



September 8, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program: Revisions to payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (CMS-1631-P)

Dear Acting Administrator Slavitt:

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-1631-P), published on July 15, 2015 in the *Federal Register*, regarding the proposed policy revisions to the 2016 Medicare Physician Fee Schedule (PFS). Our three societies represent virtually all practicing gastroenterologists in the United States.

There are a number of provisions in the proposed rule that impact practicing gastroenterologists and the Medicare beneficiaries they treat. We offer comments in the following areas:

Payment Policy

- Misvalued Code Changes for Lower GI Endoscopy Services
- Application of the Misvalued Code Target
- Phase-In of Significant RVU Reductions
- Potentially Misvalued Services under the Physician Fee Schedule
- Incomplete Colonoscopy Clarification

- Improving Payment Accuracy in Care Management and Evaluation and Management Services
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services
- Incident To Proposals
- Biosimilar Part B Drugs

Quality Improvement

- Physician Quality Reporting System (PQRS)
- Physician Value-Based Payment Modifier (VM) Program
- Physician Compare
- Merit-Based Incentive Payment System (MIPS)

MISVALUED CODE CHANGES FOR LOWER GI ENDOSCOPY SERVICES

Our societies applaud CMS for introducing a new process this year by which stakeholders can review proposed reimbursement changes in the proposed rule as opposed to the publication of the final rule. This new process allows adequate time for providers, medical practices of all sizes, medical societies, and other stakeholders to review, comment and prepare for Medicare fee schedule changes. Our societies also appreciated the opportunity to meet with CMS staff this summer to discuss the Agency's proposed valuations for lower gastrointestinal (GI) endoscopy services, specifically colonoscopy services. After review of CMS' recommendations, **our societies are disappointed and deeply concerned that the physician work values proposed by the Agency for colonoscopy, flexible sigmoidoscopy, and colonoscopy through stoma procedures are not data-driven and the methodology used to determine physician work and intensity for these services is severely flawed.**

Additionally, we believe the recommendations for lower GI endoscopy services, as proposed, are incorrect, will be detrimental to GI practices and have a stifling effect on the Nation's advancements in decreasing the incidence of and mortality from colorectal cancer.

Before we respond to specifics in CMS' recommendations for lower GI endoscopy procedures, our societies seek clarification on the rationale used to determine many of the proposed values for these services. In response to the AMA Relative value Update Committee's (RUC) recommendations, some of which we do not agree, CMS did not provide any rationale for why it did not accept the RUC recommendations.

It appears that the Agency may have made the decision to selectively lower the value of several lower GI endoscopic services, including stent placement, ablation, foreign body removal and submucosal injections. Without stating why the RUC's recommended work increments for these procedures are inappropriate compared to work component increments in which CMS found appropriate (e.g. balloon dilation or hot biopsy), these reductions appear arbitrary and punitive.

Further, while the average reduction proposed by CMS for these procedures is less than 5 percent from the RUC's recommendations, the RUC's recommendations were developed based on the concept of increment of work for endoscopic procedures which dates back to the original recommendations of Hsaio and was validated during the multi-year review of almost 120 endoscopic procedures. In the absence of providing any additional rationale, it is difficult to understand how CMS' decisions provide additional accuracy to the work values of these services.

To be clear, while the RUC and the involved specialty societies applied the incremental methodology to value the vast majority of upper and lower GI endoscopy services over several years, each recommended work value was scrutinized under the broad concept of magnitude estimation. This ensured that each recommendation was appropriate to other codes across the resource-based relative value scale (RBRVS). By accepting some increments and rejecting others, CMS has not only established inconsistencies within the family of codes, but potentially opened up anomalies across a wide range of services.

We would like to take this opportunity to review the physician work involved in these services, specialty survey data, methodology employed by the Agency, and the impact of CMS' proposals on access to care for Medicare beneficiaries.

Value of Colonoscopy

Colorectal cancer is the second leading cause of cancer death in the United States, with approximately 50,000 Americans expected to die from colorectal cancer this year. Screening colonoscopy plays an important role in colorectal cancer prevention because precancerous polyps can be detected and removed during the same exam when they are discovered. All other colorectal cancer screening options that yield a positive result are followed by a colonoscopy. According to the American Cancer Society (ACS), colorectal cancer incidence rates in the United States have dropped more than 30 percent —“the large declines over the past decade have largely been attributed to the detection and removal of precancerous polyps as a result of increased colorectal cancer screening.” (*American Cancer Society; Colorectal Cancer Facts & Figures 2014-2016*).

However, evidence shows that screening could prevent more than 50 percent of colorectal cancer deaths in the Medicare population when high quality colonoscopy is utilized as recommended in the national guidelines. When colon cancer is detected and treated early, the survival rate climbs to 90 percent, according to the Centers for Disease Control and Prevention (CDC) (*Centers for Disease Control and Prevention; Vital Signs 2013*).

While the United States is making progress reducing colorectal cancer mortality, more needs to be done to increase the use of colorectal cancer screening tests by Medicare beneficiaries. Our societies support the goal of the National Colorectal Cancer Roundtable, shared by the Department of Health and Human Services (HHS), to increase rates of colorectal cancer screening to 80 percent by 2018. The Medicare-age population, which is at the greatest risk for developing colorectal cancer, has screening rates below this 80 percent target – only 64 percent according to the ACS. Of concern, Medicare beneficiaries account for two-thirds of all new cases of colorectal cancer each year. (*American Cancer Society; Colorectal Cancer Facts & Figures 2014-2016*).

The use of colonoscopy as a screening and diagnostic test continues to be a great public health success story. As incidences and deaths from colorectal cancer are decreasing, and a community commitment has been made to increase screening rates, we need to ensure the availability of colonoscopy for the screening and detection of colorectal cancer, and that this essential procedure remains accessible for all Americans. Correct reimbursement for this lifesaving procedure is critical to achieving our common goals. The current methodology used by CMS does not capture this added value of these procedures.

If unchanged, the proposed 2016 PFS rates for lower GI endoscopy procedures would cut physician work values for some colonoscopy procedures by up to 20 percent. It is short-sighted and counter-productive to propose policies that will undermine access to proven cancer prevention strategies and endanger all of the progress and current momentum we have made as a nation over the past two decades in our fight against colorectal cancer.

The physician work of 45378 has not changed

Our societies agree with CMS' position that the best data available to determine physician work time and intensity for a particular service is derived from the surveys specialty societies use as part of the AMA RUC process. We are extremely discouraged that the Agency chose to ignore the robust survey data collected by the ACG, AGA and ASGE together with the American College of Surgeons (ACS), American Society for Colon and Rectal Surgeons (ASCRS) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) presented at the January 2014 RUC meeting. CMS noted in the 2015 PFS final regulation:

“For many codes, the surveys conducted by specialty societies as part of the RUC process are the best data that we have regarding the time and intensity of work. The RUC determines the criteria and the methodology for those surveys. It also reviews the survey results. This process allows for development of survey data that are more reliable and comparable across specialties and services than would be possible without having the RUC at the center of the survey vetting process.”

The GI and surgical societies spent significant time, effort, and resources surveying physicians to determine resources and physician work for colonoscopy. We collected robust and scientifically valid data from these studies, far above the minimum number of responses required by the RUC. Attachment A details our survey response of 165 participants for the colonoscopy base code 45378. When compared to the previous review of code 45378 in 2005 as part of the Five-Year review, and accounting for methodological shifts as a result of the 1) movement of moderate sedation from intra- to pre-service time, and 2) application of standardized pre-service time packages, the survey data reflected no change in the total procedure time of colonoscopy.

The intensity and complexity of 45378 has not decreased

The intensity and complexity measurement data collected from the RUC surveys demonstrate that the work of colonoscopy has not decreased since the last survey in 2005. The findings are supported by the development of new colorectal cancer screening protocols that have resulted in greater attention to identification and removal of pre-cancerous lesions; if anything, resulting in increased intensity since this service was reviewed in 2005 as part of the Five-Year review.

Further evidence to support increased complexity and intensity of colonoscopy since 2005 includes:

- the availability of video endoscopic systems with high-definition viewing screens that permit multiple health care professionals to watch the procedure, increasing the focus on adenoma detection, which have become predominant in use since the 1990's and the 2005 Five-Year review;
- new, evidence-based, multi-specialty task force recommendations on CRC surveillance that put a greater emphasis on the examination of the colon mucosa for the detection and removal of smaller and increasingly subtle pre-malignant lesions such as flat adenomas; and
- a change in the definition of colonoscopy, which represents an increase in the amount of large bowel examined from what was surveyed and reviewed in 2005 *Colonoscopy, flexible, proximal to splenic flexure; diagnostic, with or without collection of specimen(s) by brushing or washing, with or without colon decompression* to what was surveyed in 2014 *Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)*.

The six surveying societies did not accept the RUC recommended RVU for 45378

We believe that inaccurate and unwarranted media attention on colonoscopy prior to and during the survey period unfairly impacted the process used by the RUC when the colonoscopy codes were reviewed at their January 2014 meeting. Our societies voiced strong objections to the RUC's recommendations for colonoscopy services at that meeting, as we believe the RUC failed to follow its own processes when considering the results of the statistically valid survey facilitated by the six surgical and gastroenterological societies whose members perform the majority of colonoscopy services to Medicare beneficiaries.

The RUC recommendation of 3.36 RVUs for 45378 *Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)* was based not on the survey data from 165 practicing gastroenterologists and surgeons, but, instead, on the comparison of colonoscopy to the time and RVU of code 31625 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites*, a code not reviewed since 2003, and code 58555, *Hysteroscopy, diagnostic (separate procedure)*, which had not been reviewed since 1997. Additionally, neither of the comparison codes reflects the similar time and intensity of 45378; the section of these two unrelated and disparate codes was not explained.

