TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

June 27, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: 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; Proposed Rule

Dear Acting Administrator Slavitt:

On behalf of the Texas Medical Association (TMA) and our 49,000-plus physician and medical student members, we thank you for the opportunity to comment on the "Medicare Program: Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physicians Fee Schedule, and Criteria for Physician-Focused Payment Models" published in the *Federal Register* on Monday, May 9, 2016.

In the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress consolidated and revised Medicare penalty and incentive programs, intending to simplify and improve them. Unfortunately, as we review the draft implementing rules for MIPS, it appears that the net result is neither simplified nor improved. Revisions are needed both in Centers for Medicare & Medicaid Services (CMS) implementing rules, and, where regulatory latitude is limited by the language of the law, in the enabling legislation. Our general concerns include the following:

- Compliance and reporting is very costly – in the case of small practices, prohibitively so. The hoped-for reduction in these administrative costs with MACRA implementation has not materialized; even the draft rule's impact analysis reports that the new programs will add an additional compliance cost of $128 million above the pre-existing cost of the current Physician Quality Reporting System (PQRS), Electronic Health Record (EHR) Incentive Program, and Value-Based Payment Modifier Program (VM).

- Compliance costs exceed any likely financial return on investment through incentives and avoided penalties.

- Much of the resource use and many of the processes or outcomes that physicians are scored on are not in physician control.

- The factors that are not controlled by physicians are not evenly distributed in the population, so that physicians may be penalized if they serve disproportionate numbers of patients in certain cultural, racial, or ethnic groups, or patients who are disadvantaged in various socioeconomic measures. Those penalties create financial incentives for physicians not to treat certain patient groups.

- Because of the unpredictable factors that are beyond physician control, including patient outcomes and resource use, exacerbated by problems in the scoring criteria and currently unknown benchmarks, it is not possible for physicians to predict that participation in compliance efforts will result in any financial reward due to earned incentives or avoided penalties.

- Because small practices are the most adversely affected by the negative cost/benefit relationship, the budget neutrality requirement will result in a very large shift of Medicare payments away from small, often rural, physician practices to large, mostly urban, physician organizations and health care systems. This creates financial incentives for a massive restructuring of ambulatory care delivery systems, potentially eliminating the small physician practices that currently include nearly two-thirds of Texas physicians.

- There is no evidence that most of the requirements and incentives created in MIPS will offer any return on investment to Medicare. Many published studies of previous pay-for-performance programs, including many CMS pilot studies, have consistently shown no net savings to Medicare.

We are very aware that a number of these problems can be solved only by congressional action, but we believe that there are many regulatory actions that CMS can take within the current legislative framework that can mitigate some of these effects. Our detailed comments follow.

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COMMENTS ON PRIORITY ISSUES

Low-Volume Threshold

We agree that physicians who bill a low volume of services to Medicare should be exempt from the penalties and reporting requirements in MIPS but we strongly recommend that the low-volume threshold should be set high enough to exempt physicians who have no possibility of a positive return on the investment in the cost of reporting.

The quality reporting requirements in MIPS are substantially similar to the requirements of the predecessor program, but there are added reporting requirements and even less assurance of a return on investment. Therefore, there is no reason to expect practices who are currently being penalized under the existing programs to somehow find the necessary funds to invest in practice transformation efforts, EHR and information technology (IT) infrastructure, vendor expenses for quality reporting, clinical practice improvement activities (CPIAs), additional staff and resources, and overall program readiness, all while receiving combined payment cuts in 2017 and 2018 under the existing PQRS, VM, and EHR quality programs. Neither should it be expected that penalties and bonuses of up to 4 percent in 2019 will drive physician engagement to boost overall participation in 2017 when many physicians are being penalized at twice that percentage now.

The projections in Table 64 are indicative of how flawed the proposed rules are for the MIPS program. One only has to look at the historical PQRS data to infer that the quality reporting participation rates are unlikely to increase significantly between now and 2017. Therefore, the projected number of adversely affected physicians will remain high and MIPS implementation, as proposed, will result in a negative and dire effect for numerous physicians not only in our state, but across the nation.

Since the MIPS requirements are similar to those in the predecessor programs, we can estimate the compliance cost based on practice experience. A recent published study[1] in Health Affairs relied on the experience of Medical Group Management Association (MGMA) members to estimate the ongoing labor cost of reporting quality data to payers for primary care practices at more than $50,000 per physician. If we assume, very conservatively, that this cost distributes evenly across all payers, we can use primary care payer mix data from MGMA cost reports to estimate that the Medicare portion of this cost is approximately $10,600 per physician per year. The cost of compliance with the Advancing Care Information (ACI) requirements is somewhat more difficult to estimate, but it requires, at a minimum, implementation of an EHR system estimated in one published study[2] to be $46,659 per physician for the first year, and annual maintenance costs of $17,100. Ignoring the one-time implementation costs as well as any increased staff training costs and lost productivity, leads to a minimum annual cost per physician of $27,700 for quality reporting and EHR use.

[1] Casalino, Gans, et al. US Physician Practices Spend More Than $15.4 Billion Annually to Report Quality Measures, Health Affairs 35, No. 3(2016); 401-406
[2] Fleming et al., The Financial and Nonfinancial Costs of Implementing Electronic Health Records In Primary Care Practices, Health Affairs30, No 3(2011); 481-489

If we consider only the ongoing cost of quality reporting, compliance cost will exceed $10,000 per year per physician. Since physicians who undertake the reporting efforts can, on average, expect to avoid penalties but not earn incentives, the low volume threshold should be set in 2019 at $250,000 of Medicare revenue. At that amount, the avoided penalties at 4% would approximately equal $10,000. Below that amount there is no likely return that equals or exceeds the costs of reporting. For physicians with less than $250,000 of Medicare revenue, MIPS reporting should be optional, but physicians who attempt compliance should be exempt from penalties.

TMA Recommendation: CMS should set the low-volume threshold at $250,000 to exempt physicians who have no possibility of a positive return on the investment in the cost of reporting. For physicians with less than $250,000 of Medicare revenue, MIPS reporting should be optional, but physicians who attempt compliance should be exempt from payment penalties.

