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Executive Director
BRADLEY C. STILLMAN

Re CMS-5517-P: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Acting Administrator Slavitt,

The American College of Gastroenterology (The College or ACG) appreciates the opportunity to offer comments to the proposed rule “Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models” as published in the *Federal Register* on May 9, 2016. The ACG is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, our organization currently includes over 13,000 members providing gastroenterology specialty care. We focus on the issues confronting the gastrointestinal specialist in delivering high quality patient care. The primary activities of the ACG have been, and continue to be, promoting evidence-based medicine and optimizing the quality of patient care.

Summary of ACG’s MIPS and APM Comments

Introduction: Helping independent GI practice successfully participate in MIPS and APMs

MIPS: Quality Performance Category

The College urges CMS to revise proposed changes to the Quality component, including:

- Eliminating the cross-cutting measures requirement
- Awarding a bonus point for electronically submitting data to a QCDR
- Reducing the reporting threshold from 90% to 50%
- Reinstating the “Photo documentation of Cecal Intubation” measure

MIPS: Advancing Care Information Performance Category

The College urges CMS to make the following changes to the Advancing Care Information component, including:

- The College supports CMS' goal of reducing reporting burdens:
 - Finalizing CMS' proposal to reduce the number of the measures from the Electronic Health Record Incentive Program by removing the computerized provider order entry (CPOE) and Clinical Decision Support (CDS) measures.
 - Finalizing CMS' proposal to allow reporting at the group practice level
 - Using a 90 day reporting period
- Reiterating that the College's members should not have to rely on others to meet certain Advancing Care Information objectives
- Providing more credit to participating in a quality clinical data registry (QCDR) or other quality improvement registry

MIPS: Resource Use Performance Category

The College urges CMS to make the following changes to the Resource Use component, including:

- Delaying the episode of care measures until there is a 2 year temporary trial and review period
- Excluding Medicare Part D drug costs for attribution: ACG Members have little to no control over drug costs

MIPS: Clinical Practice Improvement Activities Performance Category

The College urges CMS to make the following changes to the Clinical Practice Improvement Activities component, including:

- Incorporating CME into the Clinical Practice Improvement Activities
- Finalizing proposal accommodating small practices
- Finalizing CMS to finalize proposals related to QCDRs with reweighting

Alternative Payment Models

The College urges CMS to revise proposed changes to the Alternative Payment Model proposal, including:

- Allowing single-specialty providers to form a "medical home"
- Lowering Advanced APM qualification thresholds
- Protecting providers forced to change in APM status mid-reporting year

Introduction

Helping independent GI practice successfully participate in MIPS and APMs

The College is committed to reducing reporting burdens among practicing gastroenterologists and other gastrointestinal (GI) clinicians. That is why the ACG commends CMS for sharing this same overarching goal in this proposed rule. The College's comments are all rooted in this same theme of reducing administrative and financial burdens borne by GI practices across the nation. We hope CMS revises the proposed initiatives that are consistent with these comments, as we believe these recommendations will further our shared goal of reducing provider burdens and increase quality of patient care.

ACG urges CMS to delay implementing reimbursement cuts for practices with 25 eligible providers or less for the first 2 years (2019-2020). If CMS believes it does not have the regulatory authority to provide a safe-harbor for small physician practices, we urge them to specifically state this lack of regulatory authority in the final regulation. Based on CMS' own estimates, smaller practices face an undue burden when participating in MIPS.

The MIPS burden estimates for smaller practices are quite alarming. According to the data in the proposed rule, less than 50% of practices with 10-24 providers will receive a positive MIPS adjustment. These estimates are even more disturbing as the practice size gets smaller: roughly 30% of practices with 2-9 eligible providers and merely 3% of solo-practitioners will receive a positive adjustment. As CMS is aware, these solo providers and small practices will also be required to participate in MIPS even if they want to enroll in an Advanced APM in the future.

Reviewing CMS' burden and cost estimates also further highlight this dire predicament for small practices. Participating in the Quality Component will require an estimated 6-18 hours per eligible provider and an estimated \$400-1,290 of administrative fees borne by the practice. The Advancing Care Information Component will require an additional estimated 4 hours in time and \$182 in costs. Finally, reporting Clinical Practice Improvement Activities will require another 3 hours of practice time and an additional \$182 in practice costs. This totals an estimated 25 hours and \$1,654 per eligible provider. These estimates also do not reflect the time and costs associated with accessing and reviewing Quality and Resource Use Reports (QRURs) for the Resource Use component. CMS does not provide updated health information technology cost estimates in this proposed rule (which includes both the initial investment and annual maintenance costs).

ACG previously compared CMS' estimated time and cost data for participating in the Medicare Electronic Health Record Incentive Program to actual feedback from members to gauge the regulatory impact by practice size. The College found that CMS woefully underestimates the time it takes to participate in Meaningful Use as well as the annual health IT maintenance costs. In previous rulemaking, CMS has also recognized that the Agency has not delineated the impact per practice size when participating in the Electronic Health Record Incentive Program.¹ ACG's feedback is also consistent with

