August 21, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5522-P
P.O. Box 8013
Baltimore, MD 21244-8013

VIA ELECTRONIC SUBMISSION

Re: CMS-5522-P Medicare Program; CY 2018 Updates to the Quality Payment Program

Dear Administrator Verma:

On behalf of the Texas Medical Association (TMA) and our 50,000-plus physician and medical student members, we thank you for the opportunity to comment on the "Medicare Program; CY 2018 Updates to the Quality Payment Program" published in the *Federal Register* on Friday, June 30, 2017.

We appreciate the efforts made by the Centers for Medicare & Medicaid Services (CMS) to continue some transitional relief for physicians, but we continue to be concerned that the compliance, documentation, and reporting requirements required by law and regulation for this program are costly and wasteful with no proven evidence of benefit. The requirements and incentives may even have the counterproductive effect of reducing access to good ambulatory care for many Medicare beneficiaries. Both TMA and the American Medical Association have long-standing policy governing pay-for-performance programs that calls for programs that: (1) ensure quality care, (2) foster the patient-physician relationship, (3) offer voluntary physician participation, (4) use accurate data and fair reporting, and (5) provide fair and equitable program incentives. The current Merit-Based Incentive Payment System (MIPS) program is arguably in violation of all these principles.

We understand that the ultimate solution to many of these program design problems will require congressional action to amend the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) or other statutes, but we urge you to continue to use your regulatory authority to mitigate the negative impact in every way possible. Our detailed comments follow, but please note that generally we are not commenting on issues that are specific to certain medical specialties. We urge you to consider carefully comments from specialty physicians on those subjects where they have particular expertise not common to all physicians.

QUALITY PAYMENT PROGRAM

General Program Concerns

Cost of Reporting Requirements

We continue to be concerned that the compliance, documentation, and reporting necessary to score well in the Quality Payment Program are prohibitively costly for many physicians. These include all the costs to learn program requirements; relearn them after annual program revisions; investigate reporting options and requirements; select compliance methods; purchase memberships, software, upgrades, or services; revise standard practice processes and guidelines to incorporate new protocols; train all relevant staff; perform related tests or interventions; document performance or results; report what was documented; verify receipt or processing of reported data; and defend the data in audit. Many of these costs are subject to economies of scale, so that they become cost-effective only for larger physician groups. Although the current transition relief offers some temporary, inexpensive opportunity to avoid penalties, small practices still may face compliance costs that make any attempt at earning incentives unlikely to show a positive return on investment.

TMA Recommendation: CMS should continue efforts to streamline and simplify all reporting and compliance requirements.

Measured Results are not in Physician Control

By legislative design, MIPS scores are aggregated from four different categories: quality, resource use, improvement activities, and advancing care information (ACI). Of these four areas, the improvement activities category may be the only one for which physicians wield substantial control over their own performance. Attribution and measurement problems in the cost category measurements result in holding physicians responsible for costs that are unrelated to any of their own services, recommendations, or orders, and over which they have no control. Many of the proxy measures used to assess quality are highly dependent on patient actions and choices. Because patients choose whether to accept physician direction or advice, which in turn affects treatment outcomes and many process measures, physicians often have little control of their quality scores. Depending on the circumstances, physician efforts to influence or modify patient decision-making may be costly but have little or no possibility of attaining the desired results. Locus of control over many ACI standards and requirements may rest with vendors, not physicians.

TMA Recommendation: CMS should eliminate measures based on actions or outcomes that are not in physician control.

Penalties for Serving Specific Patient Groups

Patient demographic factors that relate to high cost or resource use, poor outcomes, or that have adverse effects on other quality measures are not evenly distributed across the population. Many patient actions and decisions more strongly correlate to demographic or socioeconomic variables, or to local access to care issues, than to physician efforts or actions. Studies have shown that poverty and lack of education are correlated with poor health outcomes, even when access to

health care is universally available.[1] Patient demographic variables including gender and ethnicity have been shown to be related to medication compliance;[2] and racial, religious, or cultural variables affect patient preferences for care including end–of-life choices about intensive care and resuscitation.[3] Patients with a lifetime history of poverty and poor access to medical care enter Medicare, through age or disability, with pent up demand that creates high cost and poor outcomes. MIPS resource use and quality scores that are adversely affected by these variables financially penalize the physicians who serve disproportionate numbers of patients from certain population subgroups, including specific racial or cultural groups and patients who have lived a lifetime of poverty without access to good medical care. Furthermore, local access to care variables such as poor physician supply or transportation distances also can affect outcomes by reducing access to routine ambulatory care and increasing use of more costly hospital-based care. Penalizing physicians who offer services in these localities is counter-productive.

TMA Recommendation: CMS should eliminate measures that penalize physicians who disproportionately treat specific cultural or socioeconomic groups or who practice in geographic areas with access-to-care barriers.

Risk Adjustment

It is clear that Congress did not intend to penalize physicians who care for large numbers of disadvantaged or minority patients, but the current measures create incentives for physicians not to serve certain patients and not to locate their practices in areas where poverty or other specific characteristics are prevalent. In fact, Congress repeatedly has incorporated calls for appropriate risk adjustment on both cost and quality measures, including the following provision in MACRA:

> ‘‘(G) ACCOUNTING FOR RISK FACTORS.—
> (i) RISK FACTORS.—Taking into account the relevant studies conducted and recommendations made in reports under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014, and, as appropriate, other information, including information collected before completion of such studies and recommendations, the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors—
> ‘‘(I) assess appropriate adjustments to quality measures, resource use measures, and other measures used under the MIPS; and

[1] David A. Alter, Therese Stukel, Alice Chong and David Henry
Lesson From Canada's Universal Care: Socially Disadvantaged Patients Use More Health Services, Still Have Poorer Health

Health Affairs, 30, no.2 (2011):274-283

[2] Ellis, J. J., Erickson, S. R., Stevenson, J. G., Bernstein, S. J., Stiles, R. A. and Fendrick, A. M. (2004),
Suboptimal Statin Adherence and Discontinuation in Primary and Secondary Prevention Populations.
Journal of General Internal Medicine, 19: 638–645.

[3] Elizabeth D. McKinley, Joanne M. Garrett, Arthur T. Evans and Marion Danis
Differences in end-of-life decision making among black and white ambulatory cancer patients
Journal of General Internal Medicine Volume 11, Number 11, 651-656

> ‘‘(II) assess and implement appropriate adjustments to payment adjustments, composite performance scores, scores for performance categories, or scores for measures or activities under the MIPS.‘‘

We are very disappointed that the several studies already completed have not yet resulted in actionable methodologies for properly risk adjusting the affected MIPS cost and quality measures. Although we appreciate the temporary bonus proposals included here, they are not adequate substitutes for methodologies that could make the relevant measures fair for everyone.

We would note that the difficulty of developing proper risk adjustment methodology for patient data is an added reason that we oppose any use of all-payer data. While risk adjustment for the Medicare population is proving to be difficult, doing so for non-Medicare populations may be impossible.

TMA Recommendation: Unless CMS can eliminate measures that are impacted by patient demographics, CMS must act immediately to implement or improve risk adjustment for both cost and quality measures.

MERIT-BASED INCENTIVE PAYMENT SYSTEM

Priority Issues

Low-Volume Threshold

For practices without a high volume of Medicare payment, the cost of MIPS reporting can quickly exceed any possible benefit from incentives earned or penalties avoided. We therefore support your proposal to increase the low-volume threshold. We also would suggest that you retroactively apply the higher 2018 low-volume threshold to the 2017 reporting period, while allowing an elective opt-in for physicians who wish to be scored.

TMA Recommendation: Retroactively modify 2017 low-volume threshold to align with the 2018 low-volume threshold, but permit physicians and groups who are otherwise exempt to opt in to MIPS scoring for the purpose of MIPS payment adjustments.

