



3300 Woodcreek Drive
Downers Grove, Illinois 60515
630-573-0600 / 630-963-8607 (fax)
Email: info@asge.org
Web site: www.asge.org

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August 21, 2017

Ms. Seema Verma
Administrator

Centers for Medicare and Medicaid Services
Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program: CY 2018 Updates to the Quality Payment Program (CMS-5522-P)

Dear Administrator Verma:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to respond to proposed policy changes to the Quality Payment Program (QPP) for the 2018 performance year as published in the *Federal Register* on June 30, 2017.

The ASGE was founded in 1941 and since that time has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with more than 14,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

ASGE is committed to successful implementation of the QPP in such a manner that it creates value to patients and the Medicare program without creating undue burden on physicians and other clinicians. ASGE has demonstrated its commitment to helping its members successfully participate under Medicare's new physician payment system by offering educational materials and programing and by creating measures and activities that are relevant to the practice of gastroenterology and advocating for their adoption by Medicare. ASGE commends the Centers for Medicare and Medicaid Services (CMS) for taking a measured approach to implementing the QPP. We ask, however, that our concerns regarding the availability of meaningful measures and the reliability of those measures and their benchmarks, as well as the outsized investment that is required of physicians to participate in MIPS and APMs, not be overlooked in the comments that follow.

Because the Advanced APM avenue for participation in the QPP is unlikely to be a viable option for the vast majority of ASGE members, our comments on this proposed rule center on proposed policies for clinician participation in the MIPS, although we have also taken the opportunity in this letter to share our views on virtual groups and the development of Physician Focused Payment Models (PFPMs) and the Physician-Focused Payment Model Technical Advisory Committee (PTAC) process.

ASGE serves as a first-line resource for its members about QPP participation. We believe physician education could be enhanced if the Agency created a QPP “help line” designated solely for professional society staff. This designated help line could also serve to support QCDR vendors, as QCDRs may be under the administration of staff indirectly associated with a professional society or representing a stand-alone clinical registry. As entities supporting reporting for eligible clinicians, QCDRs often need answers quickly to build and enhance systems as program requirements change and for the education they deliver to a broad swath of eligible clinicians. By providing specialized support to medical society staff and QCDR vendors, this may reduce the burden on the QPP Help Desk.

MERIT-BASED INCENTIVE PAYMENT SYSTEM

ASGE appreciates that CMS proposes to continue a number of transitional policies for eligible clinicians who choose the MIPS pathway in 2018 under the QPP. When physicians participate in quality improvement activities, patients benefit and the potential exists for cost savings to accrue to the health care system. However, to realize these positive outgrowths, physicians must be first given the opportunity to succeed within the new MIPS and APM payment structures. The proposed policies for year two of the QPP provide considerable opportunity for physicians, particularly those physicians in small group practices, to avoid a negative payment adjustment and potentially earn a positive adjustment. We caution, however, that physicians remain overwhelmed with the QPP requirements and navigating the increasingly complex MIPS scoring structure. This frustration exists despite the laudable undertaking by CMS to create helpful MIPS and APM participation resources and tools and to make them available on the user-friendly QPP website.

For the second transition year of MIPS, CMS has proposed a performance threshold of 15 points. ASGE supports maintaining a low performance threshold for eligible clinicians to avoid a downward payment adjustment in the 2020 payment year. We support maintaining the bonus structures put in place for the 2017 performance year and appreciate the new proposed opportunities for bonus points, including for small practices and clinicians caring for complex patients. However, we are concerned that a complex bonus structure in lieu of maintaining a lower performance threshold disadvantages the very clinicians that we believe CMS is attempting to help. Solo practitioners and clinicians in small group practices have the fewest resources to understand how to piece together achievement, bonus and improvement points to potentially earn an incentive payment, let alone avoid a downward adjustment. **ASGE requests that CMS finalize a lower performance threshold (e.g., 6 points) for the 2018 performance period.** As ASGE has previously commented, it is critical that eligible clinicians view the MIPS requirements as achievable in order for MIPS to succeed. Toward that end, we support minimal changes to the MIPS requirements for the 2018 performance year and encourage further examination, in consultation with the physician community, about how to better streamline the MIPS performance categories and to simplify the scoring structure in such a manner that it still affords some level of flexibility for participation. We acknowledge that this is not an easy undertaking. ASGE is committed to working with CMS to make successful participation attainable for the

majority of clinicians, while, at the same time, achieving the goal of better value to patients and to the Medicare program.

ASGE is pleased to respond to CMS' request for public comment on a number of its proposed MIPS policies. Our comments are not an exhaustive critique of the entire rule; rather, we offer comments on specific components that have a significant effect on program participation, with a view to the practice of gastroenterology.

Quality Performance Category

Submission Criteria — **ASGE supports CMS' proposal to maintain current submission criteria for the 2018 performance period, including maintaining the number of required measures at six, including one outcome measure, or a high-priority measure if an outcome measure is not available.** However, ASGE is disappointed that CMS has not proposed a Colorectal Cancer Screening and Surveillance measure subset for the 2018 performance period as requested by our society in a February 2017 letter to CMS.

Tremendous strides have been made in improving colorectal cancer screening rates in the United States. According to the American Cancer Society, the significant decline (more than 30 percent) in colorectal cancer incidence rates over the past decade are largely attributable to the detection and removal of precancerous polyps as a result of increased colorectal cancer screening. Yet, colorectal cancer is still the fourth most common cancer and second leading cause of cancer-related deaths in the United States. Colonoscopy is a unique preventive service that allows for the detection of colorectal cancer and the removal of precancerous polyps during the screening procedure, thereby preventing cancer.