¹ Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule: <https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25595.pdf>: "Since the publication of the Stage 1 final rule, there has been little data published regarding the cost of EHR adoption and implementation. A 2011 study (<http://content.healthaffairs.org/content/30/3/481.abstract>) estimated costs of implementation for a five-physician practice to be \$162,000, with \$85,500 in maintenance expenses in the first year. In the absence of additional data regarding the cost of adoption and implementation costs for certified EHR technology, we proposed to continue to estimate for EPs that the average adopt/implement/upgrade cost is \$54,000 per physician

recently published peer reviewed medical literature on the costs and time burdens associated with participating in the Medicare Electronic Health Record Incentive Program. When releasing Meaningful Use regulations, CMS estimated that it will cost GI practices \$50,000 per provider for start-up costs, \$10,000 per provider in annual EHR maintenance costs, and over 8 hours in time to successfully meet Meaningful Use health IT and clinical quality reporting objectives.² Yet, survey data from ACG members demonstrates that these estimates are woefully underestimated. According to recently published articles, physician practices spend, on average, 2.6 hours per week and more than \$15.4 billion dealing with the reporting of quality measures (Health Affairs; March 2016). Physicians are also spending more than 1 hour each day, uncompensated, handling these electronic communications, positioned at the computer instead of facing the patient. (JAMA Internal Medicine; March 2016).

In the 2016 Medicare Physician Fee Schedule Final regulation, the CMS time burdens estimates associated with participating in the Physician Quality Reporting System are 5-16 hours per eligible provider.³ In 2016, providers must report at least 9 measures, covering at least 3 of the NQS domains, and must report each measure for at least 50 percent of the provider's eligible patients. While CMS reduces the measures required for the Quality Component of MIPS from 9 measures to 6 measures, CMS also significantly increases the percentage of patients required for each measure, from 50% to 80-90% of eligible patients. In doing so, CMS appears to understand this additional burden borne by providers in these proposed changes. The time per measure under the Quality Component of MIPS (18 hours/6 measures = 3 hours per measure) is *almost double* the estimated time to report quality measures under PQRS (16 hours/9 measures = 1.7 hours per measure). This will have a significant impact on solo and smaller GI practices across the country, especially since the Quality Component of MIPS (which all providers must participate in 2017) comprises of 50% of the total MIPS score in 2019, and then 45% of the provider's total MIPS score in 2020.

The College believes that until CMS has the opportunity to better assess the true impact on small practices, CMS should not move forward with reimbursement cuts for smaller physician practices (less than 25) beginning in 2019. There is much at stake for small and independent GI practices and CMS' own estimates are quite disconcerting. Further, if CMS does not have the regulatory authority to create a safe-harbor for smaller physician practices, ACG urges CMS to specifically state this lack of authority in the final rule. This will have a detrimental impact and will carry unintended consequences on smaller practices (less than 25 eligible providers). However, before MIPS is fully implemented, CMS now has an opportunity to better assess and delineate the costs and time burdens by practice size.

Thus, ACG urges CMS to review its estimates and study the potential impact to practices with less than 25 providers before finalizing any proposal to cut reimbursement for this group of providers.

FTE, while annual maintenance costs average \$10,000 per physician FTE, based on the cost estimate of the Stage 1 final rule. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by, but not limited to, the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and upgrading systems (or both)."

² Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule <https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25595.pdf>

³ Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule <https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf>

Greater incentives and practical guidance for GI practices to participate in APMs

ACG recommends that CMS delay implementing APM threshold requirements related to certified health informational technology (IT) as well as Medicare patient volume and payments for the first 2 years (2019-2020), for those practices with 25 eligible providers or less. If CMS believes it does not have the regulatory authority to do this for small physician practices, we urge the Agency to specifically state this lack of regulatory authority in the final regulation. Based on CMS' own estimates, smaller practices face a significant burden when participating in MIPS. Thus, easing APM thresholds for small practices could incentivize more APM participation if these thresholds were waived/lowered for the first 2 years.

MACRA was passed with the goals of transitioning away from traditional fee for service payments into more value-based care and alternative payment models. CMS also recently announced that the Agency's goal is to have 50% of Medicare payments through alternative payment models by 2018. As noted in the proposed regulation, MACRA does not create new alternative models, but instead, provides greater incentives to participate in APMs. The College urges CMS to incorporate better guidance and education as part of this "theme" of greater APM payment incentives, specifically showing how APMs can benefit practicing gastroenterologists and other specialty clinicians. CMS creates the framework and qualifying requirements for certain alternative payment models, such as accountable care organizations. However, CMS also recommends that stakeholders contact individual ACOs or other organizations to learn more about the details and practical benefits of participating in the alternative payment models. This requires labor-intensive resources that many busy practicing clinicians simply are not capable to undertake. Since CMS recommends that stakeholders reach out to the each individual APM organization, it is also extremely difficult for national specialty societies to provide this practical guidance for members, as there are no CMS dedicated resources for practical guidance. This may be one reason for the slow uptake in participating in current Medicare alternative payment models: the fear of the unknown.

With the advent and implementation of MACRA, and the goal of transitioning into more alternative payment models, the College recommends that CMS create "ombudsmen" for each APM or for each specialty that can help providers and physician organizations better educate our members. ACG also welcomes being an "ombudsman" for CMS, with the Agency's assistance by helping connect the College to representatives from the various CMS-approved APMs representatives nationwide. More data and practical guidance from a CMS-representative may relieve the fear and angst many GI practices have when pondering on whether to join an APM or participate in MIPS. This may also help CMS reach its goal to have 50% of Medicare payments through alternative payment models by 2018. The incentives to participate in an APM created in MACRA and outlined in the proposed rule may not be enough if this confusion persists. The College's mission is to provide the practical guidance and educational material in order for members to navigate through these complex programs and initiatives. Thus, the ACG welcomes the opportunity to collaborate with CMS in gathering and providing this information important to practicing clinicians regarding the benefits of transitioning into APMs.