Accurate comparison of the 2005 and 2013 survey data requires adjustment for moderate sedation

As Attachment A demonstrates, the issue of where the work of moderate sedation fits into these RUC-approved surveys (intra-service vs. pre-service) is critical to the accurate assignment of the time and work intensity of the colonoscopy, flexible sigmoidoscopy, and colonoscopy through stoma procedures. Code 45378 was last valued in 2005, before the RUC had developed and CMS had accepted standard Pre-time Packages which applied a uniform standard for pre-service activities. When colonoscopy was initially valued in 1993 by Harvard and reviewed by the Five-

Year process in 1995 and 2005, moderate sedation was not only inherent to the procedure, but the work of moderate sedation was expressly understood by HCFA and CMS to be part of the intra-service time. In fact, the instructions in the 2005 survey instrument for code 45378 specifically directed physicians to include the administration of moderate sedation in intra-service time. This is a critical distinction. One cannot make an accurate comparison of the 2005 to the 2013 survey data for colonoscopy procedures (presented to the RUC in January 2014) without adjusting for the movement of moderate sedation from the intra-service to the pre-service period. When CMS accepted the inclusion of moderate sedation in the pre-service package, there was also an assumption that moderate sedation was valued the same as all other pre-service activities at 0.0224/minute, without attempting to determine the work and intensity of moderate sedation when it had been valued as part of the intra-service work. When moderate sedation, as defined by the RUC Pre-time Package (Attachment B), is removed from the survey data, clearly there is no change in the intra-service time for the colonoscopy base code 45378.

Source	CPT	DESCRIPTOR	# of Responses	25th	RVW	Total	PRE-TIME*			INTRA-	IMMD
					MEDIAN	Time	EVAL	POSIT	SDW	TIME**	POST†
RUC 2005 survey	45378	Colonoscopy, flexible, proximal to splenic flexure; diagnostic, with or without collection of specimen(s) by brushing or washing, with or without colon decompression (separate procedure)	81		3.69	75	20	5	5	30	15
RUC 2005 survey adjusted	45378	Movement of 5 min moderate sedation time from intra to pre-service time	81		3.69	75	25	5	5	25	15
GI 2013 survey	45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure)	165	3.80	--	75	25	5	5	25	15

Application of the reverse building block

Although we firmly believe that the 2013 survey results validated the 2005 valuation of 45378 and clearly demonstrated that the physician work of colonoscopy has not decreased, the surveying societies understood that we may need to reconcile the removal of pre-service time from the current survey data, per the application of the RUC Pre-time Package. We applied the reverse building block, a methodology commonly used by CMS, to arrive at an adjusted value of 3.51 RVUs. In fact, CMS used the reverse building block methodology for valuing 43200 in the same manner, adjusting the RVU for removal of time in the post-service period. In the 2015 PFS Final Rule, page 67634, CMS stated:

“For CPT code 43200, which is the base code for flexible transoral esophagoscopy, we agree with commenters that another methodology is preferable to applying the work RVU ratio of 1 RVU per 10 minutes of intra-service time. In revaluing this service, we subtracted 0.07 to account for the 3 minute decrease in post-service time since the last

valuation from the CY 2013 work RVU for the predecessor base code, which resulted in a work RVU of 1.52. We are finalizing this work RVU.”

The rationale that our societies provided to the RUC in the Summary of Recommendation Form (Attachment C) states:

We recommend an RVW of 3.51 which is less than the survey 25th percentile. This value reflects an adjustment to the current RVW of 3.69 to account for less pre-service time compared with the pre-service time from the 2005 RUC review, and the movement of the time for administration of moderate sedation from intra-service to pre-service time.

Recommended RVW		Current RVW	Evaluation difference x intensity		Positioning x intensity
3.51	=	3.69	- [(25 min – 19 min)*0.0224]	-	[(5 min – 3 min)*0.0224]

The methodology CMS used to establish the RVU for 45378 is flawed

The rationale CMS used in the 2016 PFS proposed rule for code 45378 does not consider the survey results at all, which the Agency has stated are the most reliable indicator of the work. CMS’ valuation of code 45378 is based on a misapplication of the RUC’s established procedural increments. The 2016 PFS proposed rule states:

“To calculate the base RVU for the colonoscopy subfamily, we looked at the current intra-service time for CPT code 45378, which is 30 minutes, and the current work RVU, which is 3.69. The RUC recommended an intraservice time of 25 minutes and 3.36 RVUs. We then compared that service to the base EGD CPT code 43235 for which the RUC recommended a work RVU of 2.26, giving an increment between EGD and colonoscopy of 1.10 RVUs. We added that increment to our proposed work RVU for CPT 43235 of 2.19 to arrive at our proposed work RVU for the base colonoscopy CPT code 45378 of 3.29.”

The RUC has only used established increments for procedures where the work is the same across all families (e.g., biopsy, foreign body removal, etc.). The RUC has never used an “increment” **between** families to establish the RVUs for a base code and it is unprecedented and inappropriate for CMS to do so for procedures that are clinically unrelated. CMS’ methodology for valuing 45378 misapplies the concept of the “increment” as developed by Hsaio and colleagues and affirmed by both CMS and the RUC. This error is compounded by the RUC’s inappropriate comparison of two unrelated procedures (colonoscopy and bronchoscopy) to establish a value for code 45378 instead of using the robust survey data presented by the six surveying societies whose members perform the majority of all colonoscopy services provided in the United States.

During the unprecedented review of almost 120 upper and lower GI endoscopy services, our societies worked with the RUC to establish an incremental methodology that set a specific work

value increment to a specific component of physician work performed in addition to the main endoscopy procedure. These increments were then carried forward, as appropriate, to each family of service within both the upper and lower GI endoscopy services. At no time, however, were base procedures across families of services used to establish increments.

Our societies remain perplexed by CMS' analysis, as the physician work and techniques required for upper gastrointestinal endoscopy and lower endoscopy are very different. CPT code 45378 is a more intense procedure than code 43235, with nearly double the intra-service time. In view of such, the incremental approach used by CMS in this comparison is invalid. The upper GI tract is shorter and less convoluted. It is less complicated to navigate and is not associated with as significant a risk of adverse events or pain compared to the colon. On the contrary, the lower GI tract is technically quite difficult to traverse because of its length and tortuosity. Colonoscopy requires more mechanical maneuvering and is associated with more discomfort and risk of adverse events, most notably perforation, compared to upper endoscopy. These differences in procedural completion and risk demonstrate that EGD and colonoscopy should not be considered equivalent.

Relativity between services across families must be considered when valuing services. Measuring relativity differences between services with different physician work is done using magnitude estimation, not assigning an exact increment. Relying on exact comparison between completely different base procedures is counterintuitive to the incremental approach, which is trying to measure the additional work which is objectively quantifiable regardless of the procedures performed in tandem. **Given the unprecedented use of the CMS methodology, our societies again request that CMS use the robust survey data provided by the societies in making its value recommendation.**

Following CMS' position that the survey is the best available data the Agency has to value time and intensity, we ask CMS to reconsider accepting the societies' position (based on the best data available) that there is no change in time from the previous review of the colonoscopy base code.

If CMS is not going to make a determination based on the specialty societies' survey data, we urge CMS to accept the alternative recommendation of 3.51 for code 45378 and apply the appropriate incremental methodology and values to the following colonoscopy codes:

- CPT Code 45379 – GI Recommended work RVU of 4.52
- CPT Code 45380 – GI Recommended work RVU of 3.81
- CPT Code 45381 – GI Recommended work RVU of 3.82
- CPT Code 45382 – GI Recommended work RVU of 5.50
- CPT Code 45384 – GI Recommended work RVU of 4.32
- CPT Code 45385 – GI Recommended work RVU of 4.82
- CPT Code 45386 – GI Recommended work RVU of 4.02

- CPT Code 45388 – GI Recommended work RVU of 5.64
- CPT Code 45389 – GI Recommended work RVU of 5.65
- CPT Code 45390 – GI Recommend work RVU of 6.50
- CPT Code 45391 – GI Recommended work RVU of 5.10
- CPT Code 45392 – GI Recommended work RVU of 6.78
- CPT Code 45393 – GI Recommended work RVU of 5.50

This recommendation accurately reflects the time and intensity associated with services in the colonoscopy code family when the previous times are adjusted for minutes removed from base code 45378 in 2005 that were never applied to the codes in the rest of the family and the movement of time for moderate sedation from intra-service to pre-service as demonstrated in Attachment D. When colonoscopy base code 45378 was valued in 2005 the median intra-service time was 30 minutes, a decrease of 9 minutes from the 1995 valuation. CMS agreed that the work of colonoscopy had not changed from 1995 to 2005 and that the then-current value of 3.69 RVUs should be maintained; however, CMS did not apply the 9 minute reduction in intra-service time to the rest of the codes in the family, resulting in artificially inflated times for the rest of the codes in the family. Subsequently, the RUC developed standard pre-time packages, as discussed in the sections above, resulting in the movement of time for moderate sedation from the intra-service period to the pre-service period at a fixed intensity of 0.0224 RVUs/minute. In order to make an accurate comparison of the previous to the current times, both the removal of the 9 minutes of intra-service time from the 2005 valuation of base code 45378 and the movement of moderate sedation from intra-service to pre-service time

Ileoscopy

CMS reviewed the Ileoscopy base procedure CPT code 44380 *Ileoscopy, through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed* and compared it to their recommended work RVU of 3.29 for the base colonoscopy code 45378. The Agency then calculated the incremental difference between the RUC recommended work RVU for 45378 (work RVU= 3.36) and 44380 (work RVU= 0.97). The resulting RVU difference, 2.39, was then subtracted from the CMS proposed work RVU for 45378 (3.29) for a resulting work value of 0.90 for CPT code 44380.

