



August 30, 2019

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

Seema Verma
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: Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma:

The American College of Gastroenterology (ACG), American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1715-P), published on August 14, 2019 in the *Federal Register*, regarding the proposed policy revisions to the CY 2020 Medicare Physician Fee Schedule (PFS). Together, our three societies represent virtually all practicing gastroenterologists in the United States.

There are several provisions in the proposed rule that adversely impact practicing gastroenterologists and the Medicare beneficiaries they treat. Additional comments from our organizations will be subsequently submitted on other provisions within the proposed rule. In this letter, we offer comments on the following provisions.

- Coinsurance for Colorectal Cancer Screening Tests
- Scope Proposals for CY 2020
- Determination of Malpractice Relative Value Units (RVUs)
- Measures Proposed for Removal from QPP

Coinsurance for Colorectal Cancer Screening Tests

The CY 2020 MPFS proposed rule invites comment on establishing a requirement that the physician who plans to furnish a colorectal cancer (CRC) screening colonoscopy notify the patient in advance that a screening procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply. CMS seeks comment on whether the physician, or their staff, should be required to notify patients of the cost-sharing implications and Medicare coverage rules prior to performing a screening colonoscopy. Specifically, CMS seeks comment on whether physicians should be required to provide a verbal notice with a notation in the medical record, or whether CMS should consider a different approach to informing patients of the copayment implications, such as a written notice with standard language that CMS would require the physician, or their staff, to provide to patients prior to a colorectal cancer screening. CMS also seeks comments on what mechanism, if any, should be considered to monitor compliance with a notification requirement.

We applaud the Agency for addressing this important issue; however, we do not agree that the solution is to place the burden of notifying beneficiaries of Medicare's policy for CRC screening coverage onto providers or their staff. The underlying problem that needs to be rectified is the financial burden facing Medicare beneficiaries whose screenings become diagnostic procedures when a polyp is removed, which is an essential part of screening colonoscopies. Members of Congress who drafted the original law have written letters to the agency clarifying that it was never their intention for polypectomy resulting from a screening colonoscopy to be excluded from the CRC screening benefit. They appealed to Administrator Seema Verma to “urge the Centers for Medicare and Medicaid Services (CMS) to use its existing authority to increase access to colorectal cancer screenings for Medicare beneficiaries by eliminating the out-of-pocket costs associated with screening colonoscopies when a polyp is found and removed.” See Attachments A and B. Senator Sherrod Brown (D-OH) also issued a [press release](#) on July 30, 2019 titled “Proposed Rule Falls Short of Necessary Measures to Protect Seniors from Unexpected Bills after Colonoscopies.” Our societies continue to urge Congress to give CMS this regulatory authority. This legislation is bipartisan and has the support of the majority of members in both chambers of Congress. As demonstrated by Attachments A and B, we continue to hear from Congress that CMS may already have the authority to waive coinsurance when a screening colonoscopy turns diagnostic or “therapeutic.” **Our societies urge CMS to release a written statement addressing the lack of regulatory authority to include polypectomy resulting from a screening colonoscopy as part of the CRC screening benefit. We also ask the Administration to encourage legislative action to correct this oversight in law.**

Inconsistency with “Patients over Paperwork” Initiative

We believe that any CMS proposal requiring physicians to notify Medicare beneficiaries of the Agency's coverage policy is inconsistent with the “Patients over Paperwork” initiative to decrease administrative burden for physicians. “Clinicians are drowning in paperwork and reporting requirements caused by cumbersome government rules and regulations,” said CMS Administrator Seema Verma in the “Trump Administration's Patients over Paperwork Delivers for Doctors” press release from July 29, 2019 (Attachment C). Gastroenterologists often provide to patients printed information, at the expense of their practice, that explains what the patient can expect in terms of payment when having a colonoscopy. However, in addition to the uncompensated materials currently offered by many practices, CMS' proposal would now require physicians or staff to have a verbal conversation with patients and document that conversation in the medical record. This mandate represents a significant burden regardless of

whether done by staff or physicians. **Therefore, we believe any proposed requirements contradict the Administration's Patients over Paperwork initiative.**

Proposal to Educate Patients is Based on Inaccurate Assumptions

We believe CMS may have made certain assumptions about the way screening colonoscopy is provided that do not reflect coding and billing rules published by CMS concerning when Evaluation and Management (E/M) services can be reported. We believe CMS may have assumed that all beneficiaries receive an E/M visit prior to screening colonoscopy procedures and, therefore, that physicians and staff could provide education about Medicare coverage policy during that visit. However, CMS' rules do not allow billing of an E/M visit prior to a screening colonoscopy unless it is supported by documentation of a medically-necessary history, exam, and medical decision-making (e.g., the patient has complex medical comorbidities that may require special instructions prior to the procedure).

While CMS rules for screening colonoscopy in chapter 18 (Preventive and Screening Services, section 60) of the Medicare Claims Processing does not expressly address E/M visits prior to screening colonoscopy, CMS does address the issue of when one may report a separate E/M service with a minor surgical or endoscopic procedure in other publications.