The establishment of a Colorectal Cancer Screening and Surveillance measures subset would ensure that gastrointestinal endoscopists who focus largely on colorectal cancer prevention are held accountable to measures that will have a meaningful effect on patient outcomes relative to colorectal cancer. A Colorectal Cancer Screening and Surveillance measure subset will support gastroenterologists in going beyond just reporting performance measures in favor of reacting to their actual performance data relative to measure performance targets addressing a specific disease. Further, this measure subset would benefit patients making important health care decisions relative to colorectal cancer screening by assisting them in selecting physicians that provide high-quality clinical services related to colorectal cancer screening and surveillance on the Medicare Physician Compare website. **ASGE respectfully requests that CMS reconsider its request for a Colorectal Cancer Screening and Surveillance measure subset.**

We also support CMS' proposal to not require a cross-cutting measure in year two, a policy which we believe should be carried into future performance years for reasons previously expressed by ASGE. A cross-cutting measure requirement poses significant operational and financial challenges for Qualified Clinical Data Registries (QCDRs). A specialized registry collects data addressing specific aspects of care; it is not a complete electronic health record (EHR) system. This is important because there will be

patients eligible for the denominator of cross-cutting measures, but the data would not necessarily be captured in the registry if it is outside the scope of the condition or procedure. Furthermore, the proposed MIPS measure numerators and denominators are based on encounter codes, but many QCDRs are not able to collect these codes and use clinical data fields or use a combination of encounter codes and other clinical data fields to create more meaningful measures. Due to the time and resources that would need to be diverted to create the capacity of a QCDR to collect data for a cross-cutting measure, we are concerned that registries would go through the expense only to have the cross-cutting measure classified as topped-out and either removed from the program or assigned less than the optimal points for quality measures. It is important the requirements that CMS imposes on registries and EHR vendors serve to advance quality improvement, rather than divert resources toward requirements that have little value to providers or patients. We ask that CMS consider these concerns before it imposes a requirement of a cross-cutting measure for future performance years.

We understand that CMS is newly proposing to allow individual eligible clinicians and groups to submit measures and activities via as many mechanisms as necessary to meet the requirements of the quality, improvement activities, or advancing care information performance categories. The intent of this proposal to provide greater flexibility in reporting is laudable; however, we have some concerns with its implementation at this time when MIPS is still in its nascent stage. For example, how this proposal would interact with the current Eligible Measure Applicability (EMA) analysis, particularly since measure groupings for the EMA analysis are not aligned across the claims and registry submission mechanisms. **While this proposal aims to provide clinicians with greater flexibility in reporting, we are concerned it may ultimately add complexity and result in confusion as clinicians are still gaining an understanding of MIPS. Further, CMS continues to work through issues related to data analysis. Until existing identified issues are resolved, further complexity should not be added. ASGE may be able to support this proposal in a future year when CMS and clinicians have gained more experience with MIPS.**

Data Completeness Criteria — ASGE appreciates that CMS is proposing it maintain a 50 percent data completeness threshold for all measure submission mechanisms for the 2018 performance year. As CMS considers increasing the reporting threshold in subsequent years, we suggest that it may require consideration of varying data completeness thresholds based on measure submission mechanism.

Individual eligible clinicians who use GIQuIC, the QCDR founded by ASGE and the American College of Gastroenterology (ACG), for example, may be unable to meet a threshold higher than 50 percent if half of their services are provided at an ambulatory surgery center using GIQuIC and the other 50 percent at a hospital not using GIQuIC. Gastroenterologists provide services at multiple sites of service which use varying systems to capture patient data. A gastroenterologist may provide screening colonoscopy services at an ambulatory surgery center that participates in the GIQuIC registry, transferring data from an endoscopic report writer to the registry, and a broader range of services, including diagnostic colonoscopies or advanced procedures, at a hospital that is not currently

registered with GIQuIC — perhaps in part because the hospital’s EHR has not pursued certification with the GIQuIC registry.

ASGE does, however, have concerns with CMS’ proposal to award one point for measures that fall below the data completeness threshold. **While we support the continuation of current policy of a three-point floor for small practices, we believe the three-point floor should apply to all MIPS participants. CMS should only consider finalizing a one-point floor if it finalizes a performance threshold lower than 15 points.**

ASGE also asks CMS to reconsider its proposal to establish the quality measure performance period as a full calendar year. A 90-day performance period may not allow for performance to be reliably assessed. A six- or nine-month reporting period would allow for measures with larger denominators, at the same time allowing clinicians more time to evaluate available submission mechanisms. Clinicians are still adapting to quality measure reporting, and some may still have significant limitations on the availability of meaningful measures. Requiring clinicians to expand their reporting requirements in volume on measures that do not impact clinical care or seem peripheral to their specialty is a disincentive to participate in or contribute to the MIPS program—this just becomes extra work with no quality gain.