Our societies do not agree with CMS' methodology of determining incremental differences between base procedures across families, as this is a misapplication of the incremental approach. These two services have vastly different intensity and complexities, while the colonoscopy code has almost double the intra-service time. Given the vast differences between the two base procedures, ensuring these two services are relative using magnitude estimation is the most appropriate methodology.

Our societies support the RUC recommended value of 0.97 for 44380. By eschewing magnitude estimation, the CMS proposed incremental cut is arbitrary, lacking any reasonable validity to further reducing the value of this code. Since CMS, for the rest of the family of services, uses

the incremental methodology in a sound manner, our societies requests that the RUC recommended increments and values are applied to the following ileoscopy codes.

- CPT Code 44382 – GI and RUC Recommended work RVU of 1.27
- CPT Code 44384 – GI and RUC Recommended work RVU of 3.11

Pouchoscopy

CMS reviewed the pouchoscopy base procedure CPT code 44385 *Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); diagnostic, including collection of specimen(s) by brushing or washing, when performed* and compared it to their recommended work RVU of 3.29 for the base colonoscopy code 45378. The Agency then calculated the incremental difference between the RUC recommended work RVU for 45378 (work RVU= 3.36) and 44385 (work RVU= 1.30). The resulting RVU difference, 2.06, was then subtracted from the CMS proposed work RVU for 45378 (3.29) for a resulting work value of 1.23 for CPT code 44385.

As with the previous base codes, the pouchoscopy base service and the colonoscopy base code offer no directly comparable increment of physician work. CPT code 45378 has nearly three times the intensity and complexity of 44385 (44385, IWPUT= 0.036 and 45378, IWPUT= 0.100), with nearly double the intra-service time. The survey results from 63 gastroenterologists and several surgical subspecialties including general, gastrointestinal, endoscopic and colorectal surgeons determined that the 25th percentile work RVU of 1.30 was appropriate, which was a 28 percent decrease from the current value, 1.82. The RUC noted that the recommended work RVU of 1.30 maintains the appropriate rank order between this pouchoscopy diagnostic procedure and the ileoscopy and esophagoscopy diagnostic procedures. The RUC's original recommendation of 1.30 appropriately placed this service relative to services both within and outside the family of services. CMS provided no additional rationale for its proposed work value and provided no further justification as to why its proposed value is more appropriate than the RUC recommendation. Therefore, CMS should accept the RUC and societies' recommended work RVU of 1.30 for CPT code 44385.

Since CMS, for the other service in the family, uses the incremental methodology in a sound manner, our societies request that the RUC recommendations for 44385 be accepted and the RUC recommended increment be applied to the following pouchoscopy code.

- CPT Code 44386 – GI and RUC Recommended work RVU of 1.60

Colonoscopy through Stoma

CMS reviewed the colonoscopy through stoma base procedure CPT code 44388 *Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed* and compared it to its recommended work RVU of 3.29 to the base colonoscopy code 45378. The Agency then calculated the incremental difference between the RUC recommended work RVU for 45378 (work RVU= 3.36) and 44388 (work RVU= 2.82). The resulting RVU difference, 0.54, was then subtracted from the CMS proposed work RVU for 45378 (3.29) for a resulting work value of 2.75 for CPT code 44388.

As with the other base codes for endoscopic services, the colonoscopy-stoma base service and the colonoscopy base code are separate, distinct procedures and should not have values that are computed based on the difference between their individual work RVUs. The RUC reviewed the survey results of 86 gastroenterologists, general surgeons, and colon and rectal surgeons and noted that the current value of 2.82 is below the survey 25th percentile. The RUC determined that there was no compelling evidence to increase the value and recommended the current value of 2.82. However, the RUC also made it clear that there is no evidence that the work intensity has lessened since the last valuation. No technological or patient demographic changes have occurred; thus, the current value remains valid. Therefore, CMS should accept the RUC recommended work RVU of 2.82 for CPT code 44388.

When 44388 was reviewed in 2000 as part of the second Five-Year Review, the RUC recognized a rank order anomaly between the colonoscopy through stoma codes and their equivalent colonoscopy codes. At that meeting, the RUC agreed that the value for 44388 should be directly crosswalked to 45378 Diagnostic Colonoscopy (CY 2000 work RVU= 3.70) because both services had similar time and physician work intensity. However, CMS did not agree with this value or any of the recommended increases for the colonoscopy through stoma family of codes. Instead the agency chose to accept the RUC recommended physician time components but keep the Harvard work values, thus creating artificially low intensities for the entire c-stoma family. A diagnostic colonoscopy through stoma procedure is not screening in nature. It is performed on patients with existing pathology which resulted in the removal of a portion of the intestinal tract. The area examined may be shorter than a complete colonoscopy, but the examination is still at least as intense as a diagnostic colonoscopy. Due to these inconsistencies, the RUC agreed that it was inappropriate to further compound the inconsistencies by reducing the current RVUs to account for the reduction in minutes of the survey time compared to the current time.

The RUC specifically noted that while the intra-service time has dropped from 39 minutes to 25 minutes, the current work RVU of 2.82 should not change. There has been no lessening of the physician work intensity to perform this procedure. Furthermore, reducing the work RVU still further compared to the diagnostic colonoscopy service would only exacerbate the already inaccurate work RVU variance between these two services.

Since CMS, for the rest of the family of services, uses the incremental methodology in a sound manner, our societies request that the RUC recommendations for 44388 be accepted and the RUC recommended increments be applied to the following colonoscopy through stoma codes.

- CPT Code 44388 – RUC Recommended work RVU of 2.82
- CPT Code 44389 – RUC Recommended work RVU of 3.12
- CPT Code 44390 – RUC Recommended work RVU of 3.82
- CPT Code 44402 – RUC Recommended work RVU of 4.96
- CPT Code 44403 – RUC Recommended work RVU of 5.81
- CPT Code 44404 – RUC Recommended work RVU of 3.13
- CPT Code 44406 – RUC Recommended work RVU of 4.41

- CPT Code 44407 – RUC Recommended work RVU of 5.06
- CPT Code 44408 – RUC Recommended work RVU of 4.42
- CPT Code 44401 – GI Recommended work RVU of 4.77

Flexible Sigmoidoscopy

CMS reviewed the sigmoidoscopy base procedure CPT code 45330 *Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed* and compared it to their recommended work RVU of 3.29 for the base colonoscopy code 45378. The Agency then calculated the incremental difference between the RUC recommended work RVU for 45378 (work RVU= 3.36) and 45330 (work RVU= 0.84). The resulting RVU difference, 2.52, was then subtracted from the CMS proposed work RVU for 45378 (3.29) for a resulting work value of 0.77 for CPT code 45330.

As with the other base codes for GI endoscopic procedures, the sigmoidoscopy base service and the colonoscopy base code offer no directly comparable increment of physician work. CPT code 45330 has over four times the intensity and complexity of 44385 (44385, IWPUR= 0.022 and 45378, IWPUR= 0.100), with nearly triple the intra-service time. Our societies do not agree with the RUC recommendation of 0.84 work RVUs for 45330. Based on the survey results of 103 gastroenterologists, general surgeons, and colon and rectal surgeons, the 25th percentile was higher than the current value, therefore, our societies recommend a work RVU slightly lower than the 25th percentile at the current work RVUs of 0.96. Our societies request that CMS accept our recommended work RVU of 0.96 for CPT code 45330.

Since CMS, for the rest of the family of services, uses the incremental methodology in a sound manner, we request that the following recommendations for 45330 be accepted and the RUC recommended increments and other values be applied to the following sigmoidoscopy codes.

- CPT Code 45331 – GI Recommended work RVU of 1.26
- CPT Code 45332 – GI Recommended work RVU of 1.97
- CPT Code 45333 – GI Recommended work RVU of 1.77
- CPT Code 45335 – GI Recommended work RVU of 1.27
- CPT Code 45338 – GI Recommended work RVU of 2.20
- CPT Code 45340 – GI Recommended work RVU of 1.78
- CPT Code 45341 – GI and RUC Recommended work RVU of 2.43
- CPT Code 45346 – GI Recommended work RVU of 3.06
- CPT Code 45347 – GI and RUC Recommended work RVU of 2.98

Practice Expense Adjustments for the Instrument Table

We disagree with CMS' proposed practice expense (PE) adjustments to the RUC recommendations for removal of the instrument table.

CMS recommended removal of the mobile instrument table (EF027) from codes 45330, 45331 citing that the procedures do not include moderate sedation. While the mobile instrument table is part of the moderate sedation standard package, it is still a necessary part of flexible sigmoidoscopy codes 45330 and 45331. Without a mobile instrument table, the endoscopist will have no place to put his/her surgical instruments for the procedure itself.

Moderate Sedation

Given that the RUC is currently conducting surveys of moderate sedation services, we ask CMS to delay finalizing the valuation of the colonoscopy, flexible sigmoidoscopy, and colonoscopy through stoma procedure codes until the Agency can determine a proper framework for valuing moderate sedation when considered inherent to the procedure, and adjusting the value of the procedure.