The CMS [Global Surgery Fact Sheet Booklet](#), page 7 (emphasis added):

Note: The initial evaluation for minor surgical procedures and endoscopies is always included in the global surgery package. Visits by the same physician on the same day as a minor surgery or endoscopy are included in the global package, unless a significant, separately identifiable service is also performed. Modifier "-25" is used to bill a separately identifiable evaluation and management (E/M) service by the same physician on the same day of the procedure.

The CMS [National Correct Coding Initiative manual](#), Chapter 6. Page 4 (emphasis added):

If a procedure has a global period of 000 or 010 days, it is defined as a minor surgical procedure. **In general E&M services on the same date of service as the minor surgical procedure are included in the payment for the procedure.** The decision to perform a minor surgical procedure is included in the payment for the minor surgical procedure and shall not be reported separately as an E&M service. However, a significant and separately identifiable E&M service unrelated to the decision to perform the minor surgical procedure is separately reportable with modifier 25. The E&M service and minor surgical procedure do not require different diagnoses. If a minor surgical procedure is performed on a new patient, the same rules for reporting E&M services apply. The fact that the patient is "new" to the provider is not sufficient alone to justify reporting an E&M service on the same date of service as a minor surgical procedure. NCCI contains many, but not all, possible edits based on these principles.

CMS also offers specific exceptions when an E/M *can* be reported prior to a minor surgery or endoscopy. The Physician Regulatory Issues Team (PRIT) addressed a question submitted by ACG and the answer is posted [here](#) on the CMS site:

Issue - The American College of Gastroenterology has asked the PRIT if there are circumstances under which Medicare might pay for a preprocedure visit for a patient scheduled for a screening colonoscopy

Response - Medicare coverage is permitted for services which are "reasonable and necessary for the diagnosis or treatment of illness or injury" by law (Title 18 of the Social Security Act 1862(a)(1)(A)) and therefore a precolonoscopy E&M which meets this requirement will normally be covered. An E&M visit which does not meet this reasonable and necessary standard is defined as noncovered by the law. Only congress can allow exceptions to this reasonable and necessary standard by creating a special benefit category as it has for each of the preventative benefits now covered by Medicare

The AGA, ACG and ASGE published the following joint guidance in the [2017 Coding Updates](#) article (Question 9, page 16):

9. QUESTION: Our doctors see patients in the office prior to a screening colonoscopy. The doctors take a complete history, do a review of systems (ROS) and a thorough exam. If the only diagnosis is "screening for colon cancer," can we still bill an office visit?

Answer: Since December 27, 2015, the Department of Labor has mandated that commercial plans that are nongrandfathered (i.e., plan that conforms to the ACA guidelines) are required to pay for the visit prior to screening with no cost sharing by the patient. This is not a consultation since there is no request for a consult, but just a transfer of care since the request (by patient or by referral source) is for a preventive procedure to be done. The diagnosis code for screening or family history of polyps or cancer is covered at 100% and would be the primary diagnosis. If the patient has a complaint or abnormality, this would not be screening and would be subject to plan benefits. The codes to use would be S0285 since July 1, 2016, or 99201-99215. It is up to each practice to query the most common payors to find out policy, to verify the codes to be used and also to check eligibility upon patient scheduling/appointments.

For Medicare, Medicaid and those patients who participate in a grandfathered plan (those plans that do not conform to the ACA (Affordable Care Act), an E/M visit prior to the colonoscopy is not covered and will be denied with no patient responsibility, unless the patient has symptoms or a chronic condition/disease that has to be managed by the GI provider. If you inform the patient ahead of time that this visit is non-covered and they wish to pay for it out-of-pocket, that is the patient's choice. An advance beneficiary notice (ABN) is not required, but it is sensible to obtain a waiver of some type. If the patient insists that the visit is billed to Medicare, use an unlisted E/M code or preventive service code (99401-99404 series) with GY modifier, which tells the carrier it is a non-covered service and the denial shifts to patient responsibility

Impact on Doctor-Patient Relationship Not Considered

We are concerned that CMS has not considered the impact of its proposal on the doctor-patient relationship. Coverage policies and terms are determined by the insurance provider. Among commercial payers, it is the insurance provider who is responsible for discussing and clarifying the terms of its coverage policies with its clients. The terms of the client's insurance and coverage are always a discussion solely between the client and the insurance provider, leaving healthcare to the healthcare provider. In CMS' proposal, Medicare (the insurance provider) is requiring the health care provider to be the primary point of contact to explain its coverage. This is something no commercial payer requires of its in-network providers. Shifting the discussion from care to coverage forces physicians to become experts in Medicare coverage and payment policy as opposed to focusing on the practice of medicine. Shifting this responsibility to others in the office or department is also inappropriate. Nurses and other medical staff who may see the Medicare beneficiary are also not experts in Medicare coverage and payment policy and will

have limited ability to answer patients' questions about Medicare's policies. It would also be impractical logistically for the coding and billing staff to meet with each Medicare beneficiary prior to being seen by the physician. In addition, many practices outsource coding and billing services to a centralized location, making it even more unrealistic for Medicare beneficiaries to meet with billing staff prior to every screening colonoscopy. The overall goal of physicians and their ancillary staff should be to deliver high-quality effective patient care and not get distracted by having to address Medicare's complex coverage policies.