Topped-Out Measures — Consistent with ASGE’s past comments to CMS, we are pleased that CMS has proposed a three-year timeline for topped-out measures. However, ASGE disagrees with CMS’ proposal that topped-out measures should be assigned a lower point value (6 points rather than the full 10 points). By assigning lower points to topped-out measures, disincentives to report those measures are created. This may be CMS’ intent, and, if so, we ask CMS to consider the unintended consequences of creating disincentives to reporting “topped-out” measures, specifically skewing the analysis of whether the measure is truly topped out as fewer clinicians report the measure. **ASGE supports a three-year timeline for topped-out measures but opposes a reduction of the point value for topped-out measures during the topped-out lifecycle.**

While we have concerns with the special scoring for topped-out measures, **ASGE does support CMS’ proposal to restart the three-year lifecycle if a measure is not topped out for two consecutive years.**

We also support CMS’ proposal to consider whether a measure is topped out on a measure submission mechanism basis. This proposed policy is appropriate considering data is subject to greater or lesser refinement by reporting mechanism (e.g., risk stratification) and CMS analyzes data by mechanism. An example of a gastroenterology-specific measure where we see distinctly different performance by reporting mechanism is Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (measure #320 and measure GIQIC 6), which has been harmonized for the 2017 performance period. The chart below is derived from CMS’ MIPS Benchmark Results document. It shows #320 based on claims, then #320 based on registry, and then GIQuIC 6 from the GIQuIC QCDR. This shows with a large volume of validated data that this

measure continues to have performance variability and is not topped out, whereas, it is topped out via the other reporting mechanisms.

Mechanism	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10
Claims	90.00 - 95.44	95.45 - 99.99	--	--	--	--	--	100
Registry	81.82 - 90.69	90.70 - 95.44	95.45 - 98.11	98.12 - 99.99	--	--	--	100
GIQuIC QCDR	82.14 - 87.00	87.01 - 89.65	89.66 - 91.83	91.84 - 93.74	93.75 - 95.09	95.10 - 96.59	96.60 - 98.20	>= 98.21

ASGE previously called on CMS to consult with measure stewards and registry administrators to consider public comment before a topped-out measure is removed from the program. We appreciate that the proposed topped-out measure lifecycle stipulates that before a topped-out measure could be removed it would first go through a process of comment and rulemaking.

The Health Resources and Services Administration describes quality improvement as systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups. We recognize that maintaining topped-out measures in the MIPS may not necessarily lead to further measurable improvement. However, because CMS considers a measure to be topped out does not mean it is no longer a valuable metric. We suggest that measures of value and clinical significance, for example photodocumentation of colonoscopy landmarks and cecal intubation rates, should always be measured, regardless of whether they become “topped out” as they would remain measures of quality. If the measure has strong clinical importance, removing the measure will discourage those who are still low performers on the measure from improving their performance. Because of the uncertainty that surrounds CMS’ acceptance of new measures, including QCDR measures, ASGE is concerned that the removal of topped-out measures, as well as the removal of outcome measures that cannot be reliably scored against a benchmark for three years, will leave QCDRs with insufficient measures of clinical pertinence or require users to focus on measures of questionable value that will quickly “top out.”

ASGE suggests CMS consider the following factors when determining whether to remove a topped-out measure:

- the availability of other reportable measures within the specialty;
- the ability of specialists to report if the measure was removed;
- the availability of cross-cutting measures that would be meaningful to report by those specialists; and,
- the ability to capture cross-cutting measures in certain settings.

Quality Measure Benchmarks — As CMS has acknowledged, increasing the low-volume threshold could have an impact on MIPS benchmarks because a greater number of clinicians would be exempt from the MIPS. We suspect clinicians submitting data with small denominators are compromising the validity of the benchmarks. Regarding whether CMS should broaden the criteria for creating MIPS benchmarks to include other data, CMS could look at QCDR data in aggregate (i.e., MIPS reporters and non-reporters) to assess the reliability of benchmarks based on MIPS reporters only.

As ASGE has recently communicated to CMS, the decile breakdowns for the adenoma detection rate (ADR) measure #343 are inconsistent with current evidence and incongruent with current practice. ASGE-recommended performance targets for identification of one or more adenomas is 25 percent (men and women combined age \geq 50 years undergoing screening colonoscopy). The recommended performance targets for ADR were recently increased after observations suggested that raising the ADR target above 20 percent for a male/female population might have benefit.¹ The tables below show the CMS-derived 2017 Quality Measure Benchmarks for the ADR measure #343 and the ADR measure reported to GIQuIC. The decile ranges for the GIQuIC measure is what we would expect, which raises significant concern regarding the validity of the decile ranges for measure #343. It is possible that this represents a selected group of patients reported, or statistical performance being skewed by not taking into account sensitivity in assessment of the measure data.

Screening Colonoscopy Adenoma Detection Rate (#343)

Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10
29.63 - 38.09	38.10 - 41.85	41.86 - 45.70	45.71 - 48.69	48.70 - 56.51	56.52 - 63.40	63.41 - 80.32	\geq 80.33

Adenoma Detection Rate (GIQuIC #1)

Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10
28.99 - 32.18	32.19 - 35.75	35.76 - 38.80	38.81 - 41.92	41.93 - 45.74	45.75 - 49.29	49.30 - 54.69	\geq 54.70

In an effort to help CMS achieve its goal of better measure harmonization, the ADR measure in GIQuIC will be recognized as measure #343 for the 2017 MIPS performance year. In light of this new harmonization and because of the significant discrepancy in the decile ranges

¹ Quality Indicators for Colonoscopy. Volume 81, No. 1 : 2015 Gastrointestinal Endoscopy. www.giejournal.org

for measures #343 and GIQuIC #1, we are very concerned that clinicians reporting measure #343 through GIQuIC will be disadvantaged when data from GIQuIC participants are combined with clinicians who are reporting #343 through another registry or QCDR. For this reason, we recommend that CMS reconsider its policy of combining registry and QCDR data for the purpose of establishing performance benchmarks. **CMS should continue to stratify benchmarks by reporting mechanism but further delineate benchmarks by the registry and QCDR mechanisms.** Stratifying registry and QCDR data will help to improve the validity of the benchmarks. QCDR participants submitting a large volume of their cases should not be benchmarked against registry reporters who may only report a subset of their cases to meet data completeness requirements and which may be selected for high performance. CMS may also wish to stratify benchmarks by reporting QCDR since there is variability among QCDRs in data collection and refinement.