Impact of cuts to colonoscopy may impact access

The severity of CMS' proposed cuts will impact access to colonoscopy based on significant feedback from members. Our societies received many comments indicating that physicians will be forced to limit access for new Medicare beneficiaries, refer Medicare beneficiaries to the hospital for colonoscopy, limit colonoscopies for Medicare beneficiaries, or even opt-out of Medicare if the proposed cuts are finalized. **We ask that CMS perform an objective study through an outside contractor regarding the impact of projected reimbursement changes from the PFS and the Hospital Outpatient Prospective Payment System/Ambulatory Surgery Center proposed rules on colorectal cancer screening and surveillance for Medicare beneficiaries and how the added value of such procedures could be incorporated into the current AMA RUC valuation process. Our societies request a delay in the implementation of the proposed PFS changes until the study results are available.**

Role of the Refinement Panel

As part of CMS' efforts to revise the process to increase stakeholder review and feedback before Medicare reimbursement rates are finalized, CMS proposes to eliminate the refinement panel as the Agency believes it may no longer be necessary. CMS has emphasized on multiple occasions that the refinement panel should not be considered an "appeals process" for codes going through the misvalued codes review.

We do not agree with CMS. Our societies believe that CMS can further promote a more transparent and fair process by including reimbursement changes in the annual proposed rule as well as keeping the refinement panel. Unlike the proposed rule comment and review period, the refinement panel provides for an additional check and balance process that incorporates outside clinical experts' review and new clinical evidence. **We ask CMS to reconsider this proposal**

and instead incorporate the refinement panel process into the newly finalized process to improve transparency in Medicare rate setting.

As discussed in the 2011 PFS final rule (75 FR 73306), the refinement panel process provides an opportunity to review and discuss proposed and interim final work RVUs with a clinically diverse group of experts, which then provide informed recommendations to CMS. This process helps CMS balance the interests of those who have made comments on these work value changes together with the redistributive effects that would occur in other specialties should CMS decide to finalize changes to RVUs. Our societies see significant value in this process as it allows CMS to review the impact on changes made to medical services and on Medicare beneficiaries with a year's worth of data and in an open forum. We believe that discrepancies in the methodology used to determine physician work values will still be inevitable in some circumstances notwithstanding the recommendation provided in the proposed rule. There would still be a need for a refinement panel if CMS adopts our societies' suggested changes to the review process as outlined above.

Given our societies' serious concern with the methodology proposed by CMS for colonoscopy, we urge CMS to keep the Refinement Panel in place in order to provide a platform for additional information to be provided to clinical experts to help resolve this matter.

INCOMPLETE COLONOSCOPY CLARIFICATION

The CPT Editorial Panel revised the definition of colonoscopy as of CPT 2015 to describe a more complete procedure than in previous editions.

Colonoscopy is the examination of the entire colon, from the rectum to the cecum, and may include the examination of the terminal ileum. (*CPT 2014 Professional Edition, p.274*)

Colonoscopy is the examination of the entire colon, from the rectum to the cecum, and may include examination of the terminal ileum or small intestine proximal to an anastomosis. (*CPT 2015 Professional Edition, p. 283*)

This distinction is important. Prior to 2015, the descriptor of the colonoscopy procedure was *Colonoscopy, flexible, proximal to splenic flexure; diagnostic*. Code 45378 was surveyed as complete colonoscopy using the more comprehensive procedure definition reflected in CPT 2015. Medicare data for 2013 and prior years showed a three percent incomplete colonoscopy (45378-53) rate. There is no other evidence to suggest otherwise.

The question is how to address reimbursement for colonoscopy that goes beyond the splenic flexure, but does not reach the cecum or small bowel – large bowel anastomosis. While there are a number of reasons why this does not occur, the primary reasons are 1) poor preparation precluding adequate examination of the lumen of the bowel, and 2) technical limitations such as internal tortuosity and external adhesions that preclude safe advancement of the colonoscope to

the cecum. In both circumstances, the work and intensity of the physician in attempting to safely advance the colonoscope to perform a complete diagnostic examination of the colon is greater than a ‘standard’ examination, and we note that there is an increased risk of perforation in such circumstances. Thus, while the work is greater, the evaluation of the colon is incomplete, which is at odds with the reason for performing colorectal cancer screening in the first place.

The CPT Editorial Panel recommends for screening or diagnostic colonoscopy procedures that modifier 53 is appended to the procedure. CMS uses modifier 53 for two purposes: reducing payment to the physician and the facility to that of flexible sigmoidoscopy, and allowing for the patient to undergo another colonoscopy screening examination in accordance with the frequency limit under Section 1834(d) (3) (E) of the Social Security Act:

“Frequency limit.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.”

We agree with reimbursing incomplete colonoscopy as a flexible sigmoidoscopy if the scope is not passed beyond the splenic flexure, and encourage the use of modifier 53 for this circumstance. However, we do not agree with reimbursing incomplete colonoscopy as a flexible sigmoidoscopy if the scope is passed beyond the splenic flexure but does not reach the cecum or small bowel – large bowel anastomosis as we believe the physician work is the same or higher than a complete colonoscopy, and that the facility expenses are identical to the complete colonoscopy.

We recommend that CMS establish a new modifier for the physician and facility to address those circumstances where the colonoscope has passed beyond the splenic flexure but has not reached the cecum or small bowel – large bowel anastomosis for the following circumstances: 1) inadequate preparation precluding high-quality examination of the lumen of the bowel, and 2) technical limitations that preclude the ability of the physician to safely complete the examination of the colon. We recommend that payment for the professional services for colonoscopy in these circumstances be adjusted to 75 percent of the payment for the colonoscopy procedure, and that appending this new modifier to the professional services for the procedure would allow the same or other physician to bring the patient back for another colonoscopy examination within two months without triggering the frequency limitation under the Act, and that facility payment for the procedure would not be adjusted when this modifier is reported with codes 45378, G0105 or G0121. Section 1834(d) (2) (E) (ii) of the Social Security Act states:

“Frequency limit.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.”

We are concerned that the Medical Claims Processing Manual, Chapter 18, Preventive and Screening Services, Section 60.2, HCPCS Codes, Frequency Requirements, and Age Requirements, creates ambiguity with regards to the frequency limit for G0104, colorectal cancer screening, flexible sigmoidoscopy. The manual states:

“For services furnished on or after July 1, 2001:

- Once every 48 months as calculated above unless the beneficiary does not meet the criteria for high risk of developing colorectal cancer (refer to §60.3 of this chapter) and he/she has had a screening colonoscopy (code G0121) within the preceding 10 years. If such a beneficiary has had a screening colonoscopy within the preceding 10 years, then he or she can have covered a screening flexible sigmoidoscopy only after at least 119 months have passed following the month that he/she received the screening colonoscopy (code G0121).”

Our concern is that the Medicare Administrative Contractors could interpret this to mean that ICD-9 code V76.51, *Special screening for malignant neoplasms of colon* counts against the interval allowance for colorectal cancer screening procedures. We do not believe that was the intent of Congress in establishing the frequency limits for these vital colorectal cancer screening services, and urge the Agency to issue a clarification, either through a Transmittal or in the Final Rule, that V76.51 or the ICD-10 equivalent Z12.11 *Encounter for screening for malignant neoplasm of colon* does not count against the interval allowance for colorectal cancer screening procedures, specifically G0104.

APPLICATION OF THE MISVALUED CODE TARGET

We acknowledge that CMS is under statutory obligation to implement a methodology of achieving an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. We further acknowledge that if the estimated net reduction in expenditures for the year is less than the target for the year, payments under the fee schedule will be reduced to reach the target. We are concerned with the likelihood that any level of cuts sustained by gastroenterologists in 2016 due to the revaluation of lower endoscopy codes will be exacerbated by the requirement to achieve the statutory target of 1.0 percent in 2016. We urge CMS to explore its administrative authority to discriminate among services when applying PFS reductions to achieve the target.

Distinguishing “Misvalued Code Adjustments from other RVU Adjustments”

We support CMS’ approach for defining the reduction in expenditures as a result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values. We concur with CMS that the calculation of estimated net reduction should not just include RVU adjustments made to the codes formally identified as “potentially misvalued.”

We also appreciate CMS’ dilemma of how to account for changes in values for calculating the CY 2016 target since the overall change in valuation for many misvalued codes is measured across values for three years under current processes and the target only compares changes between two years. We understand and concur with CMS’ decision to exclude code-level input changes for CY 2015 interim final values from the calculation of CY 2016 misvalued code target since the value change occurred over multiple years, including years not applicable to the misvalued code target.