MIPS Performance Period

TMA continues to receive many queries from physicians who are completely uninformed or worse, misinformed, about the requirements and mechanisms for MIPS reporting. Although we have been using every communication method available to us to disseminate the information, we are extremely concerned that a large percentage of small practices will be penalized in 2019 due to a failure to report in 2017. Until 2017 performance is complete and physician participation can be evaluated, we do not support any expansion of the reporting periods.

TMA Recommendation: Retain the same performance period requirements as in 2017.

Composite Performance Score

The stated purpose of the low 3-point performance threshold for 2017 was to encourage participation and provide time for physicians to become familiar with the program. We urge you to wait until after end of the 2017 reporting period when the results of that policy can be assessed before increasing the performance threshold. If the data shows that small practices have learned about the program and are participating, then there may be some justification for gradually ramping up the minimum reporting necessary to avoid penalties. Although the new improvement category may provide opportunities for earning the required points, the reporting mechanisms have not even been created yet. Until all reporting avenues are functional, tested, and shown to be effectively utilized by reporting physicians, there should be no increase in performance requirements.

TMA Recommendation: Keep the target performance threshold at 3 points until physician participation can be assessed.

Quality Performance Category

Recognizing that practice management, clinical support systems, health information technology, and data reporting capabilities vary among physician practices, TMA appreciates the efforts CMS has taken to account for these differences within the MIPS quality performance category. We believe maintaining the same data submission mechanisms and extending flexibility for the second year of the Quality Payment Program will better support physician engagement in MIPS.

However, we caution CMS that moving forward with too many changes annually will increase the complexity of the program and only discourage physicians from MIPS participation and consideration of Advanced Alternative Payment Models (APMs). For the second and future years of implementation, TMA seeks simplification and consistency in quality reporting requirements and data completeness criteria that will ensure solo physicians, group practices, and virtual groups gain proficient knowledge of MIPS data submission criteria and reporting structures that result in a pathway to successful participation without creating undue administrative and cost burdens.

TMA acknowledges and appreciates the effort put forth by CMS and other entities that continue to provide physician education, support, and technical assistance. TMA further appreciates the agency's efforts in designing a Quality Payment Program website that is more user-friendly and efficient. We believe the new website is an improvement compared to CMS legacy program websites. We acknowledge ongoing website updates are taking place to promote physician engagement and enhance program knowledge. Particularly, we are pleased to know that a new CMS portal is under development in which physicians can manage all of their MIPS data submission via one website application along with such features as a data performance dashboard.

Given that the first MIPS performance period is still in progress, the effectiveness of many of the agency's transitional policies meant to improve the physician experience and minimize burden are yet unknown. With a category weight of 60 percent of the overall MIPS composite

performance score, we view the quality performance category as the most critical for the second year of the program, and believe the agency should provide physicians with sufficient time to learn about and adapt to the new program. TMA believes this additional time will support the ultimate goal of quality improvement across all participating physicians.

To meet this aim, TMA strongly recommends the continuation of the “pick your pace” approach and urges CMS to maintain consistency and flexibility, particularly for physicians in solo and small group practices who encounter continued challenges to successful participation and penalty avoidance.

TMA appreciates the agency’s existing efforts to extend flexibility surrounding the quality performance category for the second year of the Quality Payment Program, but offers further improvements in the following areas:

Performance Period

For the second year of the Quality Payment Program, the agency previously finalized a 12-month performance period for the MIPS quality performance category. TMA opposes this policy and reiterates the recommendation that the agency continue a “pick your pace” approach to MIPS participation. This approach would include the option to test the system by reporting a minimum amount of data to avoid a payment penalty, report data for any 90-day period within the performance period, or report data for the full 12-month performance period.

TMA believes this flexibility would support physicians and groups who need additional time to gain experience with and improve their data collection and reporting capabilities. In addition, this recommendation would align the quality performance category with the 90-day period previously finalized for the 2018 MIPS improvement activities and ACI categories, supporting those who choose to report data for a predetermined and fixed period of time that is best suited for their practice.

TMA Recommendation: For the qualify performance category, CMS should offer physicians and groups with multiple options for the 2018 MIPS performance period: test option, 90 days, or 12 months.

ICD-10 Measure Specification Changes During the Performance Period

We further recommend CMS clearly communicate to physicians how the annual ICD-10 update on Oct. 1 may impact quality measures, performance scores, and benchmarks for the last quarter of the year. The information is vital, especially for physicians and groups who may want to choose the last 90 days of 2018 as their performance period. TMA urges the agency to make this information known before the start of the 2018 MIPS performance period and future years, so that physicians and groups can take this issue into consideration and make an informed decision about the performance period best suited for their practice. In addition, CMS should release the updated ICD-10 files no later than 60 days prior to Oct. 1.

TMA Recommendation: To enhance program knowledge and help physicians and groups make an informed decision about which performance period to elect, CMS should post information and guidance on the Quality Payment Program website on how the annual

ICD-10 update may impact quality measures, performance scores, and benchmarks for the last quarter of each year. In addition, CMS should release the updated ICD-10 files no later than 60 days prior to Oct. 1.

Submission Mechanisms

Under the MIPS quality performance category, physicians and groups can select from among six data submission mechanisms to report their quality measures data to CMS: 1) Medicare Part B claims, 2) qualified registries, 3) qualified clinical data registries (QCDRs), 4) electronic health record (EHR), 5) CMS web interface, and 6) the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey.

Currently, CMS allows physicians and groups to submit data via multiple mechanisms for MIPS, but limits them to only one mechanism per performance category. TMA is pleased that the agency has proposed to revise this policy to provide physicians and groups with the flexibility to submit data on an unlimited number of quality measures via multiple data submission mechanisms but only count the submissions that result in the highest quality performance score. This policy would allow physicians and groups with an opportunity to receive the maximum number of points.

However, we note that some participants would not have the opportunity to take advantage of this proposed improvement. Due to measures gaps among specialties and subspecialties, and through no fault of their own, some physicians and groups have a limited number of applicable measures available to them. TMA sees this limitation as a fundamental issue and major flaw of the MIPS program. We urge CMS to prioritize known measures gaps and increase its efforts to facilitate a measure development and selection process to close the gaps that exist within the MIPS portfolio of quality measures. Until such gaps are improved, TMA urges the agency to re-evaluate its scoring policies for the affected participants who do not have the opportunity to achieve bonus points or take advantage of this policy due to measure limitations.

TMA Recommendation: To promote program fairness, CMS should increase its efforts to facilitate a measure development and selection process that addresses known measures gaps within the MIPS portfolio of quality measures.

In addition, because physicians and groups report that using a MIPS-related vendor to report their data on quality measures results in administrative and cost burdens for their practice, TMA recommends the agency offer reporting data via multiple submission mechanisms as an option rather than a requirement. For example, if a physician or group determines that only one submission mechanism is best for their practice -- even though their preferred reporting method limits them to fewer than the required number of measures -- they should be responsible and held accountable only for the measures that are applicable via that one method. TMA believes physicians and groups should not be required to contract with MIPS-related vendors and pay costly fees to report data on additional quality measures not reportable through their preferred method.

TMA Recommendation: To increase flexibility, but avoid undue administrative and cost burdens, CMS should offer physicians and groups the opportunity to report data on

quality measures using multiple submission mechanisms as an option and not a requirement.

Submission Deadlines
In support of program consistency, TMA is pleased that CMS is not proposing any changes to the submission deadlines, but offers a recommendation for improvement on this subject.

Currently, specific deadlines for each data submission mechanism are not easy to find on the Quality Payment Program website. In general, the only deadline readily available on the website is March 31, 2018. To learn of specific deadlines for the six data submission mechanisms available for the quality performance category, it takes additional time to sift through various CMS documents located in the Resource Library on the Quality Payment Program website. In addition, many MIPS-related vendors set their own deadlines well before the official CMS deadline, but the agency does not provide this level of detail. Because numerous MIPS-related vendors are available (e.g. over 200 combined registries and QCDRs), physicians evaluating which vendor to contract with for MIPS participation would have to spend valuable time clicking on each vendor link, searching the internet, emailing vendors, or calling them directly just to learn of their specific deadlines.