CMS is interested in whether benchmarks should be further stratified by practice size, practice mix, or site of service. Socioeconomic determinants can impact issues related to high-quality colonoscopy; however, we believe that stratification based upon practice size or site of service may otherwise defeat the purpose of increasing quality around these benchmarks. High-quality practice should not be predicated upon these factors. One of the core principles behind ASGE's Endoscopy Unit Recognition Program (EURP) is that a patient should receive a high-quality, safe colonoscopy regardless of site of service or the provider. Therefore, **ASGE does not favor further benchmark stratification by practice size or site of service.**

When developing quality measure benchmarks, ASGE strongly recommends that CMS undertake a thorough review of a measure's clinical recommendation statement in relation to that measure's decile ranges and consult with the measure steward. Had these two actions taken place prior to publication of the ADR measure benchmark, CMS could have avoided the skepticism of benchmark validity that is now being expressed by gastroenterologists who may ultimately avoid reporting this otherwise important colonoscopy quality indicator.

Quality Scoring — **ASGE supports CMS' proposal to again assign a three-point floor for each measure that is submitted but does not meet the required case minimum or does not have a benchmark for the 2020 MIPS payment year.** We believe this three-point floor is an important incentive to clinicians for reporting new measures. In fact, we suggest the point floor should be higher than three for measures that lack a benchmark. Greater incentives should lead to a greater number of clinicians reporting the measure, which, in turn, will result in more reliable benchmarks.

As stated above, **ASGE opposes an achievement point cap on topped-out measures.** Alternatively, CMS could award full points to topped-out measures during the proposed three-year life cycle and eliminate bonus points for topped-out measures that are also outcome or high-priority measures.

As also expressed above, we have significant concerns with how the measure validation process will occur when quality performance criteria are not met under CMS' proposal to allow clinicians to report quality measures using multiple submission mechanisms.

ASGE supports the use of certified EHR technology (CEHRT) to support quality performance submissions. However, we do not believe that bonus points should be restricted to end-to-end electronic reporting as finalized by CMS for the 2017 performance year. For example, GIQuIC and its sponsoring societies ASGE and ACG were informed by CMS and the Office of the National Coordinator that its registry participants are not meeting the definition of end-to-end electronic reporting because the registry allows for participants to edit data after it is uploaded from the EHR to the registry. For example, a case was electronically uploaded into the registry, but pathology results came in later thereby necessitating an update. While this is not a frequent occurrence, it demonstrates the unnecessarily restrictive nature of the end-to-end reporting definition.

Scoring Improvement — ASGE appreciates the considerable thought that CMS gave to its proposals for scoring quality improvement. In particular, we appreciate that CMS' proposals make a number of accommodations for allowing a clinician to earn an improvement score, including for clinicians who submit quality performance data using a different identifier from one year to the next, and for clinicians who did not fully participate in the Quality category during the 2017 performance year. However, we suggest that CMS' proposal to score improvement beginning with the 2020 payment year is premature given concerns with benchmark validity. Because improvement scoring relies on performance from one year to the next, we believe the basis of the improvement scores must be reliable. **Therefore, ASGE recommends that CMS postpone its proposal to score quality improvement. When CMS does proceed with improvement scoring, ASGE supports improvement at the category level rather than by individual measures for the reasons well-articulated in the proposed rule, including year-to-year variation in the selection by individuals and groups of measures for submission.**

At this time, we believe that it is paramount to continue to afford clinicians maximum flexibility to choose quality measures. Assessing improvement at the category level will allow this flexibility to prevail. Finally, while the proposed methodology for calculating improvement would create greater incentive to clinicians with lower scores to improve, we suggest that awarding points based on the rate of performance diminishes the value of improvement for those with higher scores. Therefore, ASGE is inclined toward the alternative band methodology that would recognize clinicians with high performance who show modest improvement. We do not believe the improvement scoring methodology should be skewed to mainly benefit lower performers. For example, the most important outcome measure for ASGE's members is ADR. Increased ADR directly correlates with lower rates of colorectal cancer. A 2014 study of 223,842 patients found a 3 percent reduction in colorectal cancer incidence and a 5 percent reduction in cancer mortality for each 1 percent increase in ADR.²

²Quality Indicators for Colonoscopy. Volume 81, No. 1 : 2015 Gastrointestinal Endoscopy. www.giejournal.org

This demonstrates that even modest improvements in ADR for a high performer garners significant results at the population health level. We therefore request that CMS consider the band methodology for assessing improvement rather than rates of improvement.

Improvement Activities Performance Category

It is important that clinicians earn credit for participating in improvement activities that are meaningful to their practice. Toward this end, ASGE is grateful CMS has recognized for the 2017 performance year two of its quality and safety improvement programs as qualified improvement activities under the category of Patient Safety & Practice Assessment.

