioeconomic status, subject attitude towards screening). Studies demonstrate that there is a wide variation and low

adherence to a diagnostic colonoscopy after a positive screening test.<sup>1 2 3 4 5 6 7 8 9</sup> Yet, one study concluded that patients who did not have a colonoscopy after receiving a positive fecal occult blood test had a 103% higher risk of death, compared with those who had a colonoscopy.<sup>10</sup>

### Additions to the List of ASC Covered Surgical Procedures

In the CY 2021 OPPTS/ASC Final Rule, CMS significantly revised its policy for adding surgical procedures to the ASC Covered Procedure List (CPL). CMS explained that there were several reasons why those changes were made, including that ASCs are increasingly able to safely provide services that meet some of the general exclusion criteria. Further, CMS acknowledged the importance of ensuring that the healthcare system has as many access points and patient choices for Medicare beneficiaries as possible, which includes enabling physicians and patients to choose the ASC as the site of care when appropriate and the critical role that physicians play in determining the appropriate site of care for their patients.

We believe gastrointestinal (GI) physiologic tests (CPT codes 91010-91200) can be performed safely in the ASC setting and meet CMS' current criteria; however, pricing is a critical variable to ensure that procedures that can safely be performed in the ASC setting. High-cost disposables cannot be reported separately from the procedure/test in the ASC setting. Under the current

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<sup>1</sup> Eckmann, Jason D. MD1; Ebner, Derek W. MD1; Bering, Jamie MD2; Kahn, Allon MD3; Rodriguez, Eduardo MD3; Devens, Mary E. CCRP4; Lowrie, Kari L. ACRC4; Doering, Karen CCRP4; Then, Sara ACRC4; Burger, Kelli N. BS5; Mahoney, Douglas W. MS5; Prichard, David O. MD4,6; Wallace, Michael B. MD7; Gurudu, Suryakanth R. MD3; Finney, Lila J. PhD, MPH8; Limburg, Paul MD4; Berger, Barry MD4,9; Ahlquist, David A. MD4; Kisiel, John B. MD4 Multitarget Stool DNA Screening in Clinical Practice: High Positive Predictive Value for Colorectal Neoplasia Regardless of Exposure to Previous Colonoscopy, *The American Journal of Gastroenterology*: 1 2020 - Volume 115 - Issue 4 - p 608-615 doi: 10.14309/ajg.0000000000000546.

<sup>2</sup> Kapidzic A, Grobbee EJ, Hol L, van Roon AH, van Vuuren AJ, Spijker W, et al. Attendance and yield over three rounds of population-based fecal immunochemical test screening. *Am J Gastroenterol* 2014; 109: 1257–64.

<sup>3</sup> Zorzi M, Fedato C, Grazzini G, Sassoli de' Bianchi P, Naldoni C, Pendenza M, et al. Screening for colorectal cancer in Italy, 2010 survey. *Epidemiol Prev* 2012; 36: 55–77.

<sup>4</sup> Steele RJ, McDonald PJ, Digby J, Brownlee L, Strachan JA, Libby G, et al. Clinical outcomes using a faecal immunochemical test for haemoglobin as a first-line test in a national programme constrained by colonoscopy capacity. *United European Gastroenterol J* 2013; 1: 198–205.

<sup>5</sup> Levin TR, Corley DA, Jensen CD, et al. Effects of Organized Colorectal Cancer Screening on Cancer Incidence and Mortality in a Large Community-Based Population. *Gastroenterology*. 2018;155(5):1383-1391.

<sup>6</sup> Stoop EM, de Haan MC, de Wijkerslooth TR, Bossuyt PM, van Ballegooijen M, Nio CY, et al. Participation and yield of colonoscopy versus non-cathartic CT colonography in population-based screening for colorectal cancer: a randomised controlled trial. *Lancet Oncol* 2012; 13: 55–64.

<sup>7</sup> Sali L, Mascali M, Falchini M, Ventura L, Carozzi F, Castiglione G, et al.; SAVE study investigators. Reduced and full-preparation CT colonography, fecal immunochemical test, and colonoscopy for population screening of colorectal cancer: a randomized trial. *J Natl Cancer Inst* 2015; 108: 319.

<sup>8</sup> Zavoral M, Suchanek S, Zavada F, Dusek L, Muzik J, Seifert B, et al. Colorectal cancer screening in Europe. *World J Gastroenterol* 2009; 15: 5907–15.

<sup>9</sup> Schreuders EH, Ruco A, Rabeneck L, Schoen RE, Sung JJ, Young GP, et al. Colorectal cancer screening: a global overview of existing programmes. *Gut* 2015; 64: 1637–49.

<sup>10</sup> Zorzi, Manuel, Battagello, Jessica, Rita Fiore, Memo, Laura, Senore, Carlo, Rugge, Massimo. Colorectal cancer incidence and mortality after negative fecal immunochemical tests by age 70: A prospective observational study. *International Journal of Cancer* 2021; Sep 15;149(6):1257-1265.

ASC payment methodology, the ASC reimbursement for procedures/tests with high-cost disposables will not cover their costs. Therefore, even if CMS placed the GI physiologic tests on the ASC CPL, physicians will never be able to afford to perform them in that setting. **Although the topic of ASC payment methodology is not specifically addressed in the proposed rule, we encourage CMS to engage with us and other specialty societies on this topic to gather information about how this might be addressed. We look forward to meeting with CMS to discuss our ideas.**

#### Conclusion

Our societies urge CMS to:

- Eliminate the secondary scalar for ASCs and apply the OPPS relative weights to services provided in the ASC
- Allow a 1-year payment extension for new device categories for which transitional pass-through payment would otherwise expire in 2022 and 2023, including C1748
- Add GI physiologic tests (CPT codes 91010-91200) to the ASC CPL
- Engage with specialty societies on the topic of addressing reimbursement for high-cost disposables within the ASC reimbursement methodology to gather information about how this problem might be addressed

The ACG, AGA and ASGE appreciate the opportunity to provide comments on the CY 2022 OPPS and ASC Payment Systems proposed rule. If we may provide any additional information, please contact Brad Conway, ACG, at 301-263-9000 or [bconway@gi.org](mailto:bconway@gi.org); Kathleen Teixeira, AGA, at 240-482-3222 or [kteixeira@gastro.org](mailto:kteixeira@gastro.org); or Lakitia Mayo, ASGE, at 630-570-5641 or [lmayo@asge.org](mailto:lmayo@asge.org).

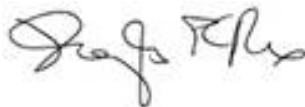
Sincerely,



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