Potential to Deter Patients From Screening

We also question whether CMS has investigated the impact its proposal on deterring patients from screening. When faced with the potential that a "free" screening service may cost hundreds of dollars out-of-pocket, some beneficiaries without Medicare supplemental insurance may forego a screening colonoscopy. This would not only be detrimental to patient health but also eventually add significant financial burden to our healthcare system by increasing the risk of developing advanced colorectal cancers. Consider that even though most patients will not have a polyp removed during their screening colonoscopy, Medicare's policy would have to be discussed with *all* patients. Because there is no way to know in advance who will have a polyp, physicians and/or staff would have to take the time to address this complex policy with all patients presenting for a screening colonoscopy. In those for whom a polyp is not discovered, this discussion will have caused unnecessary wasted time, mental effort and stress for both physicians and patients; not to mention deterring some patients from proceeding with their procedure entirely.

Lack of CMS Outreach and Education for Beneficiaries

We also note that Medicare beneficiary information often lacks an explanation of this gap in Medicare coverage. For example, while CMS provides an explanation of the cost-sharing quirks related to [screening colonoscopy](#), the "[Welcome to Medicare](#)" [initial preventive examination pamphlet](#) provided to beneficiaries lacks an explanation on screening colonoscopy. Also, the Medicare.gov [Procedure Price Lookup](#) tool does not include information for beneficiaries regarding colorectal cancer screening colonoscopy. When a Medicare beneficiary searches "screening colonoscopy" on the Procedure Price Lookup tool, only two options are provided:

Cancer screening of the colon (large bowel) using an endoscope (colonoscopy) for high risk individuals (Code: G0105); and

Cancer screening of the colon (large bowel) using an endoscope (colonoscopy) for individuals who are not high risk (Code: G0121).

For these screening services, the Procedure Price Lookup tool indicates that the patient will have zero cost sharing for the screening colonoscopy regardless of whether the procedure is performed in the ambulatory surgery center or hospital outpatient department.

Cancer screening of the colon (large bowel) using an endoscope(colonoscopy) for individuals who are not high risk

Code: G0121

Patient pays (average)

\$0

Ambulatory surgical centers

Medicare Pays	\$383
Total Cost	\$383

Patient pays (average)

\$0

Hospital outpatient departments

Medicare Pays	\$744
Total Cost	\$744

i Medicare covers some preventive services in hospital outpatient departments and ambulatory surgical centers at no cost to you.

Next Steps: Use this [checklist](#) to talk to your doctor about your costs and options, or find [ambulatory surgical centers](#) and [hospitals](#) in your area.

[Search for another procedure](#)

Cancer screening of the colon (large bowel) using an endoscope(colonoscopy) for high risk individuals.

Code: G0105

Patient pays (average)

\$0

Ambulatory surgical centers

Medicare Pays	\$383
Total Cost	\$383

Patient pays (average)

\$0

Hospital outpatient departments

Medicare Pays	\$744
Total Cost	\$744

i Medicare covers some preventive services in hospital outpatient departments and ambulatory surgical centers at no cost to you.

Next Steps: Use this [checklist](#) to talk to your doctor about your costs and options, or find [ambulatory surgical centers](#) and [hospitals](#) in your area.

[Search for another procedure](#)

Screening colonoscopy is a covered preventive service without cost sharing; however, the information provided by the Procedure Price Lookup tool does not indicate that if a polyp or other tissue is removed during the screening colonoscopy the screening must be coded as a diagnostic colonoscopy (45378, 45380, 45381, 45384, 45385) and the beneficiary will be liable for coinsurance, resulting in a surprise bill.

Application to Other CRC Tests

Another significant problem with this proposal is its unclarity on whether CMS' proposed notification requirements extends to physicians who order CRC covered screening tests, such as Cologuard and fecal occult blood tests. For example, if a primary care physician orders a Cologuard® test for a Medicare beneficiary, is it the primary care physician's responsibility to let the patient know that if the screening test result is positive, then the subsequent colonoscopy is diagnostic in nature requiring a 20 percent coinsurance payment under Medicare rules?

In summary, we urge CMS not to implement any requirement on physicians or staff who participate in providing colorectal cancer screening colonoscopies. Specifically, CMS' proposal:

- may be based on the inaccurate assumption that beneficiaries receive a pre-screening colonoscopy consultation, which is not a billable service under current Medicare rules;
- conflicts with the current Administration's "Patients over Paperwork" initiative;
- unfairly burdens physicians and their staff with becoming experts in Medicare's CRC screening coverage policy;
- interferes with the patient-physician relationship by diverting physicians' focus from patient care to understanding and explaining Medicare coverage policies
- is impractical for practices to implement; and
- will likely deter beneficiaries from screening.

Most importantly, CMS ignores the true problem facing Medicare beneficiaries: the coverage oversight in the Affordable Care Act that results in beneficiaries facing a financial burden when their "free" screening colonoscopy results in a copayment when a polyp is found and removed. This is a policy problem that CMS and Congress can resolve without passing the burden onto our members.