First, ASGE's Endoscopy Unit Recognition Program (EURP) will be incorporated into the existing *"Implementation of formal quality improvement methods, practice changes or other practice improvement processes"* activity. Second, ASGE's Skills Training Assessment Reinforcement (STAR) Certificate Programs will be incorporated into the existing *"Participate in IHI Training/Forum Event; National Academy of Medicine, AHRQ Team STEPPS(R) or other similar activity"* activity. ASGE was also pleased to recently learn that these activities are being proposed for inclusion in the MIPS improvement activities inventory as new improvement activities or incorporated into existing improvement activities contingent upon finalization of the QPP rule for the 2018 performance period.

Data Submission Criteria — ASGE supports CMS' proposal to extend current data submission requirements to the 2018 performance year and into future years. We further appreciate the opportunity to comment on modifications that CMS is considering for future program years, including whether CMS should establish a minimum threshold (for example 50 percent) of clinicians (NPIs) comprising a TIN who must complete an improvement activity for the TIN to receive credit for the activity and whether a minimum threshold should vary by practice size. **ASGE seeks clarification from CMS in the final rule whether the Agency is considering that 50 percent of NPIs in a TIN would need to complete the same improvement activity or 50 percent of NPIs could complete the same or different activities.** For a homogenous practice group, it may be reasonable to expect that a majority of clinicians in the practice would participate in the same improvement activities. However, accommodations must be made for multi-specialty practices, practices with multiple locations or practices whose members may focus their time on a distinctive cross section of services (e.g., procedural for complex patients) or in distinctive sites of service (e.g., gastroenterologist hospitalists) where the improvement activity needs may differ by specialty or site and for which a 50 percent threshold for a singular improvement activity may not be a reasonable expectation.

CMS is proposing for the 2020 payment year and future years that for a group practice to receive full credit as a certified patient-centered medical home (PCMH) or a comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a PCMH or comparable specialty practice. We would urge that it is premature to set a specific threshold for medical home certification within a specific TIN, but CMS

could consider a bonus structure to recognize successful efforts for a specific TIN to more broadly develop medical home practices.

CMS is further considering for future years establishing a threshold for the number of NPIs within the TIN who must be recognized as a certified PCMH or comparable specialty practice to receive full credit in the Improvement Activities performance category. It is unclear in this proposed rule how CMS would set a threshold for the NPIs in a TIN that would need to be recognized as a certified PCMH or comparable specialty practice since, according to the National Committee for Quality Assurance in reference to its PCMH recognition program, recognition is earned at the practice level.

Scoring — In this proposed rule CMS notes it intends in future years to score the Improvement Activities performance category based on performance and improvement, rather than continue with simple attestation. We appreciate that CMS is seeking comment on how it could measure performance and improvement in this category without imposing additional burden on eligible clinicians. However, by design there are numerous improvement opportunities to accommodate the broad and diverse spectrum of medical practices. **ASGE encourages CMS to continue to score the Improvement Activities category based on simple attestation for the near future as this category remains relatively new and requires further maturation.**

For the 2017 performance year, CMS finalized that eligible clinicians participating in an APM that is not a MIPS APM would be awarded half credit under the Improvement Activities category. While we would have preferred that clinicians participating in any other APM receive full credit, we ask that CMS, at a minimum, retain its 2017 policy for the 2018 performance year. Based upon our reading of this proposed rule, it does not appear that this policy has been extended for the 2018 performance year.

Advancing Care Information Performance Category

ASGE thanks CMS for its proposal to allow eligible clinicians and groups to participate in the Advancing Care Information (ACI) category using EHR technology certified to 2014 or 2015 editions, or a combination thereof. It is, perhaps, one of the most consequential proposals related to the ACI category in this proposed rule. While ASGE appreciates the proposed bonus structure for eligible clinicians who report the ACI objectives and measures in 2018 using only EHR technology certified to the 2015 edition, we refer CMS to our introductory comments regarding supporting clinicians through a complex bonus structure versus a lower performance threshold during the second transition year of MIPS. ASGE also appreciates that CMS is maintaining, as previously finalized, its policy to accept a minimum of 90 consecutive days of data in 2018 and is proposing to carry that policy forward to the 2019 performance year.

Base and Performance Score Weighting — CMS proposes to continue its policy of having the overall ACI performance score comprised of a base score (50 points), and a performance score (90 points), as well as bonus points. Eligible clinicians who successfully submit a numerator and denominator or yes/no statement for each measure of each objective would

earn a base score of 50 points. Failure to meet the submission criteria (numerator/denominator or yes/no statement, as applicable) and measure specifications for any base measure in any of the objectives would result in an ACI performance category score of zero. Because of the emphasis CMS is placing on the required base score measures through its “all or nothing” scoring approach, **CMS should re-weight the base and performance measures (e.g., base score = 75 points / performance score = 25 points) to encourage proficiency in the base measures and to account for the lack of control that physicians have over the patient-dependent performance measures.** Ultimately, clinicians should be allowed to engage with technology in ways that most benefit their patients and should not be disadvantaged by not collecting data on measures that irrelevant or burdensome to their practice.