TMA acknowledges that the ideal time to engage with a vendor is before or at the start of the performance period. However, many practicing physician members report they are just now learning about MIPS and exploring their reporting options. Based on participation in the Physician Quality Reporting System (PQRS) program, we know that many members report they do not have the time or resources to coordinate their data collection via EHR system or manual entry via registry until just a few weeks before the submission deadline. Because many of our practicing physician members report being too busy with patient care and have limited time and staff resources to research MIPS requirements and deadlines, TMA recommends the agency consider the physician experience when determining what information it readily makes available on the Quality Payment Program website. TMA further recommends posting specific deadlines for each vendor on the vendor list documents offered by CMS. This basic, yet critical piece of information, would help physicians and groups determine the reporting mechanism and/or vendor best suited for their practice and busy schedules.

TMA Recommendation: To improve physician communication and support adequate planning for timely data collection, CMS should make information about submission deadlines for each data submission mechanism on the Quality Payment Program website, CMS vendor lists, and other locations the agency deems more effective.

Contribution to Final Score
Contingent upon the proposal to reweight the cost performance category to zero percent, the agency proposes maintaining a 60-percent weight for the quality performance category. TMA supports the agency’s proposal and agrees that the 60-percent weight for the quality performance category should be maintained for the second year of the Quality Payment Program.

TMA Recommendation: Contingent upon maintaining the cost performance category weight at zero percent, the quality performance category weight should comprise 60

percent of the final score for the 2018 MIPS performance period and 2020 MIPS payment year.

Submission Criteria for Quality Measures Excluding CMS Web Interface and CAHPS for MIPS Survey

With the exception of the new proposal that would allow physicians and groups to report data on quality measures via multiple data submission mechanisms, TMA appreciates the agency proposal to keep the same number of required measures for the 2018 MIPS quality performance category. However, we are concerned about the limited number of available measures for some specialties and some data submission mechanisms, resulting in an inability for some physicians to receive the maximum number of points.

Our review of the proposed quality measure list for the second year of the Quality Payment Program shows that for many specialties, the number of outcome and high-priority measures remains inadequate. Adding to this issue, very few measures are reportable through claims or EHR in comparison to the registry reporting mechanism, thereby steering and encouraging physician dependency on costly registry vendors. TMA again urges CMS to facilitate a measure development and selection process that results in closing the gaps within the MIPS portfolio of quality measures, ideally resulting in an equal number of measure options for physicians in all specialties.

In addition, TMA acknowledges additional provisions in MACRA direct the Secretary to *emphasize* outcome measures under the quality performance category, but we point out that the law does not *require* physicians to report data on outcome measures. TMA strongly supports physician choice and recommends CMS eliminate the requirement for one outcome or high priority measure. Instead, CMS should allow physicians to report only on the measures they determine are most meaningful to their specialty, practice, and patients. As an alternative, CMS could emphasize outcome measures by offering bonus points rather than making them a requirement. We believe this would reduce complexity in the measure selection process and be more meaningful to physicians and their quality improvement efforts.

TMA Recommendation: To support physician choice and patient-centered care, CMS should eliminate the requirement that all physicians and groups report on at least one outcome or high priority measure. Instead, CMS should require physicians and groups to report only on six measures of choice that are meaningful to their specialty, practice, and patients. If fewer than six measures apply, then only require reporting on each measure that is applicable for their respective specialties and preferred data submission mechanism.

Submission Criteria for Quality Measures for Groups Reporting via the CMS Web Interface

In support of program consistency, TMA appreciates that the agency is not proposing any changes to the submission criteria for quality measures for groups reporting via the CMS web interface. However, TMA suggests improvements in how the agency supports groups collect and submit data for this particular submission mechanism.

In the 2015 CMS PQRS experience report, the agency reported that practices that chose the CMS web interface submission mechanism continued to experience challenges, including lack of

understanding about the assignment and/or sampling methodology, inexperience using the web interface, and challenges between those providing care and those abstracting the data for submission. These issues resulted in some users not inputting the data properly.

Currently, groups reporting via the CMS web interface are required to meet data completeness requirements on all measures in the set or accept a score of zero for measures with incomplete data. Because continued challenges remain, TMA urges the agency to improve its efforts to help groups with 25 or more eligible clinicians successfully collect and submit data via the CMS web interface.

TMA Recommendation: To prevent data submission errors, CMS should make a greater effort to educate group practices that choose to report through the CMS web interface.

Performance Criteria for Quality Measures for Groups Electing To Report CAHPS for MIPS Survey

TMA appreciates that the CAHPS for MIPS survey will continue to be voluntary and recommends that the survey remain voluntary for MIPS participation for the quality performance category in future years.

Although the agency is not proposing any changes to the performance criteria for quality measures for groups electing to report the CAHPS for MIPS survey, CMS does propose making changes to the number of summary survey measures and to the survey administration period.

The agency proposes to shorten the survey administration period from four months to a minimum of eight weeks, ending no later than Feb. 28 for the second and future years of the Quality Payment Program. CMS states the current period has become operationally problematic for the administration of MIPS and that the new proposal would better facilitate timely computing of scoring. The agency further recommends removing two summary survey measures citing issues related to reliability and to align the CAHPS for MIPS survey with the CAHPS for Accountable Care Organizations (ACOs) survey.

TMA agrees with these proposals, but only after the agency has taken into consideration the analysis it plans to conduct, shares the information publicly, and lets the medical community review the results of the analysis and provide input prior to finalizing the changes. In addition, TMA urges the agency to communicate these changes well in advance of the annual registration deadline so groups have sufficient time to review survey changes and determine whether to elect to administer the survey.

TMA Recommendation: CMS should communicate all changes made to the CAHPS for MIPS survey well in advance of the annual registration deadline.

For future rulemaking, the agency seeks comment on expanding the patient experience data available for the CAHPS for MIPS survey by including five open-ended questions to assess how patients experience care. CMS reports that the questions it would use would come from the Agency for Health Care Research and Quality (AHRQ), which is fielding a beta version of a

"CAHPS patient narrative elicitation protocol." The agency reports that beta testing is an ongoing process and a concurrent review of the results with AHRQ is pending.

TMA appreciates the agency's transparency about its proposed future changes. However, in keeping with TMA policy on physician performance measurement, we strongly oppose the use of any additional measure, such as a narrative review, that is not evidence-based, does not improve patient care, and for which research data of pilot testing have not yet been publicly shared with the medical community for adequate vetting.

TMA Recommendation: CMS should not use narrative reviews as required criteria and as a form of physician performance measurement in the CAHPS for MIPS survey.

Additionally, the agency proposes to require all-payer data, where possible, including the CAHPS for MIPS survey. CMS seeks comment on ways to modify the methodology to assign and sample patients for the CAHP for MIPS survey using data from other payers. TMA disagrees with this proposal and strongly opposes the use of all-payer data to determine physician performance affecting only Medicare Part B payment, especially when CMS has no way of validating that all payer data are used to assign and sample patients across all payers and among all practices.

TMA Recommendation: To support an equitable assessment of survey data, CMS should not require all-payer data for the administration of the CAHPS for MIPS survey.

Data Completeness Criteria

In support of program consistency, TMA agrees with the agency's proposal to retain the data completeness threshold at 50 percent for the 2018 MIPS quality performance category. TMA appreciates the agency proposal to extend transitional year policies for the second year of the Quality Payment Program so that physicians and groups can gain experience with MIPS before increasing the data completeness threshold. TMA further agrees with the agency's concern that accelerating the data completeness threshold too quickly could jeopardize physicians' ability to participate and perform well under the MIPS quality performance category. TMA applauds the agency for considering the needs of physicians and groups who are least experienced with quality data submission and for being realistic by applying an appropriate level of data completeness to all participating physicians and groups.