MIPS Performance Period

MIPS is the largest regulatory program physicians have ever had to comply with under CMS. As the proposed rules will not be finalized until on or around November 1, 2016, TMA does not believe two months is sufficient time for practice transformation efforts prior to January 1, 2017. Many of the program requirements, benchmarks, and information to assess reporting options will not be known until the proposed rules are finalized. It is not reasonable to expect all physicians to get adequately trained, make the necessary compliance decisions, coordinate with practice management vendors, redesign practice operations and clinical workflows, and train staff all within two months.

Furthermore, we have reason to question whether the multiple vendors who will be involved in this process — including EHR, registry, and practice management vendors — can complete their needed modifications in that short timeframe. Even simple product changes require extensive testing pre-and post-release to ensure data integrity for care quality and patient safety. Although Congress has provided some funding for compliance training, that training also cannot be done in such a tight timeframe to make a positive impact for practices who need the help the most within the first year of MIPS implementation.

When taking into account the CMS proposed methodology and point system, TMA recognizes that every point will matter to reach the highest possible composite performance score. To be successful in the MIPS program, we believe all physicians and other eligible clinicians should have sufficient time to evaluate the program in its entirety and weigh all options. For example, physicians should have enough lead time to review and select their quality measures well before the start of the year to align care plans and target or redesign clinical workflows to meet each quality measure and ensure data fields in either paper charts or EHRs support and meet each measure's specifications. These clinical actions and practice strategies are essential to reaching the highest benchmark decile under the new point system for the quality performance category.

Additionally, we note that qualified clinical data registries (QCDRs) are allowed to report on an additional 30 measures not on the list of measures within the proposed rule, and such measures

for each QCDR will differ from each other. However, CMS also states in the proposed rule that the list of measures available for reporting through QCDRs will not be available until spring 2017. This is unfair and unreasonable for eligible clinicians who choose to report through a QCDR. The delay in information about available measures and their specifications, such as required documentation, means that critical clinical actions will be missed for the first months of the performance period affecting clinical care delivery. This will likely result in failed reporting, low quality scores, and/or future failed audits.

For these reasons, the performance period for 2017 should be reduced to six months, from July 1, to December 31, 2017. The six-month delay will allow time for practice management vendors to prepare to meet all requirements, and for practices to make the necessary decisions and operational changes, and allow a few months for CMS to move forward with its plans to offer guidance and assistance to MIPS-eligible clinicians in practices of 15 or fewer eligible clinicians.

TMA Recommendation: To foster program readiness and compliance, the MIPS performance period in 2017 should be reduced to six months, and start no sooner than July 1 and end on December 31, 2017.

Composite Performance Score

The most important factor affecting the overall impact of the MIPS payment program on small practices is the setting of the performance threshold. CMS has complete discretion to set the performance threshold, which is the composite performance score that must be earned to avoid penalties. Furthermore, since the enabling legislation requires maximum penalties for scores below a quarter of the threshold, the threshold level controls how many physicians will receive no credit for partial compliance or reporting. The threshold also will determine the degree to which the MIPS program will result in a shift of Medicare payments from smaller physician practices to larger groups and health care systems.

Setting the benchmark higher results in a larger number of physicians who receive penalties and larger incentive payments to large practices that can absorb the necessary administrative costs to facilitate full compliance and reporting. To minimize the potential negative impact of this new, complex, and completely untested methodology, the first year performance threshold should be set very low. A performance threshold set at 15 percent would reduce the negative impact on small practices, ensuring that physicians who were at least successful in reporting clinical performance improvement activities will not be subject to penalties.

TMA Recommendation: To reduce the negative impact on small practices, CMS should set the performance threshold at 15 percent in the first year of MIPS implementation.

MERIT-BASED INCENTIVE PAYMENT SYSTEM

Quality Performance Category

Background

TMA appreciates the efforts that CMS has taken to simplify the quality reporting process, but we are extremely concerned that much more simplification will be necessary if physicians, particularly those in small practices, can be expected to attempt compliance. Many of our practicing physician members continue to report that the current PQRS program is highly onerous, administratively burdensome, and costly. Physicians report having great difficulty in keeping up with the ever-changing and complex requirements. Many who do not report state they simply do not have the time to research and read through endless CMS rules and program requirements to make an informed decision to even make an attempt to report data on quality measures to CMS.

Moreover, it has been brought to our attention that many of our members who have participated in PQRS reportedly did so only to find out that their efforts were not to be rewarded. Rather, they were financially penalized after making a good faith effort and costly investments to comply with reporting requirements. The most recent reported data in CMS' 2014 PQRS experience report shows that 1,322,529 professionals (physicians and non-physicians) were eligible to participate in PQRS nationwide. Of that total, 822,810 participated in PQRS, but only 585,037 qualified for an incentive payment, almost a 30-percent failure rate.

We also are aware that the program complexities create serious problems for CMS administration. We understand that CMS has taken great effort to implement the existing PQRS, VM, and meaningful use programs on a national scale, but has been unable to implement quality programs seamlessly and in a manner that physicians can easily understand and navigate. Physicians who do submit data on quality measures often have problems accessing accurate reports for the purposes of assessing their overall quality and cost performance. Report compilation errors like those that occurred with the 2014 feedback reports make physicians even less likely to take any action on a CMS-generated report. Feedback reports should be provided in a way that helps physicians identify gaps in care, so that they are better informed on where to target quality improvement efforts to improve patient care among their Medicare beneficiaries.

Before CMS considers raising the bar on quality reporting and increasing the degree of difficulty in meeting expanded data completeness criteria, TMA recommends CMS reevaluate its proposals to further simplify requirements to a level that is realistic and attainable by physicians for the first year of MIPS implementation. Simplified reporting and standards should also improve CMS' ability to manage program requirements.

TMA does recognize and appreciate the existing efforts to simplify reporting, including:

- Requiring only one set of quality measures instead of the previous separate measures for PQRS and the meaningful use EHR Incentive Program.

- Removing the requirement for measures to span across multiple National Quality Strategy domains.

We suggest further improvements are needed in the following areas:

Individual and Group Identifiers for Performance

CMS proposes simple methodology for clinicians to report as an individual by aggregating their performance under a single tax identification number (TIN) and national provider identifier (NPI), or TIN when reporting as a group. TMA agrees with this methodology, with the caveat that each individual clinician's data could be retained under its unique TIN/NPI identifier, such that later it may be de-aggregated to allow individual statistics for the individual clinician. This allows the portability of clinician performance information when moving from one practice to another. While groups and corporations can enhance patient care, ultimately care is provided to individuals by individuals. All systems of accountability and quality ultimately should reflect this fact.