Scope Proposals for CY 2020

In the CY 2020 MPFS proposed rule, CMS proposed establishing 23 new scope equipment codes based on recommendations from the Scope Equipment Reorganization Workgroup organized by the American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC). **Our GI societies participated in the Scope Equipment Reorganization Workgroup and submitted invoices for every type of endoscope used in GI endoscopy procedures via this process; however, we believe there may have been a misunderstanding regarding the types endoscopes used in GI procedures which resulted in CMS' perception that invoice information was missing for some GI endoscopes.** We thank CMS for the opportunity to resubmit the invoices for GI endoscopes so that we can clearly indicate which invoices go to which scope equipment codes and which scopes are used for each type of endoscopic procedure.

Below is an excerpt from Table 5 "CY 2020 Proposed New Scope Equipment Codes" of the proposed rule containing scope equipment codes for GI endoscopy.

TABLE 5: CY 2020 Proposed New Scope Equipment Codes

CMS Code	Proposed Scope Equipment Description	Proposed Price	Number of Invoices
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	\$17,360.00	1
ES086	multi-channeled flexible digital scope, colonoscopy	\$38,058.81	6
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)		0
ES088	multi-channeled flexible digital scope, esophagoscopy	\$34,585.35	5
ES089	multi-channeled flexible digital scope, ileoscopy		0
ES090	multi-channeled flexible digital scope, pouchoscopy		0
ES091	ultrasound digital scope, endoscopic ultrasound		0

We propose the following crosswalks from existing equipment codes to CMS' proposed equipment codes in Table 2 to insure the equipment currently listed for GI endoscopy procedures are appropriately attributed to the correct scopes.

Table 1

CMS Current Code	Current Scope Equipment Description	CMS Proposed Code	Proposed Scope Equipment Description
ES043	Video sigmoidoscope	ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy
ES033	Videoscope, colonoscopy	ES086	multi-channeled flexible digital scope, colonoscopy
ES034	Videoscope, gastroscopy	ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)
ES034	Videoscope, gastroscopy	ES088	multi-channeled flexible digital scope, esophagoscopy
ES034	Videoscope, gastroscopy	ES089	multi-channeled flexible digital scope, ileoscopy
ES043	Video sigmoidoscope	ES090	multi-channeled flexible digital scope, pouchoscopy
Endoscopic ultrasound procedures are performed in the hospital setting and have no PE inputs		ES091	ultrasound digital scope, endoscopic ultrasound

Attachment D contains the key for the invoices provided previously. Attachment E contains the invoices for Olympus equipment. Attachment F contains invoices for Pentax equipment.

Table 2 below indicates the scopes used for each type of GI endoscopy, including the current and proposed equipment codes, and the location of the associated invoices.

Table 2

GI Endoscopy	Code Range	Type of Scope Used	Invoice location
Esophagoscopy	43200-43233	Gastroscope Current code ES034 Proposed code ES088	Attachment E: p. 2, line 110 p. 7, line 130 p. 8, line 131 Attachment F: p. 1, line 1
EGD	43210, 43233, 43235-43259, 43266, 43270	Gastroscope Current code ES034 Proposed code ES087	Attachment E: p. 2, line 110 p. 7, line 130 p. 8, line 131 Attachment F: p. 1, line 1
ERCP	43260-43265, 43273-43278	Performed in hospital; No PE inputs	NA
Small bowel endoscopy	44360-44379	Performed in hospital; No PE inputs	NA
Ileoscopy	44380-44384	Gastroscope Current code ES034 Proposed code ES089	Attachment E: p. 2, line 110 p. 7, line 130 p. 8, line 131 Attachment F: p. 1, line 1

GI Endoscopy	Code Range	Type of Scope Used	Invoice location
Pouchoscopy	44385-44386	Sigmoidoscope Current code ES043 Proposed code ES090	Attachment E: p.19, line 140
Colonoscopy through stoma	44388-44408	Colonoscope Current code ES033 Proposed code ES086	Attachment E: p.6, line 110 p. 8, line 120 p.14, line 190 p.16, line 90 Attachment F: p. 1, line 3
Flexible sigmoidoscopy	45330-45350	Sigmoidoscope Current code ES043 Proposed code ES085	Attachment E: p.19, line 140
Colonoscopy	45378-45398	Colonoscope Current code ES033 Proposed code ES086	Attachment E: p.6, line 110 p. 8, line 120 p.14, line 190 p.16, line 90 Attachment F: p. 1, line 3

45350 Scope Recommendation

CMS stated, “We identified inconsistencies with the workgroup recommendations for a small number of HCPCS codes. CPT code 45350 (*Sigmoidoscopy, flexible; with band ligation(s) (e.g., hemorrhoids)*) was recommended to include a multi-channeled flexible digital scope, flexible sigmoidoscopy (ES085); however, we noted that this CPT code does not include any scopes among its current direct PE inputs.” **All codes in the flexible sigmoidoscopy family (45330-45350) require a flexible sigmoidoscope in order to perform the procedure; therefore, we ask CMS to add ES085 to 45350.**