Estimating the Target for CY 2016

We understand that CMS was unable to calculate an estimate of the target amount at the time the proposed rule was published because it will be establishing interim final values for codes that were received after the February 10, 2015 deadline for RUC recommendations and, consequently, not included in the proposed rule. In the proposed rule, CMS states that, thus far, they have identified net reductions totaling only 0.25 of the 1.0 percent target, not accounting for codes that will be valued in the final rule and counted toward the target. If the target is not met, CMS states that the target recapture amount will be achieved by adjustments to the conversion factor. Unfortunately, given the lack of services with revised input values in this proposed rule, if lower endoscopy code payments are reduced as proposed, they are at high risk for further reductions to meet the target. **We respectfully request that CMS review its administrative authority to achieve a “target recapture amount” in a manner other than an across-the-board adjustment to the conversion factor. We strongly believe that codes already sustaining reductions in 2016 and, consequently contributing to the target, should not be subjected to additional cuts to achieve the statutory target.**

PHASE-IN OF SIGNIFICANT RVU REDUCTIONS

By statute, if total RVUs for a service, except for new or revised codes, are decreased by an estimated 20 percent or more, the adjustments shall be phased-in over a two-year period. CMS is proposing to exclude from the phase-in those codes that are part of a family with significant coding revisions. We believe this exclusion conflicts with CMS’ statutory obligation to phase-in reductions of 20 percent or more. We, therefore, ask CMS to use its administrative authority, as set forth in the Protecting Access to Medicare Act of 2014, to smooth relative values within groups of services. We believe the intention of the statutory phase-in is to mitigate the effect of dramatic reimbursement decreases on practices and patient access to care that result from CMS’ review of misvalued codes. CMS’ proposed exclusion is not consistent with the purpose of the phase-in, and is particularly damaging for practices when the exclusion is applied to high-volume services with cuts of 20 percent or more. We acknowledge CMS’ concern about maintaining appropriate rank order among codes in a family, by avoiding years for which RVU changes for

some codes in a family are in transition while others are fully implemented. We suggest that this concern can be managed by phasing in values evenly across two years rather than CMS' proposed methodology of a 19 percent reduction as the maximum one-year reduction, followed by the phase-in of the remainder of the reduction in the second year. While CMS describes its proposed phase-in methodology as the most equitable for codes with significant reductions but less than 20 percent, we disagree. CMS' phase-in proposal is fundamentally unfair to specialties where significant reductions are occurring across several codes which cumulatively have a significant impact on a practice. CMS' exclusion of codes with a reduction of 20 percent or more that fall within a family with significant coding revisions is misguided, as well as its proposed phase-in methodology. **We urge CMS to fulfill the intent of Congress by applying the phase-in to any code with reduction of 20 percent or more, except those described as new or revised, and to equally distribute reductions over the two-year phase-in period.**

POTENTIALLY MISVALUED SERVICES UNDER THE PHYSICIAN FEE SCHEDULE

Liver Elastography Utilization Rate

In CY 2015, CMS established payment for code 91200 *Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report*. This service is performed in patient with liver conditions, such as hepatitis C, where it is important to establish the degree of hepatic fibrosis prior to making treatment recommendations to the patient, which may include the use of costly pharmaceuticals. The availability of a non-invasive method for assessing hepatic fibrosis is an important advancement in the management of liver disease, as the other option is an invasive liver biopsy with the attendant risks of perforation and even death.

Our societies believe that there is a potential error in the utilization rate. Currently, CMS has assigned a 50 percent utilization rate to this procedure; however, in order to meet the 50 percent utilization rate, physicians would need to use the equipment at least 25 hours per week. At a minimum, liver elastography procedures take 30 minutes or more, which means that a physician office would have to perform more than 50 procedures every week in order to meet the 50 percent utilization threshold. Unlike ultrasound procedures where the ultrasound equipment is in constant use by the radiologist, our physicians indicate that in a high-volume hepatology unit or practice only 15-25 liver elastography procedures are typically performed per week at maximum, and that the volume of liver elastography procedures is less in a community practice setting. We remind CMS that more than 40 percent of gastroenterologists practice in settings of one to five physicians, and that these providers are often the primary providers for the evaluation and management of patients with hepatitis C, hepatic steatosis, and other liver diseases in the rural and urban community settings. At present, the proposed technical component (TC) and global reimbursement is inadequate to provide this service in the non-facility setting, in view of the costs of the equipment and supplies needed to perform this procedure. We believe that the 50 percent utilization rate is too high and not consistent with clinical practice, and that a utilization rate of 25 percent or even less is more realistic. We, therefore, recommend an adjustment in the

equipment utilization rate from 50 percent to 25 percent or less, as the alternative is for the beneficiary to be referred to the more costly outpatient hospital setting for this service.

IMPROVING PAYMENT ACCURACY IN CHRONIC CARE MANAGEMENT AND EVALUATION AND MANAGEMENT SERVICES

CMS continues to receive requests from stakeholders to lead efforts to revise the current CPT evaluation and management (E/M) codes or to construct a new set of E/M codes. The goal is to more accurately describe and value the physician work (time and intensity) in complex care patients specific to primary care and other cognitive specialties. CMS agrees with stakeholders that it is important for Medicare to use codes that accurately describe the services furnished to Medicare beneficiaries and to accurately reflect the relative resources involved with furnishing those services. Thus, CMS seeks public comments on ways to recognize the different resources (particularly in cognitive work) involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated in the codes that describe the broader range of E/M services.

We applaud CMS for recognizing care management as a critical aspect of helping individuals achieve better health outcomes and reducing expenditure growth. We commend the agency for proposing to address the deficiencies in the existing (E/M) services, particularly as they relate to the delivery of comprehensive, coordinated care management.

We support CMS' proposal to create add-on codes to reimburse currently uncompensated physicians work associated with E/M services as a practical and expedient, though limited, solution to the undervaluation of E/M services. We believe that an initial focus on the outpatient new and established patient E/M code families is warranted, since these represent the most substantial of the many deficiencies in the existing codes.

Our societies agree with these stakeholders and appreciate CMS' recognizing this complex cognitive work in the valuations of new codes. For example, the growing complexity of the diagnosis and management of a patient with inflammatory bowel disease (IBD) patients is an example of grappling with extraordinarily complicated disease features of bleeding, abdominal pain, diarrhea, fistula, abscess, obstruction, postoperative sequelae, biologic therapies and changing paradigms of therapy. This is further confounded by the increasing obstacles of comorbidities, polypharmacy, cognitive, linguistic and social care in the growing elderly patient populations which are not reflected by the RVU system, much less the additional time required to review all prior data and communicating with past and current primary care and specialist physicians, radiologists, pathologists and surgeons. All of these efforts are essential to ensure a correct diagnosis with subsequent management so vital to intelligent care but is virtually ignored by the present E/M valuations. The incredible time commitment required for discussion with each patient and family members is equally ignored by current E/M codes.

Our societies agree that new codes for these complex and cognitive service should not, however, be limited to primary care or any other specialty. Rather, CMS should recognize that these issues persist in other specialties, such as gastroenterology, as noted above. We recommend two categories of new add-on codes be developed for use by all specialties: one for new and one for established patients. Each category should have two levels of add-on codes for both new and established outpatients that reflect the different levels of intensity of the work performed; the first for a high level of intensity and the second for even higher levels of intensity. These codes should follow the resource-based paradigm of RBRVS using work intensity as the unit of resource use. For primary care, the levels of intensity would recognize both the complexity of multiple interactions of medications and health problems and the post-visit work intensity for patients with multiple chronic conditions. For the specialist, the levels of intensity would correspond to disease state complexity and medical decision making.

While the CPT Editorial Panel has established several codes for E/M services that are important in the provision of care management services for patients with one or more chronic conditions, CMS has yet to establish payment for these services under the physician fee schedule. Yet, these services are important to the provision of value-driven services that are essential to improve the health and overall well-being of the patient, to proactively assess the patient between visits, to prevent unnecessary emergency room or duplicative services, and to reduce the likelihood of potentially avoidable complications that could be addressed through earlier assessment and intervention by the physician, whether primary care or specialist. Specifically, while we recognize that pharmacist services are not covered under part B, they are an essential component of chronic care management (code 99490) services in optimizing the pharmaceutical management of patients with multiple chronic and complex conditions. Unlike other health care professionals such as a registered nurse or radiology technician, CMS has never established a practice expense value for the work of a pharmacist in providing incident-to services to the physician. CMS should recognize the training, education, and preceptorships by pharmacists, health care professionals, in order to provide cognitive medication management services. We urge CMS to instruct the RUC to survey codes 99605-99607, Medication therapy management provided by a pharmacist, so that these services can be appropriately valued and utilized by physicians who wish to provide coordinated care management services to those elderly, frail, and complex patients who require a village of health care professionals to coordinate and optimize their care.

While we appreciate CMS' current proposal to more fairly recognize physician work in providing E/M services, it is limited in scope by its very nature and will at best be only partially successful. New payment models being studied and implemented by CMS continue to rely on the RBRVS when determining physician compensation. Yet, the existing E/M codes continue to be inadequately defined and valued – a gap that has grown substantially in the more than 30 years since their initial Harvard valuation. In particular, the variability and intensity of the E/M work done by many specialties both within the face-to-face encounter as well as during the post-

service period continues to evolve in complexity. Unfortunately, the existing E/M codes remain limited and fail to capture the diverse and growing efforts required within the current health care continuum.

We recommend that CMS improve the accuracy in the PFS by creating new outpatient E/M codes that would be developed from a research-based model. We believe that the Section 3021 of the Affordable Care Act provides the Innovation Center with the authority to conduct this research. Congress authorized the Center for the purpose of testing “innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care.” As long as new payment models use the RBRVS as the foundation for physician reimbursement, E/M services must be revised to accurately reflect the work provided to patients. More accurate reimbursement for cognitive work has the potential to enhance the quality of care provided to patients while lowering costs, both goals of Innovation Center projects. The model would be developed by studying the work done by physicians across the country before, during and after E/M services. If successful, this research-based model could then be used to address the deficiencies in the other E/M code families. We urge CMS to commit to underwriting this research by hiring an expert contractor to work with stakeholders to develop a comprehensive understanding of outpatient E/M work physicians and their clinical staff currently perform. This research would 1) describe in detail the full range of intensity for outpatient E/M services, 2) define discrete levels of service intensity based on this observational and electronically stored data combined with expert opinion, 3) develop documentation expectations for each service level that place a premium on the assessment of data and resulting medical decision making, 4) provide efficient and meaningful guidance for documentation and auditing, and 5) ensure accurate relative valuation as part of the PFS.