However, the agency states it believes it is important to incorporate higher data completeness thresholds in future years to ensure a more accurate assessment of performance on quality measures and to avoid any selection bias. TMA opposes an increase in the threshold any sooner than the 2020 performance period. Instead, TMA recommends CMS keep the data completeness threshold at 50 percent until the agency has data insights similar to the data found in CMS PQRS experience reports. Historically, these reports were published by the agency two years after the performance period. If the agency follows the same pattern, the first CMS MIPS experience report would be published in the spring of 2019. If this is the case, TMA recommends CMS include in 2019 rulemaking reporting experience data and successful submission rates from the 2017 MIPS performance year for all physicians and groups and across all reporting mechanisms.

Revealing such data in rulemaking would help inform the agency, medical community, and other relevant stakeholders in determining the right threshold increase at the right time.

TMA Recommendation: To support program consistency and ensure physicians and groups are able to meet the data completeness threshold, CMS should keep the threshold at 50 percent for the second year of the Quality Payment Program and future years until the agency has data that supports an increase without adversely affecting successful participation.

Furthermore, for policies pertaining to data completeness, the agency proposes lowering the point floor for the 2018 MIPS quality performance category for those who fall below the threshold. Specifically, for the second year of the Quality Payment Program, CMS proposes only one point for measures that fall below the data completeness threshold, with an exception for those in group practices of 15 or fewer eligible clinicians, who would still receive three or more points for measures that fail data completeness.

Although TMA appreciates the efforts made by the agency to create favorable scoring for small practices, TMA opposes this proposal. We foresee this policy as a stepping stone to more stringent scoring in future years that would ultimately include small practices. Based on historical and current data, submission errors resulting in unsuccessful reporting will likely continue. Because we feel granting partial credit offers some reward for physicians who undertake costly reporting efforts, TMA strongly urges CMS to maintain quality scoring that ensures credit is granted to practices of any size that attempt to report the required data. We believe this policy is necessary to create some incentive to report. Therefore, TMA recommends CMS maintain the three-point floor for all physicians and groups regardless of practice size.

TMA Recommendation: To support program consistency and fair scoring, CMS should maintain the minimum three-point floor for all physicians and groups regardless of practice size.

All-Payer Data

Currently, under the MIPS quality performance category, the agency requires all-payer data for the qualified registry, QCDR, and EHR reporting mechanisms, but only Medicare Part B data for the claims, web interface, and CAHPS for MIPS survey reporting mechanisms. For the second and future years, CMS would like to include data from other payers for the CAHPS for MIPS survey. The agency states it believes this approach provides a more complete picture of each physician’s scope of practice and provides more access to data about specialties and subspecialties.

TMA continues to oppose the agency’s requirement and use of all-payer data to assess physicians’ performance on quality measures to determine Medicare Part B payment bonuses and penalties. MACRA specifically states that “analysis of the performance category described in paragraph (2)(A)(i) *may include* data submitted by MIPS eligible professionals with respect to items and services furnished to individuals who are not individuals entitled to benefits under part A or enrolled under part B.” (Emphasis added.) Since the law is permissive on this subject, all-payer data should not be required of physicians and groups for several reasons.

Medicare and other payers are very different in their patient populations; medical policies; billing requirements; payment for services, procedures and preventative care; and care coordination efforts. The payers also may have different patient education and outreach programs. These differences can result in varied patient choices, experiences, and quality outcomes that will, in many instances, favor practices with commercially-insured patients over those who have a high volume of Medicare or Medicaid beneficiaries or serve a diverse or disadvantaged population.

Since quality outcomes may vary by payer type and payer mix may vary among practices, TMA reiterates that this policy results in an inequitable assessment of quality performance among physicians and practices. Furthermore, the data needed for appropriate risk adjustment will not be available for patients who are not Medicare beneficiaries. We feel strongly that physicians and groups should not be rewarded or penalized based on variations in payer mix and patient populations.

In addition, the agency requires that data contain a minimum of one quality measure for at least one Medicare patient when reporting via mechanisms that require all-payer data, thereby potentially basing Medicare Part B payment adjustments on patient care largely representing other patient populations and not Medicare beneficiaries. TMA believes that a Medicare physician payment system that requires some physicians to report a portion of the data to represent all-payers and other physicians to report only Medicare Part B data, coupled with the fact that quality benchmarks are based solely on Medicare data, is a flawed program policy.

Furthermore, because the first MIPS performance year is ongoing and many physicians have yet to collect and submit their data, we believe this requirement will contribute to undue administrative burden by increasing significantly the volume of data needed per measure and make it more difficult to meet the threshold requirements for each data submission mechanism. TMA believes requiring all payer-data and expecting such a large quantity of patient data to be submitted successfully and without submission data errors is unrealistic and will not be feasible for many physicians, especially for physicians manually entering data through registries and QCDRs.

Lastly, TMA notes that many of the MIPS policies are designed to avoid selection bias that result in “gaming the system” and higher performance scores. Yet the agency is promoting the opportunity for selection bias through the requirement for all-payer data as it currently acknowledges that it does not have the capability to validate data completeness for other payers. By the agency’s own admission in the 2017 final rule, it has no data validation process in place to determine whether data representing all payers has been submitted by participants reporting data through the registry, QCDR, EHR, and CAHPS for MIPS survey data submission mechanisms.

Overall, TMA believes that Medicare bonus payments and penalties based on all-payer data are wrong.

TMA Recommendation: For the MIPS quality performance category, CMS should eliminate the requirement for all-payer data for assessing physician performance on quality measures to determine Medicare Part B payment bonuses and penalties.

Data Submission Criteria

In support of program consistency, TMA is pleased the agency did not make any significant changes to the data submission criteria for the second year of the Quality Payment Program. However, TMA offers comments and a recommendation to improve how the agency communicates data reporting requirements to physicians.

We call the agency's attention to critical information not currently found on the new Quality Payment Program website pertaining to data submission criteria for each submission mechanism. As of August 2017, eight months into the first MIPS performance period, the agency has yet to publish official MIPS guides that serve as an authoritative source for the 2017 quality performance category for the claims, registry, QCDR, and EHR reporting mechanisms. Under the PQRS program, the agency routinely published a series of guides (e.g. "reporting made simple" guides) that outlined data criteria and provided guidance to physicians on each data submission mechanism. Theses guides provided information such as measure requirements, data completeness criteria, where to find measure specifications documents that correspond to each mechanism, what the reporting process entailed for each mechanism, tips for collecting and submitting data, submissions deadline per mechanism, and where to turn to for assistance.

TMA has heard from many practicing physician members and their practice staff who need this guidance to review the steps and/or help them evaluate other reporting mechanisms available for the first MIPS performance year. They need to understand how to collect and submit their data accurately and ensure they avoid certain pitfalls to quality reporting. The guide most requested is for reporting quality data via Medicare Part B claims. Many physicians report they prefer to review an official CMS guide with their staff, rather than seek assistance and spend additional time gathering this information from other entities (e.g. Quality Innovation Network-Quality Improvement Organization, Quality Payment Program-Small, Underserved, and Rural Support, Transforming Clinical Practice Initiative, etc.).

Although the agency has made great efforts in educating and helping physicians transition from the CMS legacy programs to MIPS, we believe the absence of such guides may be the root cause of failed attempts at quality reporting for the 2017 MIPS performance period. We are highly concerned that this issue may adversely affect physicians who already have reported data or are continuing to collect and/or report data in good faith but are committing errors without their knowledge. To help our members, TMA has repeatedly requested these types of guides through the Quality Payment Program Service Center and was informed the information was relayed to CMS for consideration of future public guidance. However, as of Aug. 2017, the agency has not published any guidance.

In keeping with the agency's objective to enhance clinician experience through flexible and transparent program design and interactions with easy-to-use program tools, TMA urges CMS to publish official guides as an authoritative source for each data submission mechanism as soon as possible and before the start of each MIPS performance year.