Determination of Malpractice Relative Value Units (RVUs)

Malpractice RVU Process

As stated by CMS in the proposed rule, to calculate the malpractice RVUs under the Medicare Physician Fee Schedule, CMS has implemented a policy that incorporates three (3) factors:

1. Specialty-level risk factors derived from data on specialty-specific malpractice premiums incurred by practitioners;
2. Service-level risk factors derived from Medicare claims data of the weighted average risk factors of the specialties that furnish each service; and
3. An intensity/complexity of service adjustment to the service-level risk factor based on either the higher of the work RVU or clinical labor RVU

As part of the ongoing revaluation process, CMS proposes to align the update of malpractice premium data used to determine malpractice RVUs with the update of the malpractice Geographic Practice Cost Indices (GPCI) (which CMS is required to update every 3 years) by also reviewing the malpractice RVUs at least every 3 years even though the statutory requirement is only that CMS update the malpractice RVUs every five years.

Our societies appreciate CMS’ efforts to improve the premium data collection process and the opportunity to provide comments on the new methodology. However, given the large malpractice RVU decreases for GI endoscopy codes resulting from the new methodology, **we urge CMS not to finalize the proposed 2020 professional liability insurance RVU changes until CMS has improved the process for obtaining data.**

Proposed Methodology Changes

In addition to incorporating updated data for purposes of revaluing the malpractice RVUs, CMS proposes several methodological changes to its calculation:

- CMS proposes using a broader set of filings from the largest market share insurers in each state, beyond those listed as “physician” and “surgeon”
- CMS proposes combining minor surgery and major surgery premiums to create the surgery service risk group
- CMS proposes utilizing “partial and total imputation” when CMS specialty names are not distinctly identified in the insurer filings

Our societies are concerned that the proposed changes are leading to an estimated decrease in overall reimbursements for gastroenterologists. The average malpractice RVU change to GI endoscopy codes is -22 percent, with some codes experiencing cuts as large as -36 percent. While malpractice RVUs are generally the smallest portion of a code’s total RVUs, the proposed malpractice cuts to GI codes will cause a 1 percent decrease in reimbursement for gastroenterology according to Table 110 in the proposed rule.

We are particularly troubled by the proposed changes to the proposed specialty risk factors for gastroenterology.

Gastroenterology Specialty Specific Risk Factors			
	2019	2020 (Proposed)	% change
Surgical	3.83	2.51	-34.5%
Non-Surgical	2.09	1.90	-9.0%

Because the causes of these decreases are not easily identifiable, **we express overall concern about CMS’ proposed data and methodological changes that would cause such a drastic shift in the specialty specific risk factors for gastroenterologists.** In particular, we are concerned with CMS’ approach to including non-physician data in the overall data set. As CMS states, when developing the malpractice RVUs for each CPT code, *“The products for all specialties for the CPT/HCPCS code were then added together, yielding a specialty-weighted service specific risk factor reflecting the weighted malpractice costs across all specialties furnishing that procedure.”* We are particularly troubled by CMS’ proposal to use the broader set of filings beyond those listed as “physician” and “surgeon.” We believe this is inappropriate and request that CMS analyze and publish the extent to which this is contributing to fluctuations in the malpractice RVUs. In particular, in the Interim Report¹ referenced in the proposed rule by CMS, we reviewed *Table 8.C.2 Source Specialty/Service Risk Group for Total Imputation for Proposed PLI Premium Data.* In that table, CMS crosswalks several non-physician practitioners to physician categories using its total imputation methodology. We are concerned that this is distorting the relativity of the malpractice RVUs and believe that CMS should consider cross walking non-physician practitioners for which there is inadequate premium data to a non-physician practitioner baseline.

Expected Specialty for Low Volume Codes

In the proposed rule, CMS reviews its policies for low-volume codes (defined as codes that have “100 allowed services or fewer”). CMS states that it applies a list of expected specialties instead of the claims-based specialty mix for low-volume services because of concerns CMS continues to receive about the volatility in PE and malpractice RVUs for low volume services. CMS then uses the expected specialty for PE and malpractice calculations for low volume procedures. For CY 2020, the list CMS provided for low-volume codes with the expected specialty of gastroenterology appeared correct, except for CPT code 96571 (*Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)*). Code 96571 is a ZZZ add-on code. Medicare 2018 claims data indicate it is provided by Pulmonary Disease 67 percent of the time, Critical Care (Intensivists) 17 percent, and Thoracic Surgery 17 percent. Gastroenterologists do not perform this service currently. **We recommend that CMS remove gastroenterology as the expected specialty for code 96571.**

¹ Actuarial Research Corporation, *CY 2020 Medicare PFS Proposed Update to the GPCIs and MP RVUs Interim Report*, Table 8.C.2 Source Specialty/Service Risk Group for Total Imputation for Proposed PLI Premium Data (April 10, 2019).