While we urge CMS to commit to the research necessary to develop new outpatient E/M codes, this research will also be critical to identifying and valuing the uncompensated work associated with E/M services that the Agency intends to support with the add-on code proposal. This research will provide the Agency with an accurate and reliable description of E/M activities. It will also help clarify what physician work should be attributed to the E/M services and allow a clear definition of what Medicare should expect from chronic care management (CCM) and transitional care management (TCM) services.

APPROPRIATE USE CRITERIA FOR ADVANCED IMAGING SERVICES

There are many clinical situations in which gastroenterologists order advanced diagnostic imaging services and, therefore, will need to comply with the requirements of the Medicare Appropriate Use Criteria (AUC) Program or risk disruption of current referral patterns. Beginning in 2020, failure to adhere to AUC also puts ordering professionals at risk for having to seek prior authorization before an advanced diagnostic imaging test can be ordered.

Statutory Requirements and Implementation Timeline

We understand that this proposed rule represents the initial component of the new Medicare AUC Program and CMS' plan for implementing the remaining components. We concur with CMS' assessment of the complexity of the program and appreciate that in this proposed rule CMS was unable to include proposals to begin implementation of the AUC program. However, we are concerned that much of the implementation is being left to CY 2017 rule-making, through which CMS intends to provide clarifications, develop definitions and establish the process by which it will specify clinical decision support (CDS) mechanisms. CMS states that requirements for qualified CDS mechanisms will also be vetted as part of the CY2017 PFS rule-making and anticipates the initial list of specified applicable CDS mechanisms will be published sometime after the CY 2017 final rule. We understand that CMS is statutorily bound to implement the AUC program on January 1, 2017; however, we have serious concerns with the timeline for implementation.

We are not confident that a range of CDS mechanisms through which providers will access AUC will be well-established or that practices will be adequately prepared to integrate CDS mechanisms into their clinical workflow under the proposed implementation timeline. We agree with CMS that to minimize administrative burden and avoid duplicate documentation, multiple CDS mechanisms would ideally be available, including those that could integrate directly into, or be seamlessly interoperable with, existing health information technology (HIT) systems. While we appreciate that CMS is willing to work with stakeholders to ensure that appropriate mechanisms are available, particularly with respect to standards for certified HIT, there are varied predictions of when CDS will be ready for use for AUC, including whether a range of CDS will be available by the program's start date. We urge CMS to use processes outside the CY 2017 PFS rule-making process to solicit stakeholder feedback on various implementation proposals under consideration by the Agency, especially for establishing requirements for qualified CDS mechanisms so adequate time is afforded to vendors and physician practices prior to implementation. Given that current timelines are unlikely to allow for CDS modules within certified EHR technology, it will be important for CMS to establish CDS mechanisms that are independent of EHR technology.

Identifying Priority Clinical Areas

CMS correctly points out in the proposed rule that there are different views on how best to roll out AUC with some advocating starting with a comprehensive library of individual AUC, and others suggesting that the program should be implemented by focusing on a few priority clinical areas at a time to ensure that providers fully understand the AUC they are using, including when they do not apply to a particular patient. CMS is proposing to combine these approaches by identifying outlier ordering professionals from within priority clinical areas. Under this proposed policy, CMS envisions that potentially large volumes of AUC would become specified across clinical conditions and advanced imaging technologies, but would be balanced with a more focused approach to identifying outlier ordering professionals. We appreciate CMS' suggestion that this approach may provide an opportunity for physicians and practitioners to become familiar with AUC in identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals. While this compromise may seem logical, we do not believe it is practical given the timeline for

implementation. We suggest that CMS instead focus implementation on a few clinical priority areas. We agree with recommendations of the HIT Policy Committee Quality Measurement Task Force that AUC implementation should be a slow process, as a phased approach will better allow for early successes while working through implementation challenges.

We recognize that CMS will establish priority areas in future rule-making. In identifying priority clinical areas, CMS states it may consider incidence and prevalence of diseases, as well as the volume, variability of utilization, and strength of evidence for imaging services. CMS states it may also consider applicability of the clinical area to a variety of care settings, and to the Medicare population. We agree with these considerations and also suggest that CMS consider those services for which there is a high volume of self-referral, while also taking into account the above considerations.

INCIDENT TO PROPOSALS: BILLING PHYSICIAN AS THE SUPERVISING PHYSICIAN

Our societies are very concerned with a fee schedule proposal that could significantly impact the way that physician practices arrange for and bill services performed by auxiliary personnel incident to the services of a physician or practitioner. In general, incident-to services must be furnished under the direct supervision of a practitioner and current regulations at 42 CFR § 410.26(b)(5) state that “[t]he [practitioner] supervising the auxiliary personnel need not be the same [practitioner] upon whose professional service the incident to service is based.” Thus, existing CMS policy provides for a simplified billing process that recognizes the valuable role of non-physician personnel in providing care as part of services billed by the practitioner that generally oversees the patient.

In the Proposed Rule, CMS indicates that this language could be interpreted as permitting a practitioner to bill for incident-to services or supplies that the billing practitioner did not directly supervise. CMS clarifies that it is the long-standing position of CMS that the practitioner billing for incident-to services must be the practitioner who directly supervised the billed-for service. CMS proposes to remove the language above from § 410.26(b)(5) and add new language explicitly stating that a practitioner billing for incident-to services or supplies must be the practitioner who directly supervised the billed-for services or supplies.

In the Proposed Rule, CMS did not further clarify whether it would consider practitioners in the same group practice/clinic to be considered the same practitioner for purposes of applying the clarified incident-to supervision requirement. CMS has previously released guidance materials stating that practitioners may bill for incident-to services supervised by another member of the same group practice. In the Proposed Rule, CMS states, “It has been our position that billing practitioners should have a personal role in, and responsibility for, furnishing services for which they are billing and receiving payment as an incident to their own professional services.” This language, particularly the phrase “their own professional services,” calls into question whether CMS would still permit the group practice/clinic option of using different physicians in the group

to supervise services than the physician upon whose professional services the incident-to service is based.

If CMS does intend to revise its approach to group practice/clinic supervision of incident-to services, it would raise significant concerns for many gastroenterology practices where patients undergo a series of treatments and the supervising physician may be different from the patient's treating physician. In some cases, the result may be that the service must be billed at a lower, non-physician rate, such as where a nurse practitioner is supervised by a physician other than the physician upon whose professional services the nurse practitioner's service is incident-to. In other cases, the result appears to be non-coverage. For example, if a physician in a gastroenterology group practice sees a patient with inflammatory bowel disease and establishes a plan of treatment, the patient may return to the practice multiple times. If, on some of those occasions, the treating physician is not present, but other physicians in the practice are present and supervise the therapy administered by practice personnel, those other physicians likely would not see the patient or perform a separate professional service. If the physician who is not present is the one who has provided the professional services upon which the incident-to service is based, and the supervising physician has not performed such a service, does this mean that the immunologic drugs and administration by nursing personnel are not incident-to the services of either physician, and therefore not covered? Currently, the assumption is that the service is incident-to the services of the physician who treated the patient, and guidance regarding the CMS 1500 form provides that the physician who supervised the incident-to service—if different from the ordering physician—is shown on the CMS 1500 form as the rendering physician, while the group practice would be shown as the billing entity.

If CMS proceeds with the fee schedule proposal as written, specialty physicians such as gastroenterologists could face difficult decisions about how their practice is structured and administered. Gastroenterologists provide ongoing care to patients with complex conditions and increasingly rely on a team approach to care incorporating nurses and care managers, social workers, pharmacists, and other healthcare professionals. CMS should address whether it is changing the rules applicable to supervision in group practices or otherwise requiring that the physician upon whose professional services the incident-to service is based must always supervise the services.

We recommend that CMS not implement this proposal related to supervising physicians for “incident-to” billing and continue the current rules applicable to supervision in group practices.

PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS UNDER SECTION 1847A

We thank CMS for taking steps to address one of many ambiguities in regulatory requirements for biosimilar and biological products in advance of the imminent marketing of biosimilars for patient use. However, we are concerned that the specific payment policies proposed by CMS –

namely, the lack of unique identifiers for average sales price determination – could create difficulties for the market. This is particularly troublesome given that the market remains in its infant stages and will be extremely sensitive to any changes to reimbursement or payment policy.

The proposed fee schedule rule for CY 2016 states that CMS plans to use a single average sales price (ASP) calculation for all biosimilar products grouped within a specific HCPCS code. This policy, which is used for other common multiple source drugs, has potential consequences for the biosimilar market that are not present in traditional generic drugs. A biosimilar product, by its nature, is not a generic drug, and regulatory and payment requirements should reflect this difference. If a biosimilar is approved as interchangeable, interchangeability is between a biosimilar and a reference product, but not between biosimilars. This is important not only to the monitoring of safety and efficacy of biosimilars, but also for reimbursement fairness among biosimilars. Regardless of research, development, and quality protocols, a biosimilar will never be an exact copy of its innovator biologic. CMS should carefully consider the impact that uniform prices for unique products will have on the marketplace and whether this proposal will enhance or diminish competition.

We are concerned that, in an effort to create uniformity in reimbursement for biosimilars, CMS may actually limit access to these critical treatments in the future. Our concern is that the payment methodology under consideration could limit the development of new treatments by reducing financial incentives for developers seeking to bring biosimilar treatments to market. Failing to provide separate billing codes would hinder the ability of HHS to accomplish the goals contained in the original Biologics and Price Competition and Innovation Act by restricting the growth of the biosimilars market and limiting knowledge of individual biosimilars, and preventing the ability to facilitate additional research and educational efforts.