Merit-Based Incentive Payment System

Quality Performance Category

The College urges CMS to revise proposed changes to the Quality component, including:

- Eliminating the cross-cutting measures requirement
- Awarding a bonus point for electronically submitting data to a QCDR
- Reducing the reporting threshold from 90% to 50%
- Reinstating the “Photo documentation of Cecal Intubation” measure

The College urges CMS to eliminate the cross-cutting measures requirement

The College and the American Society for Gastrointestinal Endoscopy (ASGE) have worked together for more than a decade on finding ways to establish scientifically sound standards for training, credentialing and quality measurement. In 2009, ACG and ASGE jointly established the non-profit educational and scientific organization, the GI Quality Improvement Consortium, Ltd (GIQuIC). GIQuIC has since been approved as a “qualified clinical data registry” or QCDR for the 2014, 2015, and 2016 Physician Quality Reporting System (PQRS) reporting years. In May, GIQuIC announced that it had hit the 3 million mark of colonoscopies in the database. We estimate that 1/3 of all practicing gastroenterologists in the U.S. are participating in this registry.

To encourage greater participation in PQRS and to help incorporate more meaningful measures for each specialty, Congress, as part of the Taxpayer Act of 2012, required the Secretary of HHS to allow individual providers to submit measures via an approved QCDR *in lieu of traditional PQRS measures*.⁴ This QCDR option was later expanded to the PQRS “group practice reporting option” in MACRA.

As CMS recognizes in this proposed rule, Congress also required for the Secretary to encourage the use of QCDRs for the Quality component of MIPS in MACRA.⁵ The College appreciates CMS providing proposals to foster the growing acceptance of QCDRs in clinical care, not only to meet the maximum allowable points in the Quality component of MIPS, but also to help eligible providers and groups meet other components of MIPS, such as Advancing Care Information and Clinical Practice Improvement Activities. We can achieve this shared goal of greater QCDR participation only if CMS recognizes that QCDRs need the flexibility to incorporate measures into the registry as each specialty sees fit for its respective members. QCDRs have experienced tremendous growth and success in improving quality, because physicians recognize that QCDR measures are meaningful to their profession and patient care. In contrast, cross-cutting measures may not be relevant or applicable to the data that some QCDRs were

⁴ American Taxpayer Relief Act of 2012. Public Law No: 112-240: “the Secretary shall treat an eligible professional as satisfactorily submitting data on quality measures under subparagraph (A) if, in lieu of reporting measures under subsection (k)(2)(C), the eligible professional is satisfactorily participating, as determined by the Secretary, in a qualified clinical data registry (as described in subparagraph (E)) for the year.”

<https://www.congress.gov/bill/112th-congress/house-bill/8/text>

⁵ “Medicare Access and CHIP Reauthorization Act of 2015” “Sections 1848(q)(1)(E) of the Act requires the Secretary to encourage the use of QCDRs, and section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage the use of CEHRT and QCDRs for reporting measures under the quality performance category under the CPS methodology, but the statute does not limit the Secretary’s discretion to establish *other* reporting mechanisms.” <https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf>

designed to collect. We do understand that CMS has a difficult task of balancing the simplicity of the MIPS program with program flexibility. However, we urge the Agency to err on the side of flexibility with respect to this requirement as originally envisioned by Congress when passing the Taxpayer Act of 2012 and MACRA.

As outlined in MACRA, measures used by a QCDR are not subject to certain requirements, such as inclusion on the annual final list of quality measures, publication in peer-reviewed journals, and endorsement by a consensus-based entity. In addition, QCDR measures are exempt from the consideration of whether or not they address measure gaps, and the priority is given to outcome, patient experience, care coordination and appropriate use measures. This reflects the intent to allow specialties to develop and select QCDR measures outside the process used to develop and select general quality reporting measures. CMS is proposing to require physicians to report on one cross-cutting measure that must be chosen from the list of general quality measures. Therefore, physicians reporting via a QCDR will be forced to select a measure outside their specialty-specific QCDR measure list. This requirement to report one cross-cutting measure is against the statute's intent to allow providers who report via QCDR the flexibility to select measures that are most relevant to their specialty and, therefore, is counter-productive to CMS' goal of more simplicity in quality reporting.

CMS further notes in this proposed rule that if a QCDR wants to use a non-MIPS measure for inclusion in the MIPS program, such measures would go through a "rigorous CMS approval process" during the QCDR self-nomination period. Once the measures are analyzed, the QCDR would be notified of which measures are approved for implementation. This "rigorous" review process will help ensure that each measure within a respective QCDR is not only meaningful for that specialty, but also rooted in science and the medical literature. Thus, it is unclear why CMS is proposing to include a cross-cutting measure that may not be relevant to the data the registry collects, especially when QCDR measures will be held to such a high threshold of review.

The College understands that one goal for the cross-cutting measure requirement is for CMS to better assess quality reporting across each specialty and across each provider participating in MIPS. If true, we remind the Agency that this is counter to congressional intent and the purpose of the QCDR reporting option. Further, CMS will already be able to compare provider performance across each specialty by the "population-based measures" proposal. As proposed, in addition to the provider reporting 6 measures, CMS will automatically calculate "population based" measures for each provider. This will be included in the provider's overall Quality score. These measures include an "acute conditions" composite, a "chronic conditions" composite, and an "all cause hospital readmissions" measure.