For example, ASGE hears from its members that there is pressure to enroll patients in online portals, which requires substantial work on behalf of practice staff, yet many patients don't really intend to use the portal and, in fact, don't. Even after confirmation that this is the patient-preferred method of communication, information may not be retrieved. As a result, physicians may send their patient messages through the portal, including laboratory results, without ever really ever knowing if the patient is retrieving such information. As another example, physicians are incentivized to send and receive clinical summaries from other providers, but very few have this connectivity. Physicians have virtually no experience about how to import, review, or accept from these clinical summaries what is pertinent and reject what is redundant or not pertinent thus increasing liability without improving clinical care. At best, the Health Information Exchange objective is creating for physicians much more hassle than benefit.

ACI Performance Category Weighting — The law gives CMS the authority to reduce the percent weight of the ACI category (but not below 15 percent) in any year in which it is estimated that the proportion of eligible professionals who are meaningful EHR users is 75 percent or greater. In the 2017 QPP final rule, CMS finalized a policy of determining a meaningful user as MIPS eligible clinicians who earn an ACI performance score of at least 75 percent for a performance period. ASGE's response to CMS' proposal to use data from the 2017 performance period to estimate the proportion of physicians who are meaningful users for purposes of re-weighting the ACI category for the 2021 payment year is that re-weighting shouldn't occur just because clinicians adapt to reporting on a set of objectives and measures. EHR technology is evolving and it is our hope that its use and the measurement of such use will become more meaningful for clinicians over time, including interoperability and greater alignment with other MIPS performance categories. **We ask that CMS refrain from any re-weighting of the ACI category at this time.** If it becomes appropriate to re-weight the ACI category, we support using data from the performance period that occurs four years before the MIPS payment year and support re-weighting in such a manner that it is spread proportionately across the other performance categories. If re-weighting occurs in 2021, any reduction in the ACI weight should be transferred to the Quality category because in 2021 Quality will be the category with which clinicians will have the most experience and which translates directly into improved patient care.

Public Health and Clinical Data Registry Reporting Objective — ASGE supports the proposed flexibility for clinicians who may practice in areas of the country where immunization registries are not available. As proposed, if a MIPS eligible clinician fulfills the Immunization Registry Reporting Measure then a full 10 percentage points would be awarded toward the performance score. As proposed, a clinician would have an opportunity to earn 10 points if he/she reports two (five points each) other measures under the objective if an immunization registry is not available. **However, to allow clinicians to report measures most meaningful to their practice, ASGE recommends that CMS modify its proposal to allow a clinician to earn 10 points for any measure reported under this objective regardless of whether an immunization registry is available.** Alternatively, CMS could award 10 points to any measure reported under this objective if a clinician can demonstrate that he/she practices in an area where an immunization registry is not available.

Bonus Points for Improvement Activities — ASGE supports the identification of additional improvement activities that would be eligible for the ACI performance category bonus score if they are completed using certified EHR technology and we encourage continued expansion in future performance years.

Hardship Exemptions — ASGE supports CMS' proposed additional hardship exemptions for the ACI performance category in 2018, including for those MIPS eligible clinicians who are in practices of 15 or fewer clinicians and solo practitioners. ASGE requests in the final rule that CMS specify what would constitute an “overwhelming barrier” to complying with the ACI performance category requirements for a solo or small group practice to be granted an exemption. ASGE also supports adding place of service code (19) to the existing definition of a hospital-based MIPS eligible clinician.

Ambulatory Surgery Center-Based Eligible Clinicians — The 21st Century Cures Act prohibits in 2017 and 2018 an EHR meaningful use payment penalty to an eligible professional (EP) who furnishes “substantially all” of his/her covered professional services in an ambulatory surgery center (ASC). In this rule, CMS is proposing to define an ASC-based MIPS eligible clinician as one who furnishes 75 percent or more of his/her covered professional services in sites identified by POS 24. We are aware that CMS has finalized its proposed definition of an ASC-based MIPS eligible clinician in the Fiscal Year (FY) 2018 Hospital Inpatient Prospective Payment System (IPPS) final rule and that it is basing the determination of “substantially all” on the standing definition of hospital-based eligible professional.

We respectfully remind CMS that as early as March 2010, in response to CMS' proposed rule for the EHR Incentive Programs, ASGE commented that because an ASC is not an entity eligible to receive an EHR incentive payment, procedures performed in the ASC should be exempt when determining whether an eligible clinician has met the 50 percent or more patient encounter threshold for determining whether the eligible clinician is a meaningful EHR user. To be a meaningful user an eligible clinician must have 50 percent or more of his/her patient encounters during the EHR reporting period at a location(s) equipped with certified EHR technology.

Eligible clinicians who provide the majority of their professional time and services at ASCs are disadvantaged under the current EHR Incentive Programs and the vast number of eligible clinicians who practice in the ASC will not be helped if CMS considers “substantially all” to be 75 percent.

In the FY 2018 Hospital IPPS final rule, CMS states that the policy set forth in the 21st Century Cures Act will “result in a reduction of burden for ASC-based eligible providers who have little control over the EHR decisions in the practice.” While we do not disagree, societies, including the ASGE, advocated for this policy because the EHR Incentive Program includes certified EHR technology for the hospital- and office-based physician, for which the criteria are not easily transferrable to the clinician who practices in the ASC.