Measures Proposed for Removal from MIPS

Our societies believe it is critically important that CMS maintain the meaningful, specialty-specific measures available for reporting by gastroenterologists, particularly relating to colonoscopy. **Our organizations request the continuation of the following two colonoscopy quality measures in the Merit-based Incentive Payment System (MIPS) until meaningful alternatives can be developed:**

- **Measure 343: Screening Colonoscopy Adenoma Detection Rate**
- **Measure 185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use**

With the introduction of the Screening/Surveillance Colonoscopy episode-based cost measure for the 2019 performance year and the proposal from CMS to introduce MIPS Value Pathways beginning with the 2021 performance year, the proposed removal of the only outcome measure specific to gastroenterology currently available for public reporting, Measure 343: Screening Colonoscopy Adenoma Detection Rate, as well as Measure 185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use, undermines the collective desire of CMS and our societies to move towards an aligned set of measure options more relevant to a gastroenterologist's scope of practice that is meaningful to patient care.

According to the American Cancer Society (ACS), in the United States, colorectal cancer is the third leading cause of cancer-related deaths in men and in women, and the second most common cause of cancer deaths when men and women are combined. It is expected to cause an estimated 51,020 deaths during 2019. The ACS further states that the death rate (the number of deaths per 100,000 people per year) from colorectal cancer has been dropping in both men and women for several decades. There are several likely reasons for this. One is that colorectal polyps are now being found more often by screening and removed before they can develop into cancers or are being found earlier when the disease is easier to treat.²

Colonoscopy is considered to be the most effective screening option for colorectal cancer. Colonoscopy permits immediate polypectomy and removal of macroscopically abnormal tissue in contrast to tests based on radiographic imaging or detection of occult blood or exfoliated DNA in stool. Following removal, the polyp is sent to pathology for histologic confirmation of adenoma or cancer. Colonoscopy directly visualizes the entire extent of the colon and rectum, including segments of the colon that are beyond the reach of flexible sigmoidoscopy. Colonoscopy therefore is the recommended screening method or a follow-up modality for all colorectal cancer screening methods and is one of the most widely performed procedures in the United States.^{3,4}

The ability of colonoscopy to reduce morbidity and mortality from colorectal cancer is a function of its abilities to detect early stage cancers and to *remove* adenomatous polyps or colorectal neoplasms. Colonoscopy is a technically challenging procedure; therefore, its effectiveness in detecting and removing polyps significantly varies based upon the skill of the endoscopist. A

² <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html> August 24, 2019

³ Regula J, Rupinski M, Kraszewska E, et al. Colonoscopy in colorectal cancer screening for detection of advanced neoplasia. *N Engl J Med* 2006;355:1863-72.

⁴ Seeff LC, Richards TB, Shapiro JA, et al. How many endoscopies are performed for colorectal cancer screening? Results from CDC's survey of endoscopic capacity. *Gastroenterology* 2004;127:1670-7.

direct indicator of a high-quality endoscopist is his/her ability to detect pre-cancerous polyps, or adenomas. Suboptimal performance of colonoscopy is a fundamental challenge to protect against incidence of colorectal cancers. Evidence of variable performance by practitioners performing colonoscopy prompted the development of quality standards for colonoscopy performance.⁵

Screening Colonoscopy Adenoma Detection Rate

The adenoma detection rate is the best-established colorectal neoplasia-related quality indicator, and is defined as the proportion of patients undergoing colonoscopy in whom an adenoma or colorectal cancer is found.⁶ Studies show that high adenoma detection rates are associated with a significant reduction in colorectal cancer risk.⁷ Yet, virtually all studies on this subject have found marked variation in adenoma detection rates among physicians.

Corley et al. published in the *New England Journal of Medicine* an examination of the association between adenoma detection rate and risks of subsequent colorectal cancer and death among 264,792 colonoscopies by 136 gastroenterologists. Patients were followed from their baseline examinations for either 10 years or until another colonoscopy with negative results, left the health care system, or were diagnosed with colorectal cancer. There was a 3% reduction in colorectal cancer incidence and a 5% reduction in cancer mortality for each 1% increase in adenoma detection rate. This observation remained for both proximal and distal cancer in both men and women.⁸ Kaminski et al published a study on the association between adenoma detection rate and interval cancer in *Gastroenterology* of 294 endoscopists and data on 146,860 colonoscopies that reviewed 895,916 person-years of follow up evaluation through the National Cancer Registry. The study concluded that there is an association of increased adenoma detection rate with a reduced risk of interval cancer and death.⁹

In the 2020 Medicare Physician Fee Schedule proposed rule, CMS proposes the removal of Measure 343: Screening Colonoscopy Adenoma Detection Rate as a quality measure from the MIPS program citing scoring implications, review of previous stakeholder feedback, and attribution to the MIPS eligible clinician. Our societies believe continued dialogue on this measure is warranted.