CMS must further recognize that changes to QCDRs require significant resources, and sufficient time to plan, incorporate, and test. These changes require significant financial resources as well. There must be ample notice in the rulemaking process for QCDRs and registries to plan and adequately meet these changes. It is unrealistic to expect that these changes can be easily adopted by the 2017 performance period following publication of the MACRA final rule.

Alternative proposal:

In order to provide better flexibility for quality reporting under MIPS, the College urges CMS to instead encourage the use of outcome-based measures in lieu of this cross-cutting measure requirement. CMS even states in this proposed rule: "We also note that we believe that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality of care patients receive. To keep the emphasis on such measures in the statute, we plan to increase the requirements for reporting outcome measures over the next several years through future rulemaking, as more outcome measures

become available. For example, we may increase the required number of outcome measures to two or three.” As proposed, a cross-cutting measure is required for all reporting mechanisms in the Quality performance category. CMS also encourages more outcome-based measures by providing 2 bonus points for each outcome and/or patient experience measure reported. However, MACRA also requires CMS to encourage the use of QCDRs.⁶ Thus, to meet these two priorities, we urge CMS to eliminate any cross-cutting measure reporting requirement for QCDR reporting, and instead, encourage or incentivize the use of any cross-cutting measure by providing additional bonus point(s) for those providers choosing to report a cross-cutting measure. Requiring the use of certain measures does not help simplify reporting among MIPS participants, and it certainly does not encourage the use of QCDRs.

The College urges CMS to award a bonus point for electronically submitting data to a QCDR

ACG believes all clinicians utilizing a QCDR and submitting data to it electronically should be eligible for a bonus point in the Quality performance category, even if they do not use certified electronic health record technology (CEHRT).

As proposed, CMS will award bonus points for reporting specific types of measures and using CEHRT systems to capture and report quality measures. However, not all EHRs are federally-certified. The GIQuIC registry for example accepts data via electronic transmission from CEHRT and non-certified EHRs, as well as via manual data entry.

Many registries still rely on both automated and manual data entry. Most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection. GIQuIC maintains both electronic and manual submission options to accommodate the diversity of workflows seen in gastroenterologists’ practices. While end-to-end electronic reporting is a goal for many registries, it is essential that CMS does not place too much value on purely end-to-end reporting. Rather, CMS should reward physicians for utilizing and incorporating registries into the daily operations, leveraging electronic capture, reporting where it makes sense, and using alternative methods when they are more efficient.

In the spirit of incentivizing the reporting through electronic sources and following the intent of MACRA, a provider should have the ability to report into a registry in the most efficient manner for the practice’s workflow, and such actions should be rewarded regardless if it is completely “electronic” from end-to-end.

ACG Urges CMS to reduce the reporting threshold from 90% to 50%

The College fears that CMS’ proposal to increase reporting thresholds from the current 50% threshold to 80-90% of eligible patient services creates an unfair and unreasonable burden for many GI practices, especially for those in smaller group practices.

As proposed, clinicians failing to meet these reporting thresholds will receive a zero score for that measure due to CMS’ data completeness standard. This must change, as there are seismic shifts in Medicare reimbursement. There must be a transitional period for our members. ACG urges CMS to

⁶ “Sections 1848(q)(1)(E) of the Act requires the Secretary to encourage the use of QCDRs, and section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage the use of CEHRT and QCDRs for reporting measures under the quality performance category under the CPS methodology, but the statute does not limit the Secretary’s discretion to establish other reporting mechanisms.”
<https://www.congress.gov/114/plaws/publ10/PLAW-114publ10>.

continue using the 50% reporting threshold in 2019 and 2020 when the Quality components of MIPS represents 50% and 45% of the provider's aggregate score, respectively.

Some approved QCDRs also do not incorporate value codes in their data collection process. This will be very challenging when QCDRs are required to incorporate a PQRS-like cross-cutting measure as proposed. QCDRs are different from traditional registries. This was the intended purpose of the QCDR—to allow providers and certain CMS-approved quality improvement registries to select measures from the registry for quality reporting purposes. Further, a specialized registry collects data addressing specific aspects of care (a condition or a specific procedure). A QCDR is also not a complete EHR system. This is important, as there will be Medicare patients eligible for the denominator of cross-cutting measures, but the data wouldn't necessarily be captured in the registry, since it may be outside the scope of data the registry collects (unrelated office visit, for example). This not only is counterintuitive to the purpose of QCDRs, but it makes the 90% reporting threshold for QCDRs nearly impossible to meet.

As stated above, CMS appears to understand this additional burden borne by our membership in these proposed changes to quality reporting. Despite the requirement to report 3 less measures in MIPS, the time per measure under the Quality Component (18 hours/6 measures = 3 hours per measure) is almost double the estimated time to report quality measures under PQRS (16 hours/9 measures = 1.7 hours per measure). This will have a significant impact on solo and smaller GI practices across the country, especially since the Quality Component of MIPS (which all providers must participate in 2017) comprises of 50% of the total MIPS score in 2019, and then 45% of the provider's total MIPS score in 2020.

Thus, we urge CMS to revert back to the 50% threshold of eligible patients currently in PQRS instead of the 80-90% threshold as proposed under MIPS.

ACG urges CMS to reinstate the "Photo documentation of Cecal Intubation" measure

The College urges CMS to reconsider the Agency's proposal to remove the following measure from the MIPS Quality Component:

"Photo documentation of Cecal Intubation": The rate of screening and surveillance colonoscopies for which photo documentation of landmarks of cecal intubation is performed to establish a complete examination.