TMA Recommendation: To improve program implementation and educate physicians about accurate collection and submission of data, CMS should publish official guides as an authoritative source for each data submission mechanism as soon as possible and before the start of each MIPS performance year.

Selection of MIPS Quality Measures Under the Annual List of Quality Measures Available for MIPS Assessment

TMA appreciates the annual call for measures and the practice of accepting quality measure submissions at any time. TMA disagrees with the agency's view that there should be no restrictions on who can submit a measure for consideration. We believe the agency should have professional standards in place to safeguard the process. TMA further disagrees with the agency's policy on how QCDR measures are considered for inclusion. We acknowledge that MACRA permits the agency to establish a process that bypasses the standard vetting process, but we strongly oppose this exception.

Consistent with TMA policy, we reiterate that CMS ensure that both MIPS and QCDR quality measures be evaluated through the standard vetting process by consensus-based entities; be published in applicable specialty-appropriate, peer-reviewed journals; and go through the notice-and-comment rulemaking and publication process in the *Federal Register*. Furthermore, TMA asserts all measures must be vetted with input from the medical community and relevant stakeholders, and must be developed and maintained by appropriate professional organizations that periodically review and update these measures with evidence-based information in a process open to the medical community.

TMA Recommendation: CMS should not use quality measures in the Quality Payment Program that have bypassed the standard vetting process.

With the use of funds authorized by MACRA ($15 million each fiscal year from 2015-19), TMA appreciates the agency's efforts and time spent working with the medical community, measure developers, and relevant stakeholders to identify measure gaps among specialties and target priorities aimed at advancing measure development to better support the Quality Payment Program. According to the CMS Quality Measure Development Plan 2017 Annual Report, the agency reports spending only $5.9 million to date. We acknowledge this amount represents costs associated with activities necessary to establish an appropriate foundation to support and inform future efforts. However, TMA urges CMS to take full advantage of all funding and accelerate its work to achieve a meaningful measure portfolio.

In our review of the list of measures, we continue to identify a deficit in quality measures for many specialties. We also note that many measures are not reportable through claims or EHR data submission mechanisms. We are concerned that the limited number of available measures per specialty and data submission mechanism will likely result in steering physicians to dependence on registries and QCDRs for data submission. TMA believes the MIPS program should be designed in a manner that minimizes financial and technological barriers to physician participation.

TMA Recommendation: To close measure gaps, CMS should accelerate its efforts and establish a more robust framework to achieve a meaningful measure portfolio for all specialties and data submission mechanisms.

Cross-Cutting Measures

TMA supports the agency's proposal to remove cross-cutting measures from most of the specialty sets and instead, place them on the general list of MIPS individual measures. We also are pleased cross-cutting measures will continue to stay on the list of MIPS measures and remain optional rather than a requirement.

The agency seeks comment on ways to incorporate cross-cutting measures into MIPS in the future. Since cross-cutting measures are intended to provide physicians with a list of measures that are broadly applicable to all specialties, we believe they should remain on the general list and remain optional in future years. TMA fully supports physician choice and believes that physicians and groups who find them relevant and meaningful to their practice will choose to report on them; those who do not should not have to report such data.

TMA Recommendation: To support physician choice, CMS should retain cross-cutting measures on the general list of MIPS individual measures and offer them to physicians on an optional basis and never as a requirement.

Topped-Out Measures

According to the agency, certain measures are considered topped out if measure performance is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made. TMA previously sought clarification on the agency's policy on topped-out measures and if such measures were retained, whether they were truly clinically relevant and meaningful to performance measurement and quality improvement. We appreciate the agency's clarification and believe the new proposal is an improvement from previous PQRS policy.

TMA agrees that topped-out measures should be removed using a phased-in approach and after taking several factors into consideration, such as specialty, case mix, practice size, location, and demographic or socioeconomic variables. TMA further supports the four-year timeline. However, we recommend that both MIPS and QCDR measures be removed only through a fair and transparent process, including through notice-and-comment rulemaking for feedback from the medical community and relevant stakeholders. TMA further opposes special scoring if it would adversely affect physicians and groups who already encounter a limited number of applicable measures with no bonus point or maximum point potential.

TMA Recommendation: CMS should use a phased-in approach to removing topped-out measures that includes a fair and transparent process, including through notice-and-comment rulemaking for feedback from the medical community and relevant stakeholders.

Cost Performance Category

While we agree that measuring cost is an integral part of value measurement, the ultimate measurement has value as a comparison tool only if the underlying component parts are fair and meaningful. The per-capita cost and Medicare-spending-per-beneficiary measures may be useful for some purposes, but they are misleading and harmful as measures of physician performance. The attribution rules used in calculating these measures can and do cause physicians to be rated based on costs of services for Medicare beneficiaries that are completely unrelated to any medical care the physician provided, ordered, or recommended. Using these measures, physicians often are being held accountable for services about which they had no knowledge, that were incurred in entirely different localities, that are completely unrelated to the services they provided to the patients. They may even be scored for the cost of services that they specifically advised against. Since this results in comparisons that are inaccurate and unfair, we oppose any scoring based on those measures.

TMA Recommendation: We support the proposal to assign a zero percent weight to the cost category.

We are hopeful that new episode-based measures will be more meaningful but remain concerned that even new, more carefully defined episode measures cannot be fair unless there are adequate adjustments to eliminate the known effects of various socioeconomic and cultural factors.

Improvement Activities Performance Category

Submission Mechanisms

TMA again appreciates the agency's inclusion of a broad range of activities to meet the requirements for the improvement activities category. We note that, of all the MIPS requirements, this may be the only one that is completely within physicians' control because they can choose which activities to participate in and complete them using their own time and efforts. We are also very pleased that CMS has increased flexibility and will allow physicians and groups to report through as many submission mechanisms as necessary in a manner that best accommodates their practice, including simple attestation. TMA recommends this flexibility for all future years of the Quality Payment Program as well.

TMA Recommendation: To increase flexibilitys and ease reporting burdens, CMS should allow physicians and groups to report their activities through as many submissions mechanisms necessary, including simple attestation.

The agency seeks comment on ways to measure performance and improvement in this category in future years. TMA opposes any new methodology that would add complexity or administrative and cost burdens for the improvement activities category. We strongly support physician choice and simplification for this category and recommend CMS simply provide full credit to any activity a physician and group chooses to engage in or implement.

TMA Recommendation: To reduce undue complexity and physician burden, CMS should not create new measure performance and improvement methodologies for the MIPS improvement activities category.

Required Activities and Special Considerations
In support of program consistency, we agree that the number of required activities and period of time for completing an activity should remain the same for the second year of the Quality Payment Program. We further appreciate that special consideration will continue to be given to non-patient-facing physicians and groups, as well as for those in small, rural, or health professional shortage area practices.

TMA Recommendation: In support of program consistency, the number of required improvement activities and period of time for completing an activity should remain the same for the second year of the Quality Payment Program.

Advancing Care Information Performance Category

Simplification. While TMA appreciates the *flexibility* that CMS is giving to the MIPS program, we also encourage the agency to adopt an underlying theme of *simplification*. Physicians report a heavy burden of participating in the program because it takes additional resources to understand all its nuances, such as how the various measures apply, when to track, for which patients, what to report, how frequently to report, etc... This burden redirects scarce resources away from patient care and reduces the likelihood of participation.

Cooperation with Surveillance and Direct Review of Certified EHR Technology (CEHRT)
The 2018 proposed rule makes no change in required cooperation with surveillance CEHRT in the physicians practice. This requirement should be removed. CMS should require EHR vendors to design systems that are interoperable and can compile needed health information to improve patient safety and meet all reporting requirements. The surveillance program is an unwelcome interruption to physicians and practice staff.