PHYSICIAN QUALITY REPORTING SYSTEM

In past comments, our societies have asked CMS to create greater Physician Quality Reporting System (PQRS) predictability for eligible professionals (EPs), rather than unanticipated year-to-year changes in measures and reporting requirements. Our societies appreciate that CMS is proposing requirements for the 2018 payment adjustment consistent with the requirements for the 2017 PQRS payment adjustment and not proposing changes in reporting requirements. Our societies were very concerned with the dramatic change in reporting requirements for CY 2015 from three to nine measures and, we are hopeful that, as a result of the efforts our societies have undertaken to educate our members about the reporting requirements and the availability of reporting using a Qualified Clinical Data Registry (QCDR), PQRS participation rates of gastroenterologists will continue to improve.

Group Practice Reporting Option Self-Nomination Flexibility

Despite the dramatic increase in the number of gastroenterologists participating in PQRS from 5,875 in 2012 to 9,003 in 2013, with variable success rates, increased complexity of the program coupled with the value modifier program and requirements for the Ambulatory Surgery Center Quality Program, our experience is that physicians remain very confused about reporting requirements, timelines, and how or whether the programs intertwine. **We are pleased that CMS is proposing to utilize data, for the purposes of the value modifier, reported through a**

mechanism other than the one through which a group registered to report under the PQRS Group Practice Reporting Option (GPRO). We believe similar accommodations should be made under PQRS for instances where a practice self-nominates to participate in PQRS through the GPRO but is unable to fulfill the reporting criteria as a group. In such cases, if individual quality data can be reported, the TIN GPRO restriction should be lifted and individual quality data should be accepted. To date, CMS' response to group practices that have made errors during the GRPO self-nomination process and wish instead to allow their EPs to report data as individuals has been to have EPs file for informal review, and the ultimate response provided back to the group has been negative to allow for individual reporting. We believe this response is short-sighted. Rather, we believe that accommodations should be made to allow EPs to submit individual data, even when the practice has self-nominated for GPRO, and then so a downward PQRS adjustment can be avoided. Similarly, for a practice that self-nominates for the GPRO, if the practice must switch reporting mechanisms after the self-nomination period has closed, the practice should not be penalized for submitting data using a mechanism other than the mechanism selected during the self-nomination process.

Requirements for PQRS Reporting Mechanisms

Collection of Demographic Data: As indicated in the Affordable Care Act, CMS states that it intends to collect quality data stratified by race, ethnicity, sex, primary language and disability status and is seeking comment regarding factors that may facilitate or hinder the collection and reporting of these attributes. We believe a phased approach to the collection of demographic is necessary to allow registries adequate time to update data fields and to ensure that vendors are capable of electronically transferring data from an Electronic Health Record (EHR) to a registry. Therefore, we recommend that a phased-approach start with the cross-cutting measures.

QCDR Self-Nomination Requirements: Our societies strongly support development and use of QCDRs, which provide a valuable reporting option for physicians based on specialty-specific measures. Organizations sponsoring a QCDR expend significant resources on researching and identifying the most useful quality measures to help enhance patient care. As such, our organizations have developed QCDRs to help gastroenterologists satisfy CMS reporting requirements in a manner that takes into account the unique nature of gastroenterological care. As organizations that have demonstrated support of the QCDR initiative, we support the provisions of the proposed rule that would expand the self-nomination period by one month in order to permit entities to self-nominate beginning December 1.

The process of creating, maintaining, and adapting a QCDR requires countless hours of work and the CMS proposal will help to mitigate the burdens associated with the QCDR process. This is particularly true for new and developing QCDRs, which will now have significantly more time to execute the self-nomination process in order to ensure their status as an approved QCDR. In the coming years, the roles of QCDRs will continue to expand as physicians see the value associated with reporting specialty-specific measures and the importance of meeting Medicare reporting requirements. We support steps that will make the process of creating or operating a QCDR more manageable and transparent, which will ensure the continued growth of registry reporting.

Participation in a QCDR for Group Practices: Consistent with requirements set forth under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), effective beginning with

the 2016 reporting period, a group practice will be treated as satisfactorily submitting data on quality measures if the group practice satisfactorily participates in a QCDR for the year. Consistent with the QCDR reporting option for individual EP, CMS is proposing that the reporting period for group practices participating in the GPRO will be a 12-month period. For the 2018 payment adjustment, the proposed reporting period is January 1, 2016 through December 31, 2016. We support this reporting period.

Also, consistent with criteria for individual EPs to participate in a QCDR, CMS is proposing that, to avoid the 2018 payment adjustment, the group practice would report at least nine measures available for reporting under a QCDR covering at least three of the National Quality Strategy domains, and report each measure for at least 50 percent of the group practice's patients. Of the measures, the group must report at least two outcome measures, or if two outcome measures are not available, report on at least one outcome measure and at least one of the following types of measures - resource use, patient experience of care, efficiency/appropriate use, or patient safety. Our societies support these reporting requirements and encourage CMS to continue its education of EPs about the advantages of registry reporting. We also ask CMS to emphasize, in the course of its education that the 50 percent threshold applies collectively to the group practice's patients. We believe confusion continues among provider groups about the application of the 50 percent threshold, with some believing it applies to 50 percent of cases for each eligible professional in the practice. Unfortunately, this confusion leads some practices to believe they are precluded from participating as a group using a registry or QCDR because the registry may not include measures that are applicable across a variety of EPs in a practice.

PQRS Quality Measures: Our societies thank CMS for the proposed inclusion of the following measures beginning with the 2016 reporting period:

- Frequency of Inadequate Bowel Preparation
- Photodocumentation of Cecal Intubation
- Age Appropriate Screening Colonoscopy

Furthermore, we support the ability of EPs to report Frequency of Inadequate Bowel Preparation and Photodocumentation of Cecal Intubation measures using both claims and registry mechanisms, and encourage CMS to also allow claims reporting for the Age Appropriate Screening Colonoscopy measure to ensure the highest level of reporting of this measure by gastroenterologists and other providers.

Consistent with our comments on the CY 2015 PFS proposed rule, we continue to encourage CMS to support medical societies with additional resources for developing EHR measure specifications. If CMS anticipates that responsibility for developing and maintaining e-specifications will continue to fall to measure stewards, offering free training, in addition to offering the measure Authoring Tool and other resources, could help standardize the process and make this a less onerous requirement for specialty societies who serve as a measure steward.

PQRS Measure Groups: Our societies appreciate that CMS has been open to new measure group proposals, and we look forward to continuing a dialogue with CMS about the future addition of a colorectal cancer screening and surveillance measures group. Our societies continue to hold the

position that all EPs need to be afforded a full range of PQRS reporting options. As CMS transitions to the Merit-Based Incentive Payment System, we encourage a review of measure group criteria to ensure the measure group mechanism is as robust as other reporting mechanisms, particularly with respect to the reporting threshold, so performance can be comparably assessed across mechanisms.

VALUE-BASED PAYMENT MODIFIER

Group Size

Beginning with the CY 2016 payment adjustment period, the size of a group (or TIN), for the purpose of applying the value modifier (VM) would be determined based on the lower of the number of EPs indicated by the PECOS-generated list or by CMS' analysis of the claims data for purposes of determining the payment adjustment amount under the VM. We recognize that if there is a discrepancy in group size between PECOS and claims analysis, the result would be the group being subject to the lower amount at risk but also lower possible upward payment adjustment. Our societies support this proposal.

Approach to Setting the VM Adjustment Based on PQRS Participation

Our societies support CMS' continued two-category approach for the CY 2018 VM based on participation in PQRS by groups and solo practitioners. As CMS points out in the rule, group practices are being unfairly penalized under the VM if they cannot report quality data to CMS using the reporting mechanism chosen during self-nomination for the GPRO. There may also be instances in which a practice self-nominates for the GPRO, but contracts with a registry to submit individual-level data. In these cases, we believe the GPRO restriction should be lifted to allow EPs within the TIN to submit individual-level data. **Therefore, we strongly support, as proposed, that CMS will determine whether a group is included in Category 1 by considering whether the 50 percent threshold has been met regardless of whether the group registers for a PQRS GPRO.** Consequently, if a group registers for a PQRS GPRO, but fails to meet the criteria to avoid the PQRS payment adjustment, the group will have an additional opportunity for the quality data reported by individual EPs in the group to be taken into account for purposes of applying the CY 2018 VM. As stated above, we believe that this flexibility should also be afforded to groups for the purpose of the PQRS adjustment.

Our societies acknowledge that CMS is under a mandate to transition to a VM for all physicians by January 1, 2017. We appreciate that CMS, thus far, has put physicians at minimal risk of payment penalties. We are concerned, however, with the proposed level of payment at risk under the VM to which small group practices and solo practitioners will be exposed. **We ask CMS to continue through CY 2018 to hold harmless from downward adjustments solo practitioners and group practices with 2-9 EPs who are subject to quality tiering.** Despite the availability of Quality and Resource Use Reports (QRURs) to all EPs, which are designed to help EPs improve performance, based on our experience, there remains a significant lack of awareness about accessing QRURs, particularly among solo and small group practices, as well as inadequate resources by those practices to interpret reports so actionable steps can be identified to improve performance. Similar to requirements CMS places upon EPs in the Medicare

Electronic Health Record Incentive Program (Meaningful Use), our societies recommend CMS receive confirmation that the QRUR was received prior to assuming EPs have downloaded, reviewed and approved the data contained in the report. This would also allow CMS and stakeholders to better determine whether QRUR reports are being used as envisioned by CMS.