The College, along with the American Gastroenterological Association and ASGE, are the joint-stewards for this measure. According to the proposed regulation, due to the agreement with the Core Measure Collaborative, CMS proposes to remove this measure. The College is very concerned over the lack of transparency that occurred in this decision. The College was never consulted during this discussion, and there are no public summaries of these meetings or discussions to review and learn more on the Core Measure Collaborative's rationale for recommending that this measure be removed from quality reporting in 2017. This also appears to be counter to MACRA, as CMS stated in the proposed regulation: "Section 1848(q)(2)(D)(viii) of the Act provides that relevant eligible clinician organizations and other relevant stakeholders, including state and national medical societies, must be consulted in carrying out the annual list of quality measures available for MIPS assessment."⁷

⁷ "Medicare Access and CHIP Reauthorization Act of 2015" <https://www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf>

The College welcomes participating in the Core Measure Collaborative, as well as being consulted for any proposals to change measures in MIPS. Until such time, however, we urge CMS to include this measure in the list of available quality measures under MIPS 2017.

Advancing Care Information Performance Category

The College urges CMS to make the following changes to the Advancing Care Information component, including:

- Reducing reporting burdens:
 - Finalizing CMS’ proposal to reduce the number of the measure from the Electronic Health Record Incentive Program by removing the computerized provider order entry (CPOE) and Clinical Decision Support (CDS) measures.
 - Finalizing CMS’ proposal to allow reporting at the group practice level
 - Using a 90 day reporting period
- Reiterating that the College’s members should not have to rely on others to meet certain Advancing Care Information objectives
- Providing more credit to participating in a QCDR or other quality improvement registry

The College supports CMS’ goal of reducing reporting burdens

The College appreciates and commends CMS for striving to reduce the significant practice management and financial burdens associated with participating in the Medicare Electronic Health Record Incentive Program. ACG agrees that with the advent of MIPS and the Advancing Care Information component, CMS now has this opportunity to “revise and reset” the significant practice management and financial challenges under the Meaningful Use Program. Thus, the College supports CMS’ proposal to remove from the Advancing Care Information the CPOE as well as the CDS measures. ACG urges CMS to finalize the changes as proposed.

ACG also supports CMS’ proposal to allow participating in the Advancing Care Information component at the group practice level. The College also urges CMS to finalize this proposal.

In the “Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017” final rule, CMS estimates that it would take 6 hours and 49 minutes for providers to report Meaningful Use objectives (this does not include clinical quality measures).⁸ The College believes these estimates are woefully underestimated, based on both the survey of ACG members and the recently published literature mentioned above. Thus, the College remains very concerned that CMS’ estimate of only requiring 4 hours to report Advancing Care Information objectives will also be inaccurate and misleading. What’s more, CMS did not provide updated cost estimates for investing in health IT or the associated annual maintenance costs. The lack of accurate data will only cause the same problems our members face today with Meaningful Use. While the College commends CMS for the goal of reducing reporting burdens, we remain very concerned that CMS does not know the extent to which the Advancing Care Information component will also be an overly burdensome MIPS component, much like its Meaningful Use predecessor.

⁸ Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rule <https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25595.pdf>

ACG recommends that CMS can further reduce reporting burden by establish a 90 day reporting period as opposed to a full calendar year. The Meaningful Use program has operated on a 90-day reporting period, rather than a full calendar year, to accommodate many issues with the program. In particular, this shorter reporting period permitted necessary technology updates, system downtime, accommodations to improve usability, and facilitated physician's transition to new health IT measures.

The College's members should not have to rely on others to meet certain Advancing Care Information objectives

In the past, the College has conveyed one major problem that our members experience when participating in Meaningful Use: those objectives and measures that require outside elements for the provider to meet an objective or measure. The College recognizes that among the goals of health IT adoption is greater coordination of care and information exchange among providers. However, CMS must also recognize that a provider's performance should not be conditioned upon the necessary actions another clinician (not using certified health IT), a software vendor (not updating formulary), or pharmacy (not using e-prescribing IT software).

According to the Medicare Payment Advisory Committee (MedPAC), roughly 40% of Medicare beneficiaries are currently aged 75+. Also, while the average age of the Medicare population will initially skew younger than in the recent past, the number and share of beneficiaries ages 85 and older will grow rapidly.⁹ This is important because a provider's Advancing Care Information score depends in part upon the electronic health care exchange participation of an aging population, many of whom, according to our membership, either do not wish to participate in electronic health exchanges or do not have the knowledge to do so. It is unfair and unreasonable for our members to make the efforts to achieve a higher MIPS score, but are limited due to the actions of others (outside of the provider's control).

The College urges CMS to assess a provider's performance in the Advancing Care Information component on the actions of that provider and *attempt to perform these health IT and/or clinical functions*. ACG recommends that CMS revise these measure specifications to focus on this *attempt to perform* these functions.

Some examples of this problem within the proposed objectives are highlighted below:

Objective: Electronic Prescribing

MIPS eligible clinicians must generate and transmit permissible prescriptions electronically.

- ePrescribing Measure: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using certified EHR technology.
- Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.
- Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using certified EHR technology.

⁹ Medicare Payment Advisory Commission (MedPAC). June 2015: <http://www.medpac.gov/documents/data-book/june-2015-data-book-section-2-medicare-beneficiary-demographics.pdf?sfvrsn=0>

Objective: Coordination of Care Through Patient Engagement

Use certified EHR technology to engage with patients or their authorized representatives about the patient's care.