We agree that CMS and the Office of the National Coordinator (ONC) should have oversight of EHR and other technology vendors to ensure patient safety through usable software that conforms to best practices of development and usability standards. As part of Health Information Technology for Economic and Clinical Health (HITECH) funding, CMS awarded grants to researchers to make recommendations for good EHR design to support physicians, but the developed recommendations have not been broadly utilized. No EHR vendors are required to adhere to best practices of design, which is known to increase patient safety.

CMS and ONC need to focus on EHR vendor requirements rather than surveillance of end users. A well-designed system will support various workflows and allow the end user to choose the best use of the product for the best patient care and outcomes. Physicians are concerned about Medicare or ONC surveillance auditors taking time and resources away from patient care. CMS needs to devise a system for surveillance and direct review that does not include interference with patient care activities.

TMA Recommendation: This requirement should be removed. CMS should require EHR vendors to design systems that are interoperable and can compile needed health information to improve patient safety and meet all reporting requirements.

Support for Health Information Exchange (HIE) and the Prevention of Information Blocking
CMS should not require physicians to attest to support for HIE and the prevention of information blocking. Rather, CMS should require EHR and HIE vendors to design systems that are interoperable and can compile needed health information to improve patient safety and meet all reporting requirements. Physicians should not be penalized for the failures of the EHR vendors. CMS should not allow EHR vendors to charge physician practices any add-on fees for information required by CMS.

We are concerned that the requirement for attestation for support for HIE and the prevention of information blocking remains part of MIPS. Physicians who are in an untenable position due to vendor interface fees, ongoing vendor maintenance fees, transaction fees, and subscription fees should not be penalized.

TMA Recommendation: CMS should not require physicians to attest to support for HIE and the prevention of information blocking.

TMA has long supported HIEs and opposed information exchange blocking. TMA policy states "Patient safety, privacy, and quality of care are the guiding principles of all HIE efforts; cost reduction and efficiency are expected byproducts." Physicians want compatibility and interoperability supported by usable products and HIE services that can operate within the clinical workflow. One of the biggest disappointments of the HITECH Act is that millions of taxpayer dollars were spent to build the HIE infrastructure that is still underutilized due to cost and lack of well-defined standards.

Many EHR vendors charge physicians high fees to map discrete data fields to the HIE. The EHR vendors also charge monthly maintenance fees to maintain those connections. Constant technical fees can drive a practice to bankruptcy. TMA policy states, "Any costs of supporting systems providing health information technology (HIT) incentives to physicians should be borne by all stakeholders, clearly defined, fair, simple to understand, and accountable, and should support the financial viability of the considered practice."

TMA strongly supports efforts that encourage EHR vendors to provide open application programming interfaces and to tag data entered in EHRs in a way that allows them to be exported, imported, and shared easily. A single common data standard format for HIT and HIE would enable entities such as post-acute, long-term care, and behavioral health to invest definitively in data systems to support their operations. As it now stands, the lack of HIE is the main deterrent to real-life utility of such systems in the daily business and operations of such facilities. For behavioral health providers in particular, the legal constraints surrounding the exchange of sensitive behavioral health data impede HIE use. However, once a common data format and transfer protocol emerges, it will be possible to classify data subsets in accordance

with levels of security and privacy, allowing such facilities and providers of behavioral health to place themselves on the common grid without material fear of inadvertent breaches.

Physicians can be penalized or held financially liable for breaches and other problems inherent to electronic data exchange between health care entities. Requiring physicians to attest that they did not block the sharing of patient information, regardless of the maturity of the systems to which they connect, therefore puts them at risk of substantial liability if a significant data breach occurs beyond their control. This risk must be addressed before requiring physicians to participate in HIE, both by reducing risk through maturation of security standards for HIE and by protecting practices from penalties and liability for information breaches that occur beyond physicians' control.

TMA feels strongly that physicians should be able to send any piece of a patient's health data from one EHR to any other electronic database. To accomplish this level of data exchange, CMS and ONC should require EHR vendors to tag all EHR data elements with standardized extensible markup language (XML) as quickly as possible. Vendors also would need to be able to receive and process data feeds using this standardized XML, storing it in their native tables. This process is already used for the continuity of care document/continuity of care record (CCD/CCR), but on a limited scale.

TMA requests that CMS conduct a cost study of connection fees, ongoing maintenance fees, transaction fees, and subscription fees required by EHR vendors and HIEs. TMA agrees that physicians can attest to the ability to connect, but that ability to connect should apply only to the local HIE, direct protocol, or other technology capable of exchanging patient information.

TMA Recommendation: Physicians' attestation of the ability to connect should apply only to the local HIE, direct protocol, or other technology capable of exchanging patient information.

Improvement Activities Bonus Score under the Advancing Care Information Performance Category

TMA agrees that additional activities for ACI bonus points when using CEHRT functionality will provide more choices for eligible clinicians. TMA urges CMS to monitor and measure progress of available CEHRT functionality to support these activities. Physicians remain limited by the usability and functionality of their CEHRT.

Performance Periods for the Advancing Care Information Performance Category

TMA agrees with and appreciates the flexibility of minimum 90-day reporting periods in 2018 and 2019. This will allow pathways to report for practices that are struggling, yet provide opportunities for high-performing practices to choose full-year reporting to increase points earned.

Certification Requirements

TMA agrees with CMS' assessment regarding the burden placed on small practices to upgrade from the 2014 to 2015 CEHRT. TMA appreciates the consideration of incentivizing practices to use the upgraded version in 2018 by offering a one-time, 10-point ACI bonus for CY 2018. This

bonus should be available for and applied to all participants and not just new participants and small practices.

TMA Recommendation: CMS should make the 10-point ACI bonus for CY 2018 available to all participants, not just new participants and small practices.

Scoring Methodology Considerations
TMA agrees that if CMS adjusts the ACI score using two-year-prior data, it could cause confusion. CMS should allow time, and using a four-year-prior performance period is appropriate. As CMS calculates the number of eligible clinicians successfully achieving ACI, it should use only those clinicians who received the full ACI score of 25 percent.

TMA Recommendation: As CMS calculates the number of eligible clinicians successfully achieving ACI, it should use only those clinicians who received the full ACI score of 25 percent.

Advancing Care Information Objectives and Measures Specifications; Patient-Generated Health Data
CMS should not require patient-generated data be captured through the EHR. Physicians clearly want to get data from patients and already have mechanisms within the EHR to capture information provided by the patient. It is a dangerous precedent to open the system in ways that could compromise patient safety and confidentiality.

TMA Recommendation: CMS should not require patient-generated data be captured through the EHR.

Exclusions
TMA agrees with CMS on the e-prescribing and health information exchange exclusions for physicians who have difficulty achieving the base score because they seldom refer or transition patients. TMA heard from several physicians with high-performing practices that were unable to meet this measure because of their specialty and the nature of the patients served. TMA further agrees that these exclusions should be effective immediately and applied to the 2017 performance period.

MIPS-Eligible Clinicians Facing a Significant Hardship
TMA agrees that CMS should use the authority provided in the 21st Century Cures Act as it relates to application of significant hardship exceptions under MIPS and should not apply a five-year limit to such exceptions. TMA further agrees that non-patient-facing clinicians should receive the exception without the burden of filing an application annually, but should have the flexibility for participation if they so choose.

Significant Hardship Exception for MIPS-Eligible Clinicians in Small Practices
TMA agrees with CMS' offer to provide significant hardship exception to physicians in practices of 15 or fewer clinicians. CMS should define exactly what is considered "overwhelming barriers." This phrase can be subjective and at the discretion of the CMS reviewer. What may seem like an overwhelming barrier to a physician practicing in rural Texas may not be

understood by the individual or panel reviewing the applications. It would be harmful to physicians submitting an application with the presumption it will be approved only to have it denied. Once the performance period is over, the physician has missed the opportunity for participation.

TMA Recommendation: CMS should define exactly what is considered "overwhelming barriers."