The simple formula on which the Quality Payment Program rests is Quality over Cost equals Value. By introducing the Screening/Surveillance Colonoscopy episode-based cost measure into MIPS and then removing Measure 343: Screening Colonoscopy Adenoma Detection Rate (the only outcome measure in the program relative to colonoscopy and gastroenterology overall) from the Quality performance category of MIPS, CMS reduces assessment of a physician's performance on screening colonoscopy to cost alone and provides a patient with no assessment of a gastroenterologist's performance of screening colonoscopy relative to value. **Our societies request continued dialogue with CMS on the points included in the Agency's rationale for measure removal prior to further consideration of removal of Measure 343: Screening Colonoscopy Adenoma Detection Rate from MIPS. We address**

⁵ Rex DK, et al. Quality indicators for colonoscopy. *Gastrointest Endosc* 2015;81:31-53/DOI:<http://dx.doi.org/10.1016/j.gie.2014.07.058>

⁶ Rex DK, Petrini JL, Baron TH, et al. Quality indicators for colonoscopy. *Gastrointest Endosc* 2006;63:S16-28.

⁷ Kaminski, M F., Regula J, et al. Quality indicators for colonoscopy and the risk of interval cancer. *N Engl J Med* 2010; 362(19): 1795-803.

⁸ Corley D, Jensen CD, Marks AR, et al. Adenoma detection rate and risk of colorectal cancer and death. *N Engl J Med* 2014;370: 1298-306.

⁹ Kaminski MF, et al. Increased Rate of Adenoma Detection Associates With Reduced Risk of Colorectal Cancer and Death. *Gastroenterology*. 2017 Jul;153(1):98-105. doi: 10.1053/j.gastro.2017.04.006. Epub 2017 Apr 17.

each of these points below and look forward to meeting with the Agency for more in-depth discussions.

CMS states in the proposed rule, “the measure does not account for variables which may influence the adenoma detection rate such as geographic location, socioeconomic status of patient population, community compliance of screening, etc.” Adenoma detection rate is an intermediate outcome measure, which the Agency defines as a measure that assesses a factor or short-term result that contributes to an ultimate outcome. Geographic location and socioeconomic status of patient population are not biological and not independent predictors of an intermediate outcome measure. Community compliance with screening would not influence the results of a test and by extension a physician’s adenoma detection rate. The measure as specified accounts for a heterogeneous population of patients of varying age, gender, and bowel preparation quality which influence adenoma detection rates, and purposely excludes patients at higher (prior history of polyps or cancer) risk of adenoma.

CMS also states, “due to the measure construct, benchmarks calculated from this measure are misrepresented and do not align with the MIPS scoring methodology where 100 percent indicates better clinical care or control.” Our societies look forward to discussing construction of an adenoma detection rate measure that would better align with CMS’ scoring methodology, given what the Agency has done so with other measures (e.g., diabetic control), or another alternative that would measure an outcome of interest to CMS and would provide useful information to gastroenterologists. Presently, we fail to see how the current measure cannot be benchmarked, recognizing an adenoma detection rate of 25% is the floor at which remediation should be triggered and an adenoma detection rate of 50% is aspirational.

CMS indicates as another concern relative to the adenoma detection rate measure that “guidelines and supplemental literature support a performance target for adenoma detection rate of 25 percent for a mixed gender population (20 percent in women and 30 percent in men).” As stated above, an adenoma detection rate of 25% is considered the floor, not the ceiling, by gastroenterologists. While an adenoma detection rate of 100% is not biologically possible, the goal of each gastroenterologist is to increase his/her personal adenoma detection rate, recognizing the impact on colorectal cancer prevention.

The final point presented as rationale for removal of the measure is that it “does not account for MIPS eligible clinicians that fail to detect adenomas but may score higher based on the patient population.” Our societies are unaware of any studies demonstrating a relationship between adenoma detection rate and patient population. As stated previously, geographic location, socioeconomic status of patient population, and community compliance of screening impact screening uptake, but would not influence a physician’s adenoma detection rate. The only measure that may capture missed adenomas is a measure relative to interval cancer rate, which is not feasible to calculate for an individual clinician given the progression from adenomatous polyp to cancer occurs over an estimated 5 to 10 years in average-risk populations,¹⁰ lack of interoperability among electronic medical records, and patient migration.

It is for these reasons stated above that our organizations request the continuation of Measure 343: Screening Colonoscopy Adenoma Detection Rate in the Quality performance category of the Merit-based Incentive Payment System until an alternative

¹⁰ Strykder SJ, Wolff BG, Culp CE, Libbe SD, Ilstrup DM, MacCarty RL. Natural history of untreated colonic polyps. *Gastroenterology*. 1987;93:1009-13.

adenoma detection rate measure that addresses scoring and benchmarking challenges can be developed.

Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use

Our societies are responding more fully to the CMS MIPS Value Pathways request for information in a separate letter. Notably, this framework supports a direction for which our societies have long advocated in relation to colorectal cancer screening and surveillance. The colorectal cancer-related quality measures currently available for public reporting provide data on the continuum, from identifying those beneficiaries who are being over-screened, the quality of the screening, and the necessary follow-up. For benchmarking purposes, uniform reporting of quality measures allows for more accurate comparisons of physicians who perform colonoscopy. The MIPS Value Pathways concept appears to address a key concern about the current construct of MIPS, specifically measures for which performance earns a greater amount of points but procedure volume can be as low as 20 cases annually. We believe this has led to skewed benchmarks for measures.