- View, Download, Transmit (VDT) Measure: During the performance period, at least one unique patient (or patient-authorized representatives) seen by the MIPS eligible clinician actively engages with the EHR made accessible by the MIPS eligible clinician. An MIPS eligible clinician may meet the measure by either—(1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the MIPS eligible clinician's certified EHR technology; or (3) a combination of (1) and (2).
- Denominator: Number of unique patients seen by the MIPS eligible clinician during the performance period.
- Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information during the performance period and the number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an API during the performance period.

Objective: Health Information Exchange

The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other health care providers into their EHR using the functions of certified EHR technology.

- Patient Care Record Exchange Measure: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider—(1) creates a summary of care record using certified EHR technology; and (2) electronically exchanges the summary of care record.
 - Denominator: Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.
 - Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.
- Request/Accept Patient Care Record Measure: For at least one transition of care or referral received or patient encounter in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician receives or retrieves and incorporates into the patient's record an electronic summary of care document.
 - Denominator: Number of patient encounters during the performance period for which MIPS eligible clinician was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.
 - Numerator: Number of patient encounters in the denominator where an electronic summary of care records received is incorporated by the clinician into the certified EHR technology.

The College urges CMS to provide more credit to participating in a QCDR or other quality improvement registry

The College appreciates CMS' solicitation for feedback on the Agency's proposal to allow the data registries to report proposed objectives on behalf of providers. We agree that many registries do not currently support such capabilities as this time. However, the College supports the Agency's "longer-term commitment to working with organizations that are agile, effective and can create less burdensome data submission mechanisms for MIPS eligible clinicians. We [CMS] believe the proposed data submission methods could reduce reporting burden by synchronizing reporting requirements and data submission, and systems, allow for greater access and ease in submitting data throughout the MIPS program." ACG also appreciates CMS' willingness to state this vision and timeline in this proposed rule. As mentioned above, registries require significant resources, and time to plan, incorporate, and test. These changes require significant financial resources as well. This time-lag limitation becomes very challenging when CMS makes annual changes to QCDR quality reporting as well as IT functionality. Thus, the College urges CMS to continue providing longer-term guidance on the vision and proposals to increase utilization of registries.

One way CMS can demonstrate this long-term commitment to reducing reporting burdens is for the Agency to increase the bonus points for those providers using clinical data registries. As proposed, clinicians will earn one bonus point for reporting any additional measures above the base score requirement for the Public Health and Clinical Data Registry Objective. To earn points in the base score, CMS proposes that a clinician would need to complete submission on the Immunization Registry Reporting measure of the objective. The completion of any additional measure under the objective, such as Public Health Registry Reporting and Clinical Data Registry Reporting, would earn one additional bonus point.

The College urges CMS to provide greater bonus points as this will encourage new participants to join registries and submit their data through these mechanisms, ultimately furthering our shared commitment to reduce provider reporting burdens across MIPS.

Resource Use Performance Category

The College urges CMS to make the following changes to the Resource Use component, including:

- Delaying the episode of care measures until there is a 2 year temporary trial and review period
- Excluding Medicare Part D drug cost for attribution: ACG Members have little to no control over drug costs

The College urges CMS to delay the episode of care measures until there is a 2 year temporary trial and review period

ACG appreciates CMS' solicitation on feedback for the Resource Use Component of MIPS. As defined in MACRA, the Resource Use category will total 10% and 15% of the provider's aggregate MIPS score in 2019 and 2020, respectively. The Resource Use component score increases to 30% after 2020. ACG believes that by incrementally increasing the weight of the Resource Use category, Congress intended for CMS to incrementally transition into cost-attribution for individual providers as well as episodes of care. According to CMS, MACRA requires that claims submitted for items and services furnished by a physician or applicable practitioner *on or after January 1, 2018*, shall, *as determined appropriate by the*

Secretary, include the applicable codes established for care episode groups. Thus, ACG seeks clarification on why episode group measures would be part of the 2017 performance year. The College requests CMS to use the authority granted under MACRA (“as determined appropriate by the Secretary”) to delay episode groups from the 2019 and 2020 payment years.

Thus, the College urges CMS to delay implementing episodes of care until 2020, and until CMS and providers have an opportunity to review and assess performance and learn how CMS will attribute costs to them. This trial period will also allow the Agency to better assess how these costs can fairly be attributed to respective providers and whether they are risk-adjusted. The trial period allows CMS to find a process by which the costs are attributed to a provider can be compared to the quality of care for performing those same services. CMS can still finalize the “total per costs capita for all attributed beneficiaries” and “Medicare Spending per Beneficiaries” measures for the Resource Use component in 2019 and 2020.

According to CMS, several stakeholders expressed the desire to transition to episode-based measures and away from the general total per capita measures used in the current value-based modifier. Therefore, CMS proposes episode-based measures for a variety of conditions and procedures that are considered high cost, have high variability in resource use, or are for high impact conditions. However, as structured under MIPS, there is no link between cost attribution and quality measurement for those same services.

CMS noted in the proposed rule that the Agency believes they meet the statutory requirements for the appropriate measures of cost as defined in MACRA, because the methodology eliminates the effects of geographic adjustments in payment rates and takes into account risk factors. However, after reviewing each episode of care in gastroenterology the College still seeks guidance on how these measures will be attributed to our members and how they are risk-adjusted. There is much confusion over how these episodes will work in the practical, day-to-day operations. A trial period to specifically educate specialty societies as well as MIPS providers will not only allow a better transition into MIPS, but will also provide a greater understanding of the Resource Use component. The lack of understanding plagues the value-based payment modifier today, even for those providers who have studied the process and reviewed QRUR reporting with CMS. CMS now has the opportunity in the early years of MIPS to provide a trial period for greater understanding and awareness. This trial period also affords the MIPS provider the opportunity to review these episodes of care and to make changes to his/her practice prior to the 2021 payment year.