TMA Recommendation: Individual physician data should remain accessible and portable when reporting as a group.

Submission Mechanisms

TMA opposes the proposal to require data for multiple performance categories to come through a single submission mechanism. Eligible clinicians know what is best for their practice and should always have the option to use any submission mechanism of their choice for each performance category as best determined by them and not CMS.

TMA Recommendation: To add flexibility and avoid undue complexity, CMS should allow multiple mechanisms of choice to submit data for all MIPS performance categories.

Group Reporting and Registration

We are pleased with the elimination of the registration requirements for many physician groups. This is a useful simplification of current rules.

Claims Processing of Quality Data

Given that the claims reporting mechanism is the most utilized reporting mechanism under PQRS, TMA opposes the CMS proposal to shorten the claims data run-out timeframe from 90 to 60 days. Reducing the timeframe will increase administrative burdens on physician practices as office staff will have to rush their billing to submit data on quality measures at the end of the performance period, likely resulting in claims data submission errors, which will result in practices falling below threshold, and failed reporting.

TMA Recommendation: CMS should use claims data that are processed within 90 days after the end of the performance period for purposes of assessing performance and computing the MIPS payment adjustment.

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

TMA appreciates that CMS has decreased the requirement in the number of measures from nine to six measures. TMA further appreciates the proposal to allow a broad choice of reporting methods for the quality performance category, but we are concerned about the limited number of available measures per reporting mechanism. Our review of the proposed quality measure list shows that for many specialties, there are few outcome and high-priority measures, as well as very few measures that are reportable through claims or EHR in comparison to the registry reporting mechanism.

TMA recommends CMS eliminate the requirement that calls for one cross-cutting and one outcome or high priority measure, and should require only the number of measures that are actually available per reporting mechanism and specialty measure set. We believe this option will reduce complexity in the measure selection process and will be more meaningful to physicians and their quality improvement efforts.

TMA Recommendation: CMS should keep it simple. For the first MIPS performance period in 2017, physicians should report at least six measures of choice that are meaningful to their practice and patients. If fewer than six measures apply per specialty and preferred reporting mechanism, then only require reporting on each measure that is applicable.

TMA does not agree with "appropriate use" measures in the MIPS quality performance category when there are differing professional opinions and a lack of evidence of what constitutes overuse or underuse of services, treatments, or testing. These types of measures interfere with clinical decisionmaking and the patient-physician relationship. MIPS should not use measures based on economic data rather than evidence-based, scientifically sound medical data. The criteria used to evaluate eligible clinicians must be evidence-based, fair, and truly evaluate quality and efficient care.

TMA Recommendation: CMS should not use "appropriate use" measures in the MIPS quality performance category unless they are evidence-based, fair, accurate, and broadly disseminated, and that truly evaluate quality and efficient care, not just cost.

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

Per the 2014 PQRS experience report, some web interface participants experienced challenges, such as a lack of understanding about the assignment and/or sampling methodology, inexperience using the web interface, and challenges with the layers between those providing care and those abstracting the data for submission. This resulted in some users not inputting the data properly.

TMA Recommendation: CMS should improve its efforts to adequately educate group practices who choose to report through the CMS web interface reporting mechanism.

Performance Criteria for Quality Measures for Groups Electing To Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

TMA appreciates that the CAHPS for MIPS survey will not be made mandatory for group practices with two to 99 MIPS eligible clinicians, and that the draft rule instead makes surveys an option. However, to further add flexibility to the measure selection process and reduce administrative and cost burdens, CAHPS for MIPS surveys also should be voluntary for all MIPS eligible clinicians. These surveys should be used only by group practices who find them meaningful to their practice and beneficial to their patients. Additionally, they should not be expanded to patients representing all payers.

TMA Recommendation: CMS should not require CAHPS for MIPS surveys for group practices of any size, and nor should the surveys be expanded to patients representing all payers. Instead, they should be made available, as an option only, to group practices that choose to conduct such surveys.

Data Completeness Criteria

To meet the data completeness criteria, CMS should improve and increase its efforts to adequately educate physicians and other eligible clinicians about how to avoid the pitfalls to quality reporting per each reporting mechanism. In the 2014 PQRS experience report, physicians who made a good faith effort to comply faced numerous challenges. Since voluntary measure validation audits have been conducted over the past three years, CMS should make an increased education effort to prevent the known root causes of data submission errors. Information should be readily available on its website so physicians and other eligible clinicians can learn best practices. TMA requests that CMS not continue its current confusing, confounding, and convoluted website with links to additional information and webpages, which is highly frustrating and wasteful.

TMA Recommendation: To avoid presenting confusing information similar to what is currently found on the PQRS website, CMS should disseminate best practices from MIPS experts, instructional designers, practicing physicians, eligible clinicians, and others as appropriate to simplify the content on its MIPS web site and make it more user-friendly, efficient, and effective.

All-Payer Data

Under MIPS, we note that CMS is proposing all-payer data for the qualified registry, QCDR, and EHR reporting mechanisms, but only Medicare Part B data for the claims, web interface, and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey reporting mechanisms. 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.) Although the law is permissive on this subject, it does not require the use of all-payer data.

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. They have different patient education and outreach programs. These

differences can result in varied quality outcomes that will, in many instances, favor regional practices over those who have a high volume of Medicare beneficiaries or serve a diverse population.

Requiring a portion of the data to represent all-payers and the remainder only Medicare, coupled with the fact that quality benchmarks are based only on Medicare data, will result in an inequitable assessment of quality performance. This requirement also will increase significantly the volume of data needed per measure and make it more difficult to meet the threshold requirements, which will result in failed reporting and payment penalties. Additionally, 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 those manually entering data through the registry reporting mechanisms.

TMA Recommendation: CMS should eliminate the proposed requirement for all-payer data for the purposes of performance assessment in the MIPS program.

Claims Reporting Mechanism

For the claims reporting mechanism, data completeness criteria should be reduced. The first year of MIPS implementation is not the time to significantly raise the bar and increase the degree of difficulty to meet quality reporting requirements. As previously stated, the agency assumes that the claims reporting mechanism will remain the most utilized mechanism to report data on quality measures to CMS in its first year of MIPS implementation; the agency has projected that 299,169 out of an estimated 703,467 MIPS-eligible clinicians will choose to report through claims. We believe that number will be higher. Either way, this means any change made to the claims reporting requirements will adversely affect a large number of physicians and other eligible clinicians.