Application of the VM to Shared Savings Program ACO Participants

We acknowledge that beginning with the CY 2017 payment adjustment, the VM will apply to physician groups with two or more EPs and solo practitioners who participate in an Accountable Care Organization (ACO), and to non-physician EPs in ACOs beginning with the CY 2018 payment adjustment. In instances where a TIN participates in multiple Shared Savings Program ACOs, we support CMS' proposal to allow a Shared Savings Program ACO TIN to compare the performance of the highest-performing ACO in which they participate to national benchmarks.

Application of VM to Pioneer ACO Model, Comprehensive Primary Care Initiative, or other Innovation Center Model Participants

We support CMS' proposal to waive application of the VM for EPs who participate in the Pioneer ACO Model, the Comprehensive Primary Care Initiative and any other similar Innovation Center models, as well as waive the application of the VM for EPs who do not participate in one of these models, but bill under the same TIN as the EPs who do participate.

Minimum Episode Count for the Medicare Spending Per Beneficiary Measure

We support the proposal to increase the episode minimum to 100 episodes for the Medicare Spending Per Beneficiary (MSPB) Measure beginning with the CY 2017 payment adjustment period. We agree with CMS that, although this change reduces the number of groups and solo practitioners for whom CMS would be able to include a MSPB calculation in the cost composite, the measure is not reliable at a 20 episode minimum.

Quality Measures

We acknowledge that beginning with the CY 2014 performance period, measures reported through a PQRS QCDR that are new to PQRS will not be included in the quality composite for the VM until such time as there is historical data to calculate benchmarks for them. The proposed rule states that once historical data is available from measures submitted via QCDRs, "the benchmark for quality of care measures will be the national mean for the measure's performance rate during the year prior to the performance period." We ask for clarification in the final rule about how benchmarks for quality of care measures reported through a PQRS QCDR will be calculated. Specifically, we seek clarification that QCDR measures will only be benchmarked against identical measures that are reported through a different QCDR or other reporting mechanism. We also seek clarification on whether QCDRs will be allowed to develop their own benchmarking methodology or if CMS will calculate, using its methodology, a benchmark based on a national mean for the measures. Our societies ask CMS to clarify these issues in the final rule.

PHYSICIAN COMPARE

In the years since its creation, our societies have worked diligently to educate members on the importance of the Physician Compare website and the role it plays in improving quality and providing new levels of transparency to patients. We remain encouraged by CMS' ongoing improvements to the website and appreciate steps taken in the past to ensure that the information contained in each provider's profile is accurate and current. CMS has worked to ensure that consumers are given statistically valid and reliable information that provides real value to consumers as they seek to make informed decisions about Medicare professionals that they choose to oversee their health care needs. In previous rule-making, we have stressed the importance of providing meaningful metrics for specialty physicians that provide consumers with contextualized quality information to create a level playing field across specialties and primary care. We appreciate CMS' repeated acknowledgement that consumers are best served by realistic quality measures and patient-friendly information.

As CMS looks to move the Physician Compare website beyond its initial stages, it is important to look for new sources of information that are both reliably measured and suitable for the consumer-friendly approach of Physician Compare. When undertaking new efforts to expand the scope of information provided in Physician Compare, our societies urge CMS to take into consideration both the ultimate goals of improving quality and transparency as well as the nature of the information being presented. While some consumer groups will benefit from different indicators, our societies caution that in order to be useful, the information provided on the website must be accurate and meaningful.

We are concerned with multiple data sources that the proposed rule indicates may be considered moving forward. Initially, we have serious concerns about the use of Open Payments data in the Physician Compare system due to the nature of the data and lack of explanation surrounding its impact on patient care. Physician groups have repeatedly argued that Open Payments does not provide an adequate context that allows consumers to derive value from the information being published. The physician-specific information fails to provide any context or background on the nature of reported transactions between physicians and health care industry stakeholders, which can distort the message and dilute the program's value. For example, there is still significant confusion among manufacturers, medical societies, and physicians on what continuing medical activities and non-continuing medical education activities would constitute an "indirect payment" thus, a reportable event under Open Payments rules. By including this information on Physician Compare, consumers will be faced with a daunting quantity of new information that has little or no direct relationship to quality or cost. **Until CMS adapts the Open Payments program to provide adequate context about the services and value provided by physician and industry relationships, we ask that CMS not include proposals in future rule-making to include Open Payments data in Physician Compare.**

Our societies would also have concerns with any eventual proposal to include VM designations in Physician Compare, especially as CMS transitions to the MIPS. While we have worked to educate our members on the intricacies of the VM since its inception, the program continues to struggle with a lack of transparency and accessibility. We do not believe that this information has been sufficiently refined to warrant its placement on the Physician Compare website. We believe that including a designation of the VM could overwhelm the website's other quality

information and lead to consumer decision making based solely on the VM designation. To that end, we appreciate that CMS acknowledges the limitations of current methods for reporting this information and agree that the current value modifier setting is not conducive to inclusion on Physician Compare (just like data in Open Payments).

Finally, we would like to express our concerns with proposals to include quality information that is stratified by race, ethnicity and gender. Our societies strive to address health care quality disparities that endanger the health of racial and ethnic minority groups and our physicians work with many conditions and disease states that disproportionately affect these groups. However, calculation of stratified quality data would require significant research to ensure that the information provided is both meaningful and accurate. Any steps to include such information must take into account differences in practice settings, geography, patient mix and population health. While we think that this information could eventually provide value, we do not believe that CMS currently has the ability to refine existing data in a manner that provides consumers with information that takes into account differences across practice settings. **We ask that CMS not move forward with proposals to stratify data on Physician Compare or include the value modifier until additional research has been done to address the necessary elements of collecting and presenting this information in a fair and reliable manner.**

MERIT-BASED INCENTIVE PAYMENT SYSTEM

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires the creation of the Merit-based Incentive Payment System (MIPS), applicable beginning with payments for items and services furnished on or after January 1, 2019. Our societies look forward to reviewing the forthcoming “Request for Information” on implementing this new payment system and providing more detailed comments. As sought by CMS in the proposed rule, below are preliminary comments on the new payment system.

In the proposed rule, CMS seeks comment on what would be an appropriate low-volume threshold for purposes of excluding certain EPs from the definition of a MIPS eligible professional, and whether CMS should consider establishing a low-volume threshold using more than one or a combination of factors or, alternatively, whether CMS should focus on establishing a low-volume threshold based on one factor. CMS also seeks comment on what activities could be classified as “clinical practice improvement activity” under MACRA.

As CMS notes in the proposed rule, low-volume thresholds are currently used in other CMS reporting programs. For example, EPs and acute care hospitals must meet certain Medicaid patient volume thresholds (in general, 30 percent for EPs and 10 percent for acute care hospitals) to be eligible for the Medicaid EHR Incentive Program. **Our societies agree that CMS should consider excluding professionals that do not have at least 10 percent of their patient volume derived from Medicare Part B encounters from participating in the MIPS.**

“Clinical practice improvement activities” is one of the performance categories used in determining the composite performance score under the MIPS. MACRA defines “clinical practice improvement activities” as activities that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the

Secretary determines, when effectively executed, are likely to result in improved outcomes. Further, MACRA provides that the clinical practice improvement activities under subcategories specified by the Secretary for a performance period of a year must include at least the following subcategories:

- (1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
- (2) Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.
- (3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.
- (4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.
- (5) Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.
- (6) Participation in an alternative payment model.

Our societies believe that the MIPS program allows CMS to reset and improve practice management issues and burdens related to Medicare quality reporting currently endured by our members. Implementing the MIPS program provides CMS with the opportunity to align practice and quality improvement initiatives in order to avoid duplicative requirements under MIPS and required initiatives in and outside of Medicare. However, our societies understand Congress has provided the parameters and examples of what constitutes a “clinical practice improvement activity.” Thus, we support the inclusion of participation in QCDRs in this category, as EPs will not only use QCDRs to meet the separate “Quality” performance in MIPS, but also members continue to see significant performance improvement across their practices and specialty overall simply by participating in these registries. One of the reasons for significant uptake in the use of registries in GI is that these registries are populated with well-accepted and scientifically sound quality metrics.

Our societies urge CMS to incorporate into these subcategories the EPs’ significant investment in time, cost, and educational activities to meet current board certification requirements. Our societies continue to voice our hope that these certifying organizations make changes to the current process, as many of our members believe this process is financially unfair, onerous, and burdensome. However, there will still be board certification and maintenance of certification requirements our members must undertake, even if these organizations recognize these problems and make changes to improve this process. Thus, these activities should be considered within the MACRA definition of the “clinical practice improvement activity.” Otherwise, our members would be required to undertake and report more clinical practice improvement activities as defined by MACRA as well as clinical practice improvement activities as defined by other board certification organizations, and others, which would result in less time spent with patients.

CONCLUSION

The ACG, AGA, and ASGE appreciate the opportunity to provide comments on the 2016 physician fee schedule proposed rule. If we may provide any additional information, please contact Brad Conway, Vice President of Public Policy, ACG, at 301-263-9000 or bconway@gi.org; Joshua Keepes, Director of Regulatory Affairs, AGA, at 240-482-3223 or jkeepes@gastro.org; or Camille Bonta, consultant to ASGE, at 202-320-3658 or cbonta@summitthehealthconsulting.com.

Sincerely,



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Attachments

- Attachment A: GI RUC recommendations with movement of moderate sedation
- Attachment B: RUC detailed description of pre-service time packages
- Attachment C: AMA RUC Summary of Recommendations for 45378
- Attachment D: Colonoscopy family with time adjustments for 2005 base revaluation and moderate Sedation