CMS is scheduled to provide performance information on episode-based measures to MIPS eligible clinicians through the Supplemental Quality and Resource Use Reports (QRURs), which are released in the fall of 2016. This is the first time many providers will read a QRUR report and there will be much confusion among providers. It will also be the first time these proposed episodes for gastroenterology will even be included in the QRUR.

As noted in the proposed rule, the Agency remains uncertain as to how many of these measures CMS will ultimately include in the final rule, as these measures have never previously been used for payment purposes. In requiring episodes for Resource Use, CMS believes Congress defers to the Secretary on how to best implement these payment episodes.¹⁰ Thus, these episodes of care for the Resource Use category

¹⁰ “Section 1848(r)(4) of the Act requires that claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, shall, **as determined appropriate by the Secretary**, include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories under sections 1848(r)(2) and (3) of the Act, as well as the NPI of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner).”

should be for provider review purposes only during the initial years of MIPS (2019 and 2020) pursuant to the Secretary's regulatory authority.

The College urges CMS to exclude Medicare Part D drug cost for attribution: ACG Members have little to no control over drug costs

In the proposed rule, CMS noted that the Agency seeks feedback on how to best incorporate Part D drugs costs into the Resource Use category and seeks input from the public stakeholders.

The College urges CMS to exclude Part D drug costs as physicians do not control the costs of drugs. ACG also urges CMS to exclude physician-administered drugs under Medicare Part B as well. Thus, it is unreasonable to attribute these costs to providers.

Clinical Practice Improvement Activities Performance Category

The College urges CMS to make the following changes to the Clinical Practice Improvement Activities component, including:

- Incorporating CME into the Clinical Practice Improvement Activities
- Finalizing proposal accommodating small practices
- Finalizing CMS to finalize proposals related to QCDRs with reweighting

The College urges CMS to incorporate CME into the Clinical Practice Improvement Activities

ACG members should receive credit for participating in continuing medical education (CME) activities that are designed to further the objectives of the Clinical Practice Improvement Activities component.

Utilizing accredited CME to further physician awareness and compliance with best practices represents an intelligent and efficient use of our nation's network of CME providers. Accredited CME activities involve assessment and improvement of patient outcomes and quality of care.

Furthermore, reliance on CME to drive greater clinical practice improvement activity participation has the advantage of incorporating a reporting system that has been proven effective. The Accreditation Council for Continuing Medical Education's (ACCME's) Program and Activity Reporting System (PARS) is a web-based portal designed to streamline and support the collection of ACCME program and activity data from accredited continuing medical education (CME) providers. The ACCME uses the information collected in PARS to support the performance-in-practice reviews that are part of the process for initial accreditation, reaccreditation, and progress report reviews. In addition, the ACCME uses data from PARS to produce annual reports as a service to accredited CME providers and other stakeholders.

MACRA defines a clinical improvement activity as “an activity that relevant eligible clinician organizations and other relevant stakeholders identify as improving clinical practice or care delivery, and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.” Also, MACRA requires the Secretary to specify clinical improvement activities under subcategories for the performance period, and in doing so, to give consideration to the circumstances of small practices (consisting of 15 or fewer clinicians), and practices located in rural areas and geographic health professional shortage areas (HPSAs).

The College commends CMS for having the goal of eliminating duplicative reporting activities and reducing practice management burdens among clinicians. ACG believes that linking accredited CME

activity with Clinical Improvement Activities MIPS category helps meet this shared goal, especially among smaller GI practices.

The College urges CMS to finalize proposal accommodating small practices

As discussed above, the College has grave concerns over the future impact on small practices. Thus, ACG supports CMS' proposal to accommodate smaller practices to help meet the Clinical Practice Improvement Activities component.

As discussed in the proposed rule, in establishing clinical practice improvement activities, MACRA requires the Secretary to give consideration to small practices (15 or fewer clinicians) and practices located in rural areas. CMS proposes to accommodate small practices and practices located in rural areas by allowing MIPS eligible clinicians or groups to submit a minimum of one activity to achieve partial credit or two activities to achieve full credit. These MIPS-eligible clinicians or groups can receive partial or full credit for submitting two activities of any type of weighting (for example, two medium activities will qualify for full credit). ACG urges CMS to finalize this proposal.

The College urges CMS to finalize proposals related to QCDRs with reweighting

ACG commends CMS for striving to create opportunities for QCDRs to report new and innovative quality measures. In addition, the College appreciates the Agency for proposing several clinical practice improvement activities that emphasize QCDR participation. However, ACG urges CMS to reweight these activities as "high" as Congress and CMS (as noted below) see the importance in greater participation in quality improvement registries. We agree that QCDRs may also provide the opportunity for longer-term data collection processes which will be needed for future year submission on improvement, in addition to achievement. Thus, it is imperative that CMS promote and foster the use of QCDR participation in MIPS and APMs.