Per the 2014 PQRS experience report, failing to meet the existing 50-percent reporting threshold is among the top three errors when reporting through claims. In 2014, only 44 percent of participants who reported quality data codes on claims were successful and incentive eligible; 18 percent of those who attempted to report via claims were unable to submit any measure correctly at all. The majority of participants have yet to master this reporting mechanism. Increasing the threshold will result only in additional administrative and cost burdens as billing clerks will be required to spend more of their time entering and reporting quality data codes on each claim. The reporting threshold should be realistically attainable based on past evidence before raising the requirement. The threshold should remain at 50 percent until CMS has taken action to adequately educate program participants.

TMA Recommendation: CMS should reduce the proposed MIPS reporting threshold for the claims reporting mechanism from 80 percent back to the existing 50 percent level.

QCDR, Qualified Registry and EHR Reporting Mechanisms

For the QCDR, qualified registry, and EHR reporting mechanisms, data completeness criteria also should be reduced. The law does not specify the amount of information that physicians and

other eligible clinicians must report. For these reporting mechanisms, the agency assumes and projects that a combined total of 214,590 eligible clinicians will report via qualified registry or QCDR in the first year of MIPS implementation, making registry reporting the second most utilized reporting mechanism in 2017. The agency also projects that 77,241 will report via the certified EHR technology mechanism. Again, this means any change made to reporting requirements may adversely affect a large number of physicians and other eligible clinicians.

Currently, registry reporting requires either a costly manual data entry process or additional fees paid for data integration services to obtain data from EHR and IT systems. The increased threshold will result in undue administrative and cost burdens as physicians and their staff will have to enter data on additional patients to meet the raised threshold. It will not be feasible for practices to follow through on 90 percent, resulting in failed reporting and payment penalties. The reporting threshold should remain at the 50-percent level for the first performance period and until all eligible clinicians, groups, and third party data submission vendors have collectively demonstrated accurate quality reporting without data submission errors and failed quality reporting.

TMA Recommendation: CMS should reduce the proposed MIPS reporting threshold for the QCDR, qualified registry, and EHR reporting mechanisms from 90 percent to 50 percent.

Annual List of Quality Measures Available for MIPS Assessment

Although improved risk adjustment is mandated by law, and CMS claims some intention to expand risk adjust in the future, there is still no immediate, concrete plan to do so. TMA requests that CMS immediately implement risk adjustment for all relevant socioeconomic factors that are not in physician control. No financial incentives of any kind should be based on quality measures that are not properly risk-adjusted. Additionally, volume minimums on all measures should be set high enough to avoid the statistical volatility of small numbers.

TMA Recommendation: For all quality measures, CMS should make no financial incentives of any kind based on measures that are not properly risk-adjusted. CMS should immediately implement risk adjustment for all relevant socioeconomic factors that are not in physician control and should set volume minimums on all measures high enough to avoid the statistical volatility of small numbers.

TMA appreciates that CMS is providing a preview of the proposed measures for inclusion in the annual list of quality measures and is providing physicians and other eligible clinicians the opportunity to select specialty-specific measure sets in the first year of MIPS implementation. It would be expected that the total list of quality measures available for MIPS assessment would consist of measures with the most significant clinical value and relevance to each physician's specialty or subspecialty and respective patient populations to truly improve quality of care and reduce costs.

However, in our review of the list of measures, we identified a deficit in quality measures for many specialties. We also noted that many measures are not reportable through claims or EHR

systems. The limited number of available measures per reporting mechanism and per specialty will likely result in dependence on third-party data submission vendors, which will add administrative and cost burdens for many practices.

TMA Recommendation: CMS should establish a more robust list of quality measures and offer more quality measures that are reportable through the claims and EHR reporting mechanisms across all specialties.

Peer Review

TMA recommends that CMS make the peer review process as transparent as possible and agrees with the agency's proposal to notify the public via the CMS web site of the requirement to submit new measures for publication in applicable specialty-appropriate, peer-reviewed journals. We also recommend that CMS use any other possible mechanism to meet this requirement. As required by the Act, TMA appreciates that CMS will follow through and publish new measures in applicable specialty-appropriate, peer reviewed journals before including such measures in the final, annual list of quality measures to ensure the measures are meaningful and comprehensive.

TMA Recommendation: CMS should make the peer review process for quality measures as transparent as possible before including new measures in the annual list of quality measures.

Measures for Inclusion and Exception for QCDR Measures

Recognizing that evidence-based medicine is continually evolving, measures should be evaluated and subject to regular review at intervals in accordance with current standards and whenever there is a major change in scientific evidence. TMA opposes the use of any quality measure in the MIPS program that has bypassed the standard vetting process by consensus-based entities and that has not been published in applicable specialty-appropriate, peer-reviewed journals, or has not gone through the notice-and-comment rulemaking, or publication process in the *Federal Register*. All measures must be adequately vetted with input from the medical profession 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 profession.

TMA Recommendation: CMS should not use quality measures in the MIPS program that have bypassed the standard vetting process.

Consultation with Relevant Eligible Clinician Organizations and Other Relevant Stakeholders

TMA appreciates the effort set forth by CMS and the Core Measure Collaborative to reach a consensus on core quality measure sets. However, TMA is disappointed that more measures from the sets were not included. TMA believes there is more work to be done to simplify and align quality measures among all payers.

TMA Recommendation: To ease administrative burden among all physicians, CMS should make measure alignment across all payers a top priority.

Scoring the Quality Performance Category

TMA is very concerned that the new MIPS scoring criteria, unlike the PQRS program, is not a pay-for-reporting program and does not offer physicians any guarantee that successful reporting will provide relief from program penalties. Since points are not awarded for reporting, but only for meeting yet-undefined benchmarks and performance standards, physician return on investment in reporting cost is even less certain than it was for PQRS. We strongly urge CMS to revise all quality scoring so that half of the available quality credit is granted to any practice that attempts to report the required data. Although reporting efforts may be unsuccessful, granting partial credit offers some reward for physicians who undertake the costly reporting efforts. Since performance outcomes and scores are highly unpredictable for small practices, this change is necessary to create some incentive to report.

TMA Recommendation: CMS should revise all quality scoring so that half of the available quality credit is granted to any physician who reports data on quality measures.