CMS should offer significant hardship exceptions to physicians who are more than 65 years old. Physicians are retiring early to prevent the red tape of participation in MIPS. This is impacting access to care, especially for the most vulnerable populations of elderly and indigent. Physicians older than 65 should be exempt from the potential payment penalties from these programs. In some cases, forcing older physicians to implement technologies is more disruptive and may interfere with patient care or outcomes. Yet, these physicians are highly trained and experienced, and losing them to early retirement is a brain trust drain on health care.

TMA Recommendation: CMS should offer significant hardship exceptions to physicians over 65 years old.

Hospital-Based MIPS Eligible Clinicians
TMA agrees that hospital-based clinicians should have the opportunity to participate in ACI if they desire to do so and to be scored appropriately.

Ambulatory Surgical Center (ASC) – Based MIPS Eligible Clinicians
TMA agrees that CMS should set the ACI score to zero for ASC-based eligible clinicians, while still allowing the opportunity for participation in ACI if desired.

Exception for MIPS-Eligible Clinicians Using Decertified EHR Technology
TMA agrees that clinicians should be exempt from ACI if their CEHRT is decertified under ONC's Health IT Certification Program. Physicians should never be penalized when the ability to participate in MIPS is out of their control.

Hospital-Based MIPS-Eligible Clinicians
TMA agrees that CMS should modify its policy to allow an exception for physicians who practice in an off-campus outpatient hospital using place-of-service code 19. CMS correctly surmises that these physicians will not have control over development and maintenance of EHR systems in this setting.

MIPS Scoring and Bonuses

We support the proposals for bonuses for complex patients and for small practices, but understand that those bonuses are temporary provisions designed to offset existing flaws in program measures and reporting. We urge you to continue to improve the validity of program measures through redesign or improved risk adjustment and to continue efforts to simplify program reporting requirements.

TMA Recommendation: CMS should implement the proposed bonuses for complex patients and for small practices and should continue them until the program measures and design are simplified and improved.

EHR and Third-Party Data Submission Vendors

TMA acknowledges the role MIPS-related vendors play in supporting physician participation in the Quality Payment Program. If finalized, the agency's new proposal that would allow physicians and groups to submit their MIPS data through as many data submission mechanisms necessary would likely increase utilization of such vendors.

While the use of multiple submission mechanisms can help maximize scoring, TMA reminds CMS of the financial burden to physicians and groups who must make costly investments to connect or retool systems to interface with the required CMS technology. We also remind CMS that vendors continue to commit data submission errors regularly. Physicians report that they are sometimes reimbursed for the fees they paid for reporting though the vendor, but CMS does not remove the payment penalty and does not require that vendors reimburse physicians for payment penalties that stand for an entire calendar year.

CMS acknowledges that it cannot guarantee that vendors will be successful in submitting data. Instead, the agency suggests physicians and groups carefully consider the reputation of the entity when making their vendor selection as it believes practices are ultimately responsible for the data that are submitted by their vendors and expects that they are holding them accountable for accurate reporting.

We strongly disagree with the agency's view on this matter. TMA believes CMS should institute physician protections and create a hold harmless policy or new hardship exemption for physicians and groups who are adversely affected by a MIPS-related vendor. TMA urges CMS not to penalize physicians when vendors fail at any step of the data collection and submission process that affects performance scores or results in a payment penalty, especially when the issue is out of a physician's control.

TMA Recommendation: CMS should create and apply a hold harmless policy or offer a new hardship exemption for uncontrollable circumstances when any MIPS-related vendor commits data collection and submission errors that result in poor performance scores or payment penalties.

Furthermore, TMA recommends CMS create a Physician Compare-like website (e.g. "Vendor Compare") where the agency would publicly report data and submission error rates annually, as well as probationary and disqualification statuses for the following MIPS-related vendors: registry vendors, QCDR vendors, EHR vendors, CAHPS for MIPS survey vendors, or other health IT vendors that obtain data from CEHRT. This information would help physicians and groups "consider the reputation" as CMS suggests to make an informed decision about the

quality of their services. We believe this website would also help drive improvements and performance among the vendor community.

TMA Recommendation: For all MIPS-related vendors, CMS should create a "Vendor Compare" website and annually report data and submission error rates, as well as probationary and disqualification statuses.

Performance Feedback

MACRA requires that CMS provide timely feedback reports to physicians on their performance under the quality and cost performance categories. However, TMA believes feedback reports should contain data for all four categories. TMA further believes timely access to feedback reports is vital for physicians to identify gaps in care and then make improvements where necessary within the same performance period care.

TMA appreciates the agency's efforts in creating a new MIPS portal that will include features such as a data performance dashboard. TMA continues to urge CMS to allow submission of data more frequently throughout the year to provide timely feedback for corrections or compliance issues, as well as to avoid delays in performance improvement that affect scores or result in payment penalties.

For the 2017 MIPS performance year, CMS finalized the requirement that registries and QCDRs provide feedback at least four times a year within the performance period. The agency reports it also will leverage other MIPS-related vendors to aid in the dissemination of performance feedback reports to physicians. TMA appreciates this approach but believes physicians should not have to pay such vendors exorbitant fees for data and information that CMS is tasked by law to share and offers annually at no cost.

TMA Recommendation: CMS should accelerate its efforts on the new MIPS portal and develop new data submission processes and structures that facilitate real-time feedback for physicians.

Targeted Review

TMA appreciates that CMS will continue to offer requests for targeted reviews for physicians to appeal inaccurate data or calculation of their MIPS payment adjustments.

However, we remind the agency that under the PQRS program it sometimes experienced data issues, committed calculation errors, and mistakenly levied payment penalties on physicians. Since performance feedback reports are central to the MIPS program and the quality improvement process, TMA believe it is critical that physicians have the option to appeal data or calculation errors so they can base their improvement efforts on accurate data.

Many of our members encountered several challenges when they went through the informal review process under CMS legacy programs. Because a request for review is only a one-level review process, many physicians reported they did not have a sufficient opportunity to explain their unique cases and circumstances as to why they felt strongly their data was incorrect or why their payment penalties should be overturned.

According to our members, the previous process involved completing an online form with a response received only through email stating that the request had been denied or approved and that the final determination was final. When a request was denied, no further opportunity was provided to physicians. To enhance the physician experience and support program fairness, we urge CMS to improve and expand the targeted review beyond a one-level process. We further urge CMS to include the capability of speaking with a live person upon request rather than electronic communication via email. In addition, TMA also urges CMS to help physicians understand what went wrong so that they may identify areas for improvement and avoid repeating the same errors annually. Lastly, to ensure program transparency, physicians should receive detailed written feedback based on the results of targeted reviews.

TMA Recommendation: To promote program fairness and provide physicians and groups with a sufficient opportunity to appeal inaccurate data or calculation of their MIPS payment adjustments, CMS should expand targeted reviews beyond a one-level process. Further, CMS should include the capability of speaking to a live person upon request and provide detailed written feedback to physicians describing the nature of the results of targeted reviews.

Physician Compare

We continue to be concerned that the impact of unrelated variables on the measures used in reporting on Physician Compare make the reported information misleading. Although no risk-adjustment protocol is ever perfect, the validity of the measures used to compare physician performance could be improved by risk adjustment, which includes factors related to patient educational attainment, race, ethnicity, or religion, and a better factor to measure poverty. Alternatively, accuracy could be improved by implementing stratification or some other measure to compare physicians only to physicians with comparable patient populations, based on socioeconomic and cultural variables. Furthermore, efforts also should be undertaken to factor out the effects of local physician supply, which can affect access to ambulatory care and the use of high-cost emergency room services.

If measures were published on the Physician Compare website in a way that transparently displayed the nature of the measure, we believe that more patients could intuitively understand the data limitations and relevance. Patients realize that physicians often have limited control of patient behavior and choices and that a lower level of patient compliance with recommended treatments or tests may be a meaningless measure of the quality of care that physicians provide. The current practice of using ratings instead of reporting the actual measures is not transparent and tends to obscure the actual meaning of the data. Reporting should be completely transparent,

including the actual measure value, accurate descriptions of the measure itself, and qualifiers explaining what unrelated factors may affect the data.