For colonoscopy to be cost-effective, the intervals between examinations must be optimal. Our multi-society endorsed *Quality indicators for colonoscopy*¹¹ states “post-polypectomy surveillance colonoscopy in the United States is frequently performed at intervals that are shorter than those recommended in guidelines,” and “Assessments of actual practice identified both overuse of surveillance examination in low-risk patients and underuse in high-risk patients.” Measure 185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps is an important measure in assessing overuse of colonoscopy. The benchmarks established by CMS derived from public reporting that suggest this measure is topping out do not align with the evidence from surveys of practice.^{12,13,14,15,16,17} **Our organizations request the continuation of Measure 185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps in the Quality performance category of the Merit-based Incentive Payment System so that it may be included in a MIPS Value Pathway for colorectal cancer screening through which we believe more accurate benchmarks for the measure will be developed.**

CMS also states in its rationale that this measure “was previously proposed for removal but was retained to allow for the measure to be updated to align with newly released guidelines. This measure was not updated to align with new guidelines.” CMS suggests that the measure is now being proposed for removal from MIPS because the measure was not updated by the measure steward to align with new guidelines. The measure specification is *based* on the US Multi-Society Task Force (MSTF) on Colorectal Cancer’s Guidelines for Colonoscopy Surveillance

¹¹ Rex, DK, et al. Quality Indicators for Colonoscopy. *Am J Gastroenterol* 2015; 110:72-90.

¹² Mysliwiec PA, Brown ML, Klabunde CN, et al. Are physicians doing too much colonoscopy? A national survey of colorectal surveillance after polypectomy. *Ann Intern Med* 2004;141:264-71.

¹³ Saini SD, Nayak RS, Kuhn L, et al. Why don’t gastroenterologists follow colon polyp surveillance guidelines? Results of a national survey. *J Clin Gastroenterol* 2009;43:554-8.

¹⁴ Burke C, Issa M, Church J. A nationwide survey of post-polypectomy surveillance colonoscopy: too many too soon! *Gastroenterology* 2005;128:A566.

¹⁵ Boolchand V, Singh J, Olds G, et al. Colonoscopy surveillance after polypectomy: a national survey study of primary care physicians. *Am J Gastroenterol* 2005;100:S384-5.

¹⁶ Kim ER, Sinn DH, Kim JY, et al. Factors associated with adherence to the recommended postpolypectomy surveillance interval. *Surg Endosc* 2012;26:1690-5.

¹⁷ Shah TU, Voils CI, McNeil R, et al. Understanding gastroenterologist adherence to polyp surveillance guidelines. *Am J Gastroenterol* 2012;107:1283-7.

After Screening and Polypectomy published in 2012,¹⁸ and the MSTF has not published updated recommendations regarding *surveillance* colonoscopy intervals for patients with a history of adenomatous polyps. The American Cancer Society (ACS) published a qualified recommendation that *screening* begin at age 45;¹⁹ and the MSTF issued a statement in response on January 8, 2018, but both of these updates concern intervals for *screening* rather than *surveillance* colonoscopy which is the focus of Measure 185. Measure 185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use should remain in the Quality performance category of MIPS until updated guidelines are released and the impact on this measure can be evaluated.

It is for the reasons stated above that our organizations request the continuation of Measure 185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use in the Quality performance category of the Merit-based Incentive Payment System.

Meaningful Measures Available to Gastroenterologists

Our societies appreciate CMS' move to a parsimonious measure set, although caution to ensure the evaluation still supports each specialty in having enough measures for its providers to be able to report in a meaningful manner. CMS is proposing to remove 33 percent of the Gastroenterology-specific quality measures from the Quality Payment Program in 2020, which is 5 percent of all measures proposed for removal from the QPP. Two of the three Gastroenterology quality measures, 185 and 343, are designated by CMS as high-priority measures and measure 343 is the sole Gastroenterology-specific outcome measure available for reporting in the MIPS program. The CMS Meaningful Measures Framework was launched in 2017 to identify high-priority areas for quality measurement and improvement. The proposed removal of these measures appears to contradict this initiative. Furthermore, these measures are integrated in multiple programs, such as the Core Quality Measures Collaborative, and Measure 343: Screening Colonoscopy Adenoma Detection Rate establishes the framework for the Screening/Surveillance Colonoscopy episode-based cost measure such that, if removed, its absence would have unintended consequences across multiple programs.

¹⁸ Lieberman et al., *Gastroenterology* 2012;143:844-857.

¹⁹ Wolf et al., *Ca Cancer J Clin* 2018;68:250-281.

Conclusion

The ACG, AGA and ASGE appreciate the opportunity to provide comments on the CY 2019 Physician Fee Schedule proposed rule. If we may provide any additional information, please contact Brad Conway, ACG, at 301.263.9000 or bconway@gi.org; Kathleen Teixeira, AGA, at 240.482.3222 or kteixeira@gastro.org; or Lakitia Mayo, ASGE, at 630.570.5641 or lmayo@asge.org.

Sincerely,



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