TMA finds it troubling to learn that of the approximate 270 measures proposed for the first year of MIPS implementation, CMS reports that approximately half of the measures are "topped out" measures when using 2014 PQRS data. Yet, CMS is leaving them on the list because otherwise there would not be enough measures to report across all specialties. By CMS's own definition, these measures are considered topped out because performance is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made. Under the PQRS program, CMS retired such measures.

We further note that the use of topped out measures is contrary to what is stated in the final CMS quality measure development plan for MIPS and APMs published in May that states that CMS is committed to retiring existing measures that do not add value for clinicians or patients, such as topped out measures. It is TMA's assessment that there is a serious foundational issue that results in a flawed quality payment program when CMS is using topped out measures for the sake of having enough measures across all specialties.

TMA seeks clarification on what CMS's official policy is on topped out measures and whether such measures are truly clinically relevant and meaningful to performance measurement and quality improvement.

TMA Recommendation: CMS should use only those quality measures that are clinically relevant and meaningful to performance measurement and quality improvement.

Our review shows that CMS must simplify the point system for the quality performance category to establish an equitable point system for all physicians and other eligible clinicians. The focus should be on quality measures that are most meaningful to a practice and not what will result in the most points. As designed, the proposed methodology and point system provide bonus points for reporting on extra outcome measures and high-priority measures or for reporting mechanisms

that require the use of third-party data submission vendors, and lower points for topped out measures or measures without benchmarks. This will create a perverse incentive for physicians to select only measures that will result in the most points, rather than on what is most meaningful to their practice and patients. Some specialties have very few measure options and will not have the option to work toward bonus points.

Because physicians have no control over what and how many measures apply to them and their patients, it is unfair to score topped out measures and measures with no benchmarks with fewer points. It is also unfair to provide bonus points for outcome measures and high-priority measures when not all physicians and other eligible clinicians will have the same options. TMA strongly urges CMS to revise the proposed scoring of the quality performance category and assign a full 10 points per measure for all measures types and eliminate the availability of bonus points until the agency has enough measures to offer the same options to all physicians and establishes an equitable point system among all participants.

TMA Recommendation: CMS should simplify the scoring of the quality performance category and establish an equitable point system for all physicians.

Resource Use Performance Category

Value Modifier Cost Measures Proposed for the MIPS Resource Use Performance Category

We are very concerned that CMS is proposing to continue to use the same measures that are used in the current value-based payment modifier program. Measures such as per capita cost and spending per beneficiary are not in physician control. Although physicians are held responsible for the cost of all resources used, Medicare's benefit design grants patients unrestricted access to covered benefits and providers, creating conditions where beneficiaries have more control over many types of resource use than any individual physician has. Furthermore, problems in categorization and attribution rules mean that physicians are held accountable for the costs of hospitalizations and other services that are completely unrelated to any of their own services, recommendations, or orders. Patients choose whether to accept physician direction or advice, affecting treatment outcomes and cost. Many patient actions and decisions are more strongly correlated to demographic or socioeconomic variables, or to local access to care issues than they are to physician efforts or actions. Depending on the specific circumstances, physician efforts to influence or modify patient decisionmaking may be costly but have little or no possibility to attain the desired results. If physicians face financial penalties for patient choices, the incentives that are created are not in the public interest.

If measures used in the MIPS payment program are related to patient demographic characteristics and are not adequately risk-adjusted for demographic differences that affect resource use — including poverty, educational attainment, race, ethnicity, or religion — the result will be penalties for physicians who treat patient populations that are lower-income, poorly educated, or members of particular demographic groups. Physicians faced with these penalties have incentives not to treat these populations and not to locate their practices in areas where these populations are prevalent. Because cultural and socioeconomic differences sometimes vary

regionally, poorly designed incentive programs could have negative consequences on local physician supply in some areas, creating or exacerbating problems with patient access to care.

TMA strongly urges CMS to eliminate measures affected by patient choices, education, abilities, culture, or socioeconomic status from the design and implementation of all aspects of MIPS. An incentive system that penalizes physicians who care for some types of patients could have dire effects on access to care for Medicare beneficiaries.

TMA Recommendation: CMS should eliminate measures affected by patient choices, education, abilities, culture, or socioeconomic status from the design and implementation of the MIPS incentives and penalties.

We are also concerned about the effect of poor physician supply on local cost and performance measures. In areas where there are shortages of physicians, good ambulatory care is less available and patients are more likely to rely on hospital emergency rooms for care. The net effect is an increase in total care cost and an adverse impact on quality of care measures that depend on good ambulatory care. The long-term outcome may be an exacerbation of the local physician supply problems if physicians who practice in the area are disproportionately subject to payment cuts. We urge you to analyze the effect of the current value-based payment reductions for 2016 to determine whether they are having an adverse impact on physicians who serve patients who live in poverty or those who live in areas where there are physician shortages or other barriers to care, and to immediately eliminate the use of all measures that are causing penalties to physicians based on those factors.

TMA Recommendation: CMS should analyze the effect of the current value-based payment reductions for 2016 to determine whether they are having an adverse impact on physicians who serve patients who live in poverty or those living in physician-shortage or where there are other barriers to care. CMS should immediately eliminate the use of all measures that are causing penalties to physicians based on those factors.

We note that validity of the measures could be enhanced if the patient preference and compliance variables were somewhat factored out of the statistics using appropriate risk adjustment. Although no risk adjustment protocol is ever perfect, the validity of the measures used to compare physician performance could be improved by risk adjustment that includes factors related to educational attainment, race, ethnicity, or religion, and a better factor to measure poverty. Although MACRA requires improvements to risk adjustment methods, there appears to be no current plan to make those improvements. We urge you to act quickly to revise the risk adjustment calculations of both cost and quality to account for the factors listed above. If CMS is not able to appropriately risk-adjust for patient demographic variables, none of the measures affected by those factors are statistically valid, and should not be used.

TMA Recommendation: Until CMS revises the risk adjustment methods used in the calculations of both cost and quality to adjust for factors related to educational attainment, race, ethnicity, religion, and poverty, no measures that are correlated to those factors should be used to reward or penalize physicians.

Attribution

The problems inherent in the per capita cost measures is exacerbated by the continuation of the current flawed attribution methodology. We are dismayed at the proposed efforts to improve the attribution methodology by adding further administrative cost and reporting burden on physicians by requiring them to report details of patient relationships — presumably with every claim filed. The necessity to add even more cost to make the measure meaningful is another reason to discontinue its use.