CMS also states in the final Hospital IPPS rule that it does not believe that an eligible clinician who furnishes only slightly more than half of his or her covered professional services in an ASC setting is furnishing substantially all of such services in that setting. We again request that CMS examine how many eligible clinicians would benefit from the policy if the “substantially all” threshold was set at 65 or 70 percent. This policy is not intended to continue in perpetuity, but rather until certified EHR technology applicable to the ambulatory surgical center setting is available. **For the above reasons, we ask to CMS examine whether a greater number of eligible clinicians who practice in the ASC would benefit from the policy if the threshold was set below 75 percent (e.g., 60-70 percent).**

Lastly, we agree with CMS’ policy to calculate an ACI performance score for any MIPS eligible clinician who reports on the ACI measures even if that clinician qualifies for an ACI hardship exemption of exclusion. Allowing all MIPS eligible clinicians to report and be scored on the ACI performance category is consistent with affording clinicians participation flexibility.

Cost Performance Category

Cost Category Weighting — ASGE strongly supports CMS’ proposal to weight the cost category at zero for the 2020 payment year rather than at 10 percent as previously finalized. We acknowledge the statute requires that the Cost category be weighted at 30 percent by the 2021 — a timeline that ASGE believes remains too aggressive given that development of episode groups, which have the potential to more accurately measure cost, are still underway. In this proposed rule, CMS states that maintaining a Cost category weight of zero for the 2020 payment year could lead to a lack of understanding by clinicians of the Cost measures when the category weighting is set at 30 percent in 2021. We agree it is important for clinicians to understand the measures on which their cost will be measured. However, current measures do not provide an accurate evaluation of resource use and after episode groups are developed, a testing period of those measures will be required which would also create a transitional period during which clinicians could become more proficient in the measures upon which they will be scored. For these reasons, **we urge CMS to finalize a weight of zero for the Cost category for the 2020 payment**

year and until such time that cost measures coupled with appropriate severity adjustment methods that have been thoroughly vetted and tested are incorporated into the program.

Episode Group Measure Development — ASGE appreciates CMS' demonstrated commitment to ensuring the input of physicians in the development of episode groups that are specific to their specialty through Acumen's convening of a Clinical Committee to develop care episode and patient condition groups, and subsequently through the creation of specialty clinical subcommittees. ASGE is pleased to have six physician nominees appointed to the Gastrointestinal Disease Management Subcommittee, including one who has been appointed as chair of the Subcommittee. We are encouraged by the progress that is being made on the development of a Screening and Surveillance Colonoscopy episode group. As ASGE has commented previously, the process for using episode groups for cost measurement should include: 1) public comment on revised episode groups, resulting from the Acumen work; 2) collection of data on a trial set of episode groups resulting from the Acumen process and reflective of public comment; 3) evaluation and refinement of the trial set of episode groups by relevant clinical subcommittees; and 4) notice and public comment on proposed episode groups prior to finalizing for use in the MIPS. Collection of data on a trial set of episode groups should take place through the creation of a pilot program for the 2019-2021 performance years during which the use of patient relationship categories to attribute costs within the episodes could also be selectively pilot tested. For clinicians who volunteer to test new episodes of care measures, a cost score would be calculated on care episodes but measures undergoing testing would be assigned a minimum achievement point floor (e.g., five points).

Improvement Scoring — CMS states in this proposed rule that the total available cost improvement score would be limited at first (i.e., 2021) because only two cost measures would be included (total per capita cost and Medicare spending per beneficiary [MSPB]) and that more opportunities for improvement scoring would be available in the future as additional cost measures, including episode-based measures, are added in future rulemaking.

ASGE continues to hold the position that it is inappropriate to use broad measures such as total per capita costs and MSPB to evaluate the resource use of individual physicians. Despite the lack of confidence that medical societies have in the MSPB and total per capita cost measures, as well as their reliability, CMS continues to consider these measures appropriate for assessing resource use. Medical societies, like ASGE, and their member volunteers are investing considerable time in the development of episode groups for measuring costs. Therefore, we urge once again for CMS to abandon the MSPB and total per capita cost measures at this time. Secondly, we also question a reliability threshold of 0.4. In most disciplines, a 0.4 percent reliability standard would be viewed as unacceptable, and many in the health care field believe that a standard of at least 0.8 should be required. At a minimum, CMS should focus on improving the reliability of these measures.

For the above reasons, CMS should not consider cost measure improvement scoring until sufficient data for such scoring is available for episode groups.

Virtual Groups

Effective the 2018 performance year, solo practitioners and groups with 10 or fewer eligible clinicians will be allowed to join together to participate in the MIPS as virtual groups. We appreciate this proposed rule begins to address many of the operational aspects of virtual groups.

ASGE supports that CMS is generally adopting group practice reporting requirements for the virtual groups, realizing that accommodations may need to be made on how group-related policies apply to virtual groups. For example, it is unclear how a virtual group would be expected to meet the ACI requirements. Would all taxpayer identification numbers that constitute the virtual group be required to have certified EHR technology?

Consistent with CMS' proposals to provide assistance to solo practitioners and clinicians in small practices, ASGE supports CMS' proposal that a virtual group would be identified as having small practice status if the virtual group does not have 16 or more members (NPIs). We understand CMS considered higher threshold requirements (e.g., at least 50 or 100 clinicians in a virtual group), but agree with CMS' position that limitations should not be placed on the size of virtual groups at this time and that virtual groups that are too substantial in size would make it difficult to compare performance among clinicians.