The College appreciates CMS' guidance and vision for QCDR reporting in MIPS performance categories. Providing insight on CMS' future plans is very important for both QCDRs and GI practices. ACG shares CMS' statements regarding QCDRs allowing MIPS-eligible clinicians to more easily meet the submission criteria for clinical practice improvement activities (and all MIPS performance categories). As discussed above in the cross-cutting measures discussion, changes to QCDRs require significant resources, time to plan, incorporate, and test. These changes require significant financial resources as well. There must be ample notice in the rulemaking process for QCDRs and registries to plan and adequately meet these changes.

Alternative Payment Models

The College urges CMS to revise proposed changes to the Alternative Payment Model proposal, including:

- Allowing single-specialty providers to form a “medical home”
- Lowering Advanced APM qualification thresholds
- Protecting providers forced to change in APM status mid-reporting year

The College urges CMS to allow single-specialty providers to form a “medical home”

CMS notes that MACRA does not provide a specific definition for what constitutes a “Medical Home Model.” Thus, the College urges CMS to modify this definition in the final rule to allow specialty practices to form a “medical home.”

As proposed by CMS, the Medical Home Model must have the following: (1) participants such as primary care practices or multispecialty practices that include primary care physicians and practitioners and offer primary care services; and (2) an empanelment of each patient to a primary clinician. CMS also only accepts the National Committee for Quality Assurance (NCQA) accreditation for a specialty recognition program. However, there is very limited guidance assistance and guidance from the NCQA and this requires providers to undergo additional hurdles via a third-party accrediting organization. Instead, APM participation and specialty medical home models should be encouraged and welcomed.

In addition, CMS would require that a Medical Home Model must have at least four of the following seven elements: (1) Planned coordination of chronic and preventive care; (2) Patient access and continuity of care; (3) Risk-stratified care management; (4) Coordination of care across the medical neighborhood; (5) Patient and caregiver engagement; (6) Shared decision-making; and (7) Payment arrangements in addition to, or substituting for, fee-for-service payments (for example, shared savings, population-based payments). CMS also proposes that a Medical Home Model is required to incorporate specific design elements related to clinicians practicing under one or more of the following specialty codes: General Practice; Family Medicine; Internal Medicine; Pediatric Medicine; Geriatric Medicine; Nurse Practitioner; Clinical Nurse Specialist; and Physician Assistant.

The College recognizes the need for more coordinated care across all specialties, including primary care. However, many Medicare beneficiaries with chronic GI illnesses and other comorbidities actually consider the GI clinician as their respective “primary care provider.” Thus, it is important not to exclude certain specialties simply because the practice lacks a certain specialty code. These types of multispecialty practices that would qualify for a medical home are likely to be large groups, thereby already being a “de facto medical home;” these practices may not need to assume the financial risk of an APM as outlined in the proposed rule.

The College urges CMS to lower Advanced APM qualification thresholds

The College believes that more specialty providers would opt for the APM track if CMS lowers the threshold for being considered an APM “qualifying professional.”

CMS proposes that for 2017, an Advanced APM must require that at least 50% of eligible clinicians who are enrolled in Medicare use the certified health IT. Under the proposed rule, CMS would increase the

minimum CEHRT use threshold from 50% to 75% in future years. Providers considering the APM track must also meet Medicare payment and patient volume requirements: 25% of Medicare payments must go through the APM as well as 20% of the provider's Medicare patients (2019). This is increased to 75% of payments and 50% of patients by 2024+.

The College urges CMS to lower these thresholds in order to encourage more participation in APMs. This includes replacing the qualifying professional Advanced APM requirements as proposed with the partial qualifying professional requirements (as also proposed). Thus, changing the payment threshold from 25% to 20%, and the patient count threshold from 20% to 10% beginning with the 2019 implementation year. Lower thresholds, both for qualifying and partial qualifying professionals, will likely help more provider meet APM qualifications as CMS reviews and assesses respective Medicare patient volumes and payments in 2018 for APM determination. The College also urges CMS to lower the thresholds for certified health IT to encourage more participation in APMs as well.

Protecting providers forced to change in APM status mid-reporting year

The College urges CMS to provide a safe-harbor for providers forced to change APM status during a reporting year. As proposed, these providers would be subject to MIPS reporting.

There may be scenarios where providers change taxpayer identifier numbers (TINs), change their APM participation status, and/or change other practice affiliations during a performance period. This change may make it extremely difficult or impossible to meet the MIPS requirements. The proposed policy may be a disincentive physicians or groups from joining an APM entity. Thus, we urge CMS to develop a policy that allows these providers to be assessed as satisfying MIPS in these scenarios.

Conclusion

ACG thanks Congress CMS for implementing policies to help improve the quality of patient care. However, ACG also believes policy makers should instead focus on lowering regulatory and administrative burdens placed upon gastroenterologists and GI clinicians. We thank CMS for recognizing this concern. The College believes these comments will help this transition into a new payment model, and also help foster a successful future for our nation's physicians. In April 2016, the Association of American Association of Medical Colleges reported that there will be significant shortage of physicians by 2025, including a shortage in non-primary specialty care.¹¹ In times of lower Medicare reimbursement rates for GI services we must recognize that we are at crucial point in health care delivery in the United States. The College welcomes the opportunity to work with CMS on implementing MIPS and APMs and help facilitate a smooth transition into these new payment models.

Please contact Brad Conway, Vice President of Public Policy, Coverage & Reimbursement, at 301-263-9000 or bconway@gi.org with any questions.

Sincerely,



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¹¹ The Complexities of Physician Supply and Demand: Projections from 2014 to 2025
https://www.aamc.org/download/458082/data/2016_complexities_of_supply_and_demand_projections.pdf