TMA Recommendation: CMS should eliminate any measure that cannot be properly attributed without detailed reporting by physicians about every patient relationship.

Clinical Practice Improvement Activity Category

We are very pleased with your inclusion of a broad range of possible methods to meet the CPIA requirements. 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 take and complete them using their own time and efforts. We are also very pleased that the proposed rule will allow physicians to report through multiple submission mechanisms using simple attestation.

We note, though, that compliance with the CPIA requirements does not replace the burdensome reporting for quality and ACI, but instead adds to it. While the compliance and reporting for each of the CPIA activities could be relatively manageable for physician practices, CMS has made attaining full credit prohibitively costly by requiring the completion of multiple CPIA activities to gain full credit.

Because compliance with the CPIA category grants a very small part of the total MIPS credit, burdensome compliance requirements are not merited. We are pleased that requirements are reduced for some physicians in certain practice sizes and designated locations, but we strongly recommend further reducing the requirements for all physicians and groups. Since the category is new for practices, physicians will need more time to understand the requirements and options, choose the CPIA activities that are most meaningful to their practice and patients, develop business and compliance plans within the context of the new MIPS program, and train their practice staff.

TMA Recommendation: To add further flexibility and ease administrative and cost burdens in the first year of MIPS implementation, CMS should reduce the required number of CPIAs for all physicians and groups regardless of practice size and location. Instead, for the first year of MIPS implementation, CMS should require only one CPIA of choice for solo and small practices of 24 eligible clinicians or less, and two CPIAs of choice for larger practices of 25 eligible clinicians or more. Using these requirements, physicians and groups should achieve the full 15 percent weight for the CPIA category.

Scoring the CPIA Performance Category

TMA notes that the MIPS strategic goal for the CPIA performance category is to establish policies that will be scaled in future years as the bar for improvement rises. We recognize that the first year of MIPS implementation will serve as the baseline that CMS will use to create more stringent requirements in future years and lay the groundwork for expansion towards continuous improvement over time. Because of this, we foresee onerous rules and regulations that will add even more administrative and cost burdens and undue complexity to the MIPS program over the course of the next few years.

TMA Recommendation: To reduce administrative and cost burdens and undue complexity in the MIPS program, CMS should simplify the CPIA performance category as much as possible and should not establish policies that create onerous rules and regulations for physicians.

Additionally, we do not agree with CMS to use a differentially weighted model for the CPIA performance category that uses "medium" or "high" weights. There is no evidence that this model results in clinical practice improvement within the context of a national and complex quality program. As stated in the proposed rule, CPIA standards are not nationally recognized and there is no professional entity for CPIAs that serves the same function as the National Quality Forum does for quality measures. Of the 94 CPIAs on the proposed CPIA inventory, we note that 83 are weighted as medium and only 11 are weighted as high. We find the assignments of medium and high weights for each CPIA, and the required 90-day time period for performing an activity to be highly arbitrary and disruptive to physician practices.

This approach to CPIAs will only make participation more difficult. Physicians should always be able to choose any CPIA of choice that is most meaningful to their patients and feasible to their practices based solely on their judgement and not on a CMS-designed weighted model that is not evidence-based.

TMA Recommendation: To ease administrative and cost burdens for the first year of MIPS implementation, selection of a CPIA should be based on physician choice regardless of medium or high weights and time period, and scoring should be further simplified.

Advancing Care Information Category

We appreciate the efforts to simplify reporting but several further improvements are needed. Our specific comments include the following:

Base Score

We approve of the proposal to downgrade computerized physician order entry (CPOE) and clinical decision support (CDS) criteria from the incentive program as it was irrelevant and burdensome, but CMS needs to increase flexibility so that clinicians only have to report on measures relevant to their specialty as needed for better patient care. For all the prior key domains for the meaningful use program, eligible professionals (EPs) still must indicate at least one patient in the numerator position for each domain. While this will be easier than achieving threshold percentages, many clinicians will find several of the domains irrelevant, and will end

up spending unnecessary funds to hire a consultant to assist with achieving 'one test case' for each domain. CMS should focus on needed flexibility by not requiring clinicians to attest to technical features that are not useful or relevant to better patient care.

TMA Recommendation: CMS should increase flexibility so that physicians only have to report on measures relevant to the specialty as needed for better patient care.

Electronic Prescribing

We appreciate the consideration by CMS to allow physicians to choose whether to include controlled substances in the definition of permissible prescriptions. While many states now allow ePrescribing of controlled substances, not all vendors have enabled the functionality needed to comply with the law.

TMA Recommendation: CMS should continue to monitor whether EHR vendors have functionality for ePrescribing of controlled substances.

Patient Electronic Access

CMS should permit physicians to count transmission of consolidated-clinical document architectures (CCDAs) to patient personal health records in meeting the patient electronic access measures. If the patient has a personal health record, the physician should get credit for sending the information to the patient without having to prove the patient received or opened it. Patients want consolidated portals and personal health records. When CMS incentivizes physicians to maintain a separate portal to meet performance requirements, physicians are forced to go against patient wishes. Patient preference must be honored.

TMA Recommendation: CMS should permit physicians to count transmission of CCDAs to patient personal health records in meeting the patient electronic access measures.

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 the safety and confidentiality of patients.

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

***Immunization Registry* Reporting**

CMS indicates that the MIPS-eligible clinician is in active engagement with a public health agency to submit immunization data. This is not indicated as an optional measure. The measure needs to be optional as not all physicians administer immunizations. It is a waste of resources for clinicians to build interfaces to registries they simply do not need and will not use**.**

TMA Recommendation: CMS should not require physicians who do not administer immunizations to connect to immunization registries.

Hospital-based MIPS Eligible Clinicians

TMA believes that place of service (POS) code 22 should be included in the hospital-based definition, even though it is considered outpatient. Physicians who use POS 22 typically are using the hospital-based EHR during the patient observation period.

TMA Recommendation: CMS should include POS code 22 in the hospital-based definition.

Medicaid

Do not require physicians participating in the Medicaid EHR incentive program to report on two separate programs to satisfy the requirements for meaningful use and MIPS. CMS should choose one program for reporting, whether meaningful use or MIPS, and allow physicians to receive credit for participation for both programs.