ASGE looks forward to further guidance from the Agency on the formation of virtual groups and MIPS participation requirements. CMS has proposed a virtual group election deadline of Dec. 1, 2017, which will provide little time for clinicians to become fully informed and organized following finalization of this rule. Furthermore, for a group to be eligible to join a virtual group, in addition to having a TIN size that does not exceed 10 eligible clinicians, it cannot be excluded from MIPS based on the low-volume threshold at the group level. Therefore, a group would need to know if it meets the new low-volume threshold (if finalized) before the December 1 election deadline. In light of this timing, we predict few clinicians and practices will form virtual groups in 2018 unless CMS creates a more accommodating election deadline for the inaugural year of the MIPS virtual group participation option. If 90-day reporting periods are incorporated into the 2018 Final Rule, an election deadline of mid 2018 should still allow for 2018 reporting by a newly formed virtual group.

MIPS ALTERNATIVE PAYMENT MODELS

ASGE has heard from its members that they remain confused about implications to their quality reporting for MIPS if they "participate" in an Accountable Care Organization (ACO). ACOs still fail to make distinctions between a physician being a participant in an ACO and being an auxiliary provider. We are aware that members of single-specialty groups submitted QCDR data through GIQuIC only to find out that their "participant" status in an ACO, which accounted for a very small percent of practice volume, led to CMS denying the data submission and requiring the physician's quality measures to be the ACO's measures.

In either case, ACOs should be required to ask a physician whether they intend to have ACO quality data submitted on their behalf or if they choose to submit their own NPI-specific or own group TIN's quality data for MIPS.

ALTERNATIVE PAYMENT MODELS

This year, ASGE watched with great interest PTAC deliberations on four PFPMs, including two relevant to the gastroenterology community: 1) The Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Cancer Screening, Diagnosis and Surveillance; and 2) Project Sonar. While an APM centered on colorectal cancer screening is of significant interest to ASGE, we were not involved in the creation of the colorectal cancer screening bundle as proposed by the Digestive Health Network nor did the bundle receive ASGE's endorsement. While ASGE is eager for the availability of APM options for gastroenterologists beyond ACOs, ASGE has concluded that the most effective route to the development of PFPMs is the creation of episodes of care through a multi-specialty and transparent process, such as that currently being led by Acumen. A well-constructed and thoroughly vetted episode of care for screening colonoscopy should serve as the backbone of any colorectal cancer screening PFPM considered by the PTAC and ultimately CMS. As mentioned earlier in this letter, the development of a screening colonoscopy episode group is currently underway through the Acumen-led process and involves the participation of physicians representing the three major gastroenterology societies (ASGE, the ACG, and the American Gastroenterological Association). **Considering the resources that CMS and medical societies are dedicating to the episode group development process, we suggest that CMS consider expanding the PFPM Payment Methodology criterion to include consideration of whether episodes of care defined in the PFPM have undergone thorough stakeholder vetting, including through the Acumen-led episode group development process.**

ASGE, like many other medical societies, are closely watching how CMS will respond to the three PFPMs that were recommended by the PTAC to the Secretary earlier this year. CMS has made clear that it is under no statutory obligation to test proposals that are recommended by the PTAC. Furthermore, CMS has not specified a timeline for the development process of PFPMs recommended by PTAC to the Secretary. We acknowledge that PFPMs may emerge from PTAC with varying levels of readiness for testing, making a one-size-fits all process and timeline difficult. However, we firmly believe the need exists for some level of process predictability for stakeholders that spend enormous time and resources to develop a PFPM and take it through the PTAC process. **CMS' deadline to respond to PTAC recommendations should not be indefinite. ASGE therefore recommends that CMS adopt a deadline (e.g., two months) for posting a detailed, official response to PTAC recommendations.**

Technical assistance to organizations that want to develop APMs is still lacking. **Because the PTAC is prohibited from providing this technical assistance, we ask CMS to consider options for providing technical assistance to PFPM submitters. An example**

across specialties and patient populations is the availability of actuarial claims data and abilities to perform analysis of such data.

With regard to the PFFM criterion, we suggest there needs to be some consistency in the interpretation and application of the criterion. The lack of consistency was most apparent as the first round of proposals moved from the Preliminary Review Team to the full committee, thus raising questions about the validity of the process and conclusions.

As ASGE has commented previously there needs to be a pathway to help MIPS APMs transition to Advanced APMs. Those involved in the development of MACRA did not contemplate two types of APMs — MIPS APMs and Advanced APMs. The appropriate role for MIPS APMs is as a transitional step to Advanced APMs, and we urge CMS to develop a vision of what that transition looks like.

Finally, the 2017 QPP final rule established that APMs would meet the MACRA standard for “more than nominal financial risk” if they risk losing 8 percent or more of their revenues, instead of tying risk of losses to total costs. This option is especially important for physician-led APMs because physician services are only a small proportion of total costs. ASGE supports that CMS has extended the nominal risk threshold of 8 percent through performance year 2020 and asks that this threshold be maintained, which creates stability and predictability for APMs. ASGE also supports that CMS has extended the 8 percent nominal risk threshold to the APM all-payer combination option.

CONCLUSION

ASGE appreciates the opportunity to provide comment on this proposed rule and looks forward to continued discussions with CMS on how to help physicians continue their transition to MIPS and APMs in 2018. Should you have questions or require additional information, please contact Lakitia Mayo, Senior Director of Health Policy, Quality and Practice Operations at lmayo@asge.org or (630) 570-5641.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Woods", with a stylized flourish extending to the right.

Karen L. Woods, MD, FASGE
President
American Society for Gastrointestinal Endoscopy