TMA Recommendation: CMS should focus its efforts on making Physician Compare data more transparent and meaningful.

Data Validation and Auditing

In the 2017 final rule, CMS finalized policies that would allow the agency to selectively audit physicians and groups on an annual basis. Those selected would be required to comply with Medicare in accordance with applicable law, including reopening and revising MIPS payment determinations, and/or recoupment of payment. TMA feels strongly that such audits conducted for the first MIPS performance period only should be for education and support of physicians and groups.

TMA appreciates the guidance on audits and data validation criteria posted in the Resource Library of the Quality Payment Program website, but we find it inadequate. Although the first MIPS performance period began on Jan. 1, 2017, we remind CMS that it did not publish information about data validation criteria and documentation requirements for physicians until late April 2017 and then added additional documents after that time period. Many of our practicing physician members are just now learning about the criteria. Because much of the language is vague, many are having to use their best judgement on what the agency will accept.

For physicians who are selected for an audit, we appreciate the agency will provide them with an opportunity to set an alternate timeframe beyond the initial 45 days for data sharing requests. We recommend this flexibility be applied to the initial audit notice requiring physicians to respond within 10 business days. We believe Medicare should accommodate to physicians' schedules and extend the timeframe as needed for reasonable and valid reasons.

Additionally, TMA urges CMS to establish a fair and transparent auditing process with clear documentation requirements and data validation criteria for each MIPS category so there is no misinterpretation by physicians and groups. In addition, audit criteria should be readily available on its website prior to the beginning of each year rather than months into the performance period.

TMA Recommendation: To promote program fairness, CMS should establish a fair and transparent auditing process with clear documentation requirements and data validation criteria for each MIPS category so there is no misinterpretation by physicians and groups.

MIPS VIRTUAL GROUPS

Application of MIPS Groups Policies to Virtual Groups, Reporting Requirements
TMA is pleased the agency will establish policies for MIPS participation at the virtual group level. Virtual groups will increase flexibility for physicians and allow them to engage in the MIPS program individually, as a group, or as a virtual group. We further appreciate the agency's

proposal to implement virtual groups in a manner that offers them the flexibility to determine their own composition regardless of specialty, location, and size.

In support of program consistency, TMA agrees with the agency's proposal to apply group policies to virtual groups and offer the same measures and activities, unless otherwise specified. We further appreciate that special practice status will continue to apply if the entire virtual groups consists of 15 or fewer eligible clinicians, for those who meet the definition of non-patient facing groups, and for those who practice in rural and health professional shortage areas. However, given that virtual groups would comprise solo physicians and small group practices, TMA recommends virtual group policies allow for more flexibility in their first year of implementation, where possible.

TMA Recommendation: For the first year of implementation of virtual groups, CMS should implement policies that allow more flexibility, where possible.

We seek clarification on how virtual groups would ease administrative and cost burdens and benefit solo physicians and small group practices in both the short and long term. Additionally, TMA urges CMS to be transparent in describing known and potential advantages and disadvantages of virtual group formation for the purposes of MIPS participation and provide such guidance in writing before the registration deadline.

TMA Recommendation: CMS should be transparent in describing known and potential advantages and disadvantages of virtual group formation for the purposes of MIPS participation and provide such guidance in writing before the registration deadline.

Virtual Group Agreements

Although additional clarification in many areas will be necessary to give guidance to physicians, we are particularly concerned that information on antitrust enforcement relating to virtual groups is lacking. Although the relationships among virtual-group-eligible clinicians may be looser than what one might find in an ACO, the requirement that virtual groups execute a formal written agreement could amount to an express agreement among competitors and thus could invite antitrust enforcement scrutiny. Additional guidance from the Health and Human Services Department, but more importantly from the Department of Justice and Federal Trade Commission, could help to identify safe harbors and help clinicians identify and avoid potential pitfalls.

TMA Recommendation: CMS should request additional clarification on antitrust enforcement from the Department of Justice and the Federal Trade Commission relating to virtual groups.

ALTERNATIVE PAYMENT MODELS

Nominal Risk Amount

You requested comments on whether CMS should consider a different, potentially lower, revenue-based nominal amount standard for small practices and rural areas that are participating

in a Medical Home Model for the 2019-2020 Medicare Qualifying Participant (QP) performance periods.

TMA notes that small and rural practices have unique risk considerations that are important for CMS to recognize. Small and rural practices have operational risks, such as the training of staff, information technology maintenance, and other overhead expenses that put their practices at greater financial risk than other larger practices. Nevertheless, these practices work diligently to provide quality care for their patients.

In June 2016, TMA commented on the initial MACRA rule proposal that it was apparent that the long-term purpose of MACRA is for most physicians to participate in an alternative payment program. We noted that this would have the effect of pushing physicians into larger groups. We continue to believe that insurance-type risk when applied to small patient populations is unacceptably volatile. In patient populations served by one or a few physicians, a single poor outcome or high-cost case can cause the average cost to be well outside of acceptable results, potentially exposing the risk-bearing practice to financial losses. Physician practices do not have insurance-type reserves and cannot absorb financial losses other than those they already accept due to charity care, bad debt, and underpayment or nonpayment by Medicare, Medicaid, and some other payers.

TMA Recommendation: TMA strongly recommends that CMS require a lower nominal amount standard for small practices and other rural areas that are participating in an Alternative Payment Model for the 2019-2020 Medicare QP performance periods.

Medical Home Model

The regulations propose that to be considered Advanced APMs, the floor for nominal risk for Medical Home Models start lower than for more conventional APM entities. The regulations propose that beginning in 2018 the annual risk be two percent of the average total Medicare Parts A and B revenue of all providers and suppliers in the participating APM, with the percentage increasing by one percentage point per year until the floor reaches five percent in 2021.

TMA Recommendation: While TMA agrees that starting the nominal risk requirement at two percent is appropriate, we encourage CMS to hold the percentage constant for at least two years prior to an increase, rather than an annual increase. We believe this fosters a greater opportunity for the Medical Home Models, which traditionally have little experience with risk, to adapt and become successful.

Medicare Advantage Plans

The proposed regulations request comments on allowing those participating in Medicare Advantage to receive credit for that participation in QP determination.

TMA Recommendation: While TMA realizes there are statutory limitations in allowing Medicare Advantage providers to participate in Other Payer APMs, we strongly encourage CMS to explore ways to allow physicians' contracts with Medicare Advantage plans to meet the risk, quality, and certified electronic health information technology requirement

to be included under the beneficiary count test for the expected Advanced APM bonus in 2019 and 2020.

Other Payer Advanced APM - All-Payer Performance Period

The regulations propose a separate All-Payer QP Performance Period for the All-Payer QP/PQ determinations from Jan. 1 – June 30. The proposed All-Payer QP Performance Period would last, and determinations would be made based on two snapshot periods: Jan. 1 – March 31, and Jan. 1 – June 30. TMA notes that this is different than the Medicare QP Performance Period, which the regulations propose to maintain at Jan. 1 – Aug. 31.

TMA Recommendation: TMA is supportive of the All-Payer QP Performance Period proposals, but believes that the All-Payer QP Performance Period should align with the Medicare QP Performance Period. We believe this would make it easier for APM entities to predict whether they satisfy QP requirements under the Medicare option or the All-Payer option

Conclusion

We appreciate the opportunity to comment. Our comments have not addressed many provisions that may be of primary concern to physicians in individual specialties. With regard to these matters, we defer to specialty societies, which have the relevant clinical expertise to evaluate the rules.

Sincerely,

John T. Carlo, MD, MS
Chair, Council on Socioeconomics
Texas Medical Association

Ghassan F. Salman, MD, MBA, MPH, FACP
Chair, Council on Health Care Quality
Texas Medical Association