TMA Recommendation: CMS should not require physicians participating in the Medicaid EHR incentive program to report on two separate programs to satisfy the requirements for meaningful use and MIPS.

Health IT Vendors that Obtain Data from MIPS Eligible Clinician's Certified EHR Technology

TMA agrees with CMS that it would be helpful to expand certified EHR vendors' capability to submit data on all MIPS performance categories thus streamlining the process for physicians. TMA is cautiously optimistic that the certified EHR technology (CEHRT) vendors will provide the needed services at reasonable costs with solid, usable interfaces that work well with certified EHRs. Physicians should have choices that allow them to participate in the program and report their data whether through approved vendors or by attestation. At no time should physicians suffer due to the inability of a certified vendor to submit information to CMS when the physician contracted with such entity in good faith that the work would be performed satisfactorily.

TMA Recommendation: CMS should monitor certified EHR vendors' capabilities to submit data for all MIPS performance categories. There should be CMS incentives to vendors that can comply with reporting in all categories.

Hardships and Exclusions

CMS should retain all existing hardships and exclusions from the meaningful use program. CMS developed the hardship categories understanding the significant barriers that would prevent physician participation.

TMA Recommendation: CMS should retain all existing meaningful use hardships and exclusions.

90-Day Reporting Period

CMS should maintain the 90-day reporting period for ACI first-year participants. There are numerous challenges with workflow and data collection when physicians first begin participation in the meaningful use (now ACI) program. Participants should retain the opportunity to crawl, walk, or run with these complex programs.

TMA Recommendation: CMS should maintain the 90-day reporting period for ACI first-year participants.

Performance Feedback

The law requires CMS to provide timely feedback reports to physicians on their performance under the quality and resource use performance categories beginning July 1, 2017. However, we note that CMS proposes to initially provide feedback in the first reports using only historical data based off performance that occurred in 2015 and 2016 and does not plan on providing feedback on performance that occurs in 2017 until sometime in 2018. This timeframe relative to the performance period is not considered timely. TMA believes that rewarding and penalizing physicians in 2019 using two year old data and expecting that feedback reports in 2018 that include information on performance that occurred in 2017 will somehow improve patient care is unrealistic and unacceptable.

TMA Recommendation: CMS should immediately design a process that provides real-time feedback for physicians.

Timely access to feedback reports is vital for physicians to identify gaps in care. This also provides them the opportunity to make improvements where necessary. CMS indicates they plan to provide timely and confidential feedback on performance under the quality and resource use performance categories. However, feedback regarding the CPIA and ACI categories is left to the discretion of CMS. All data reported by physicians should be provided within the same feedback reports.

TMA Recommendation: To reduce undue complexity and administrative burden, CMS should provide timely performance feedback on all data reported by physicians within the same feedback reports.

Physicians need time to review their reports and potentially file an appeal with CMS regarding inaccurate data. The agency had problems last year with providing accurate PQRS feedback reports and quality and resource use (QRUR) reports. Two months after initially releasing them, CMS issued notice that updated 2014 quality reports were available. CMS said it identified problems with data submitted by vendors on behalf of physicians through EHR and QCDRs. CMS also found technical issues with claims used to determine claims-based measures. Those

errors should not have been attributed to physicians and again show the importance of allowing vendors adequate time to make sure their systems are fully ready for MIPS implementation.

TMA Recommendation: CMS should employ effective communication strategies and notify physicians immediately when the agency is aware of errors that affect data in performance feedback reports. CMS also should be transparent about the nature of the issue and provide physicians with a detailed description as to why errors occurred and what the agency plans to do to prevent them from happening again.

TMA agrees with CMS that many physicians are still unaware of their performance feedback through QRURs and/or have difficulty accessing their reports in the portal. The reports are perceived as complex and difficult to understand, thereby defeating the purpose of the current CMS quality programs. CMS should make data available online and through a dashboard. Any new portal set up to obtain the data should not require additional sign-up steps that require the physician to wait several days for approval of a log-in. Additionally, CMS should provide advance training on using the online portal and the dashboard, and physicians should be able to assign their log-in to designated staff since they will most likely be downloading the information for the physician.

Furthermore, TMA believes CMS should work with physicians to develop a report structure that contains relevant and necessary information for physicians to assess their performance. Multiple pages of unnecessary and useless data create an administrative burden and serve little purpose. A streamlined report that could easily be compared to data physicians can access from their EHR and other vendors would provide incentives for accessing the reports in a timely manner.

TMA Recommendation: CMS should include input from physicians and work diligently to make reports easily accessible and develop accurate, timely, and relevant performance feedback reports that present data in a manner that is meaningful and easy to understand by all physicians.

Targeted Review

TMA appreciates that CMS will continue to implement an informal review process, now referred to as targeted reviews. In the past, CMS has experienced data quality issues, committed calculation errors, and mistakenly levied payment penalties on many physicians. Since the performance feedback reports are central to the MIPS program and the quality improvement process, it is critical that physicians have the option to appeal inaccurate data or calculation errors. To facilitate the targeted review process, CMS should minimize administrative burden and allow more time for physicians and other eligible clinicians to appeal the content in their reports and calculation of their MIPS adjustment factor(s).

Additionally, to ensure transparency, physicians and other eligible clinicians should receive detailed written feedback based on the results of targeted reviews. Under the current informal review process, physicians report receiving a statement simply stating they were “denied,” with no further explanation as to why they will receive a payment penalty. CMS should help

physicians understand what went wrong so that they may identify areas for improvement and avoid repeating the same errors year after year.

TMA Recommendation: CMS should provide detailed written feedback to physicians describing the nature of the results of targeted reviews. CMS should extend the targeted review process from 60 calendar days to 90 business days and extend the time period when physicians are requested to submit additional data from 10 calendar days to 30 business days. If CMS issues revised reports at any time during the targeted review period, the time period should be reset for all physicians and start with another 90 business days.

Data Validation and Auditing

TMA opposes combining the past program integrity processes of the data validation process used in PQRS and the auditing process used in the Medicare EHR Incentive Program. The data validation process used in PQRS has been voluntary and should remain so until CMS has provided a sufficient time period for program readiness to ensure full compliance with each MIPS category. Otherwise, the short time frame at the end of 2016 will only set up physicians to fail such audits in the future.

TMA Recommendation: For the first year of MIPS implementation, CMS should continue to conduct data validation for quality measures on a voluntary basis.

Third-Party Data Submission Vendors

TMA appreciates that physicians and other eligible clinicians will have several options when selecting a submission mechanism to report data on quality measures. TMA acknowledges that the use of third-party data submission vendors may help to streamline reporting processes among the performance categories as well, but only when done correctly. While a single reporting submission mechanism can simplify the process, CMS should be aware of the financial burden to physicians and other eligible clinicians who must retool current systems to interface with the required CMS technology. TMA cautions that what may seem like a simple solution to CMS, will be burdensome to physicians.

We note that many physicians and other eligible clinicians will have to pay costly fees to submit their data on quality measures via several fee-based quality reporting mechanisms managed by third-party data submission vendors. We remind CMS that third-party data submission vendors continue to commit data submission errors annually. 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.

We strongly believe that physicians should be held harmless when the technology fails at any step during the quality reporting and data submission process. Therefore, TMA strongly urges CMS to institute physician protections for these instances.

TMA Recommendation: CMS should create and apply a "hold harmless" policy, meaning no payment penalty, when third-party data submission vendors commit data submission errors that result in poor quality performance scores or failed reporting, especially when the issue is out of a physician's control. CMS should also finalize all the data to be reported and have vendors develop the software for physicians to comply with these requirements. Vendors should not be allowed to add additional charges for any reporting requirements that fall within the criteria that CMS has established.

CHANGES TO EXISTING PROGRAMS

Cooperation with Surveillance and Direct Review of Certified EHR Technology

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 effectively choose the best use of the product for the best patient care and outcomes. The suggested surveillance will result in unwelcome interruptions and increased administrative burden in busy medical practices. Physicians are concerned about Medicare or ONC 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. ONC and CMS can solicit input from physicians through other avenues and venues, allowing end users to speak candidly about patient safety and usability issues.

TMA Recommendation: 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 as described in the proposed rule would be unduly burdensome and an unwelcome interruption to physicians and practice staff. Therefore, CMS should not require physicians to participate in an EHR surveillance program.

Support for Health Information Exchange and the Prevention of Information Blocking

We are concerned about the way that the proposed attestations will be understood or applied. If it is cost prohibitive for a physician to connect to the health information exchange due to vendor and exchange fees, is he or she knowingly and willfully limiting or restricting the compatibility or interoperability of certified EHR technology? 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 has long supported health information exchange (HIE) 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 the fact 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 physicians with monthly maintenance fees to maintain those connections. Constant technical fees can drive a practice to bankruptcy. TMA policy further states, "Any costs of supporting systems providing 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 it to be easily exported, imported, and shared. 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 determinant in the lack of 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 from a practical standpoint. However, once a common data format and transfer protocol emerges, it will be possible to classify certain data subsets in accordance with levels of security and privacy; finally allowing such facilities and providers of behavioral health to place themselves on the common grid without material fear of inadvertent breaches.

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.

Regarding the three statements that physicians must attest to, the second provision states that the clinician is required to attest that he or she "implemented technologies, standards, policies, practices and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law that the certified EHR technology was, at all relevant times: connected in accordance with the applicable law;…" This is akin to asking a pilot to certify that the plane's engine is built and installed according to set standards. Pilots are not required to understand the mechanics of an airplane, nor should they. Their skillset is flying the plane. Physicians should not be required to be computer experts. They should be trained to use the EHR effectively for patient care, including recording of information needed for continuity of care.

Additionally, TMA suggests that as part of EHR certification, vendors indicate product capability to comply with current and future MIPS requirements. Many times physicians are caught between regulations and product capability. Physicians should be held harmless if a product does not conform. The third required attestation is confounding, seeming to imply that all requests for information should be exchanged electronically. Not only are there limits to technical capabilities, but, as discussed above, not all physicians will be able to use their health information exchange due to financial burden. TMA requests that CMS conduct a cost study of fees required by EHR vendors and HIEs to determine 1) connection fees, 2) ongoing maintenance fees, 3) transaction fees, and 4) subscription fees.

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: Again, 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. Physicians should not be penalized based upon failures of the EHR vendors. CMS should not allow EHR vendors to charge physician practices any add-on fees for information required by CMS.

ALTERNATIVE PAYMENT MODELS

It is apparent that the long-term purpose of the new payment strategies is for all physicians to participate in an alternative payment program. This requirement, too, will have the effect of pushing physicians into larger groups. Insurance-type risk, when applied to small patient populations, is unacceptably volatile. Insurance companies accept risk only for larger populations. Those companies are required by state regulation to hold large financial reserves precisely because, even in larger groups, costs are not entirely predictable and can vary due to unexpected events. In small 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 face due to charity care, bad debt, and underpayment or nonpayment by Medicare, Medicaid, and some other payers.

TMA Recommendation: CMS should protect the individual and small group physicians by not forcing any physicians to accept more risk than they can financially manage.

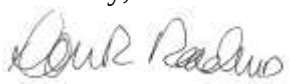
In response to Medicare's efforts to encourage the development of alternative payment programs, many Texas physicians have worked diligently over the past several years to build collaborations or groups with the appropriate relationships and infrastructure to successfully participate in various APM models. In many cases, these groups have undertaken substantial investment in developing working APMs, including investment in software and report customization, developing new communication methods, revising standard protocols and operational procedures, and retraining the medical team and all support staff. Some of these groups were early adopters and have been successfully participating in Medicare-approved

programs for several years. We find it shocking that these successful APM programs will be unable to qualify for the promised APM incentives. If CMS wishes to encourage, rather than discourage, APM participation, physician practices should not see APM status as unattainable due to the high burden set by these regulations. Rather than creating barriers that prevent existing APM participants from qualifying as advanced APMs, we urge CMS to revise the proposed rule definitions to ensure that the considerable efforts undertaken by currently qualifying APM participants do not go unrewarded.

TMA Recommendation: CMS should find a way to include existing, successful APM program participants in the definition of Advanced APMs eligible for MACRA's financial incentives.

In conclusion, we appreciate the opportunity to comment on the proposed implementing rules, both in this form, and in other arenas. We strongly believe that Congress did not intend many of the adverse consequences that will be the result of the new MIPS payment formula. We are hopeful that CMS will use its considerable discretion to act in every way possible to minimize the adverse impact.

Sincerely,



Don A. Read, MD
President