TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

September 1, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Sirs:

On behalf of the Texas Medical Association and our 45,000 physician members in the state of Texas, we thank you for the opportunity to comment on the proposed rule "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016" published in the *Federal Register* on Friday, July 15, 2015. Detailed comments follow but please note that we are not commenting on various RVU revisions and other changes that are specialty-specific. We urge you to carefully consider comments from specialty societies on these subjects where they have particular expertise not common to all physicians.

General Administrative Burden

We are generally concerned that the growing Medicare administrative burden, added to the recent history of and future plans for inadequate fee updates, is making Medicare participation and compliance increasing difficult and costly for practicing physicians, and will impair access to care for Medicare beneficiaries. The administrative burdens of compliance and reporting in programs such as PQRS, coupled with growing penalties for non-compliance or for unsuccessful efforts to comply, make participation in Medicare an increasingly unattractive proposition to the smaller sized practices common in Texas. Administrative costs include the costs of acquiring and maintaining current knowledge of changing rules and compliance methods and the purchase or update of practice software, in addition to the actual work of documenting and reporting. Requirements which take physician and staff time and attention away from the direct clinical care of patients are increasing the cost of medical practice and decreasing physician productivity. Although almost all physicians will treat some Medicare beneficiaries, even if only when they take emergency room call, 37 percent of Texas physicians report that they now have limits on accepting new Medicare patients. Continuing to add administrative burden without increasing fees commensurately will mean that treating Medicare patients will become increasingly unprofitable and Medicare business increasingly unattractive for physicians. Medicare beneficiaries who cannot access outpatient physician care will increasingly seek care in emergency rooms, driving total Medicare cost higher. **When Medicare adds administrative burdens, those added burdens should be accompanied by RVU or conversion factor increases to offset the added costs**.

Improving the Valuation and Coding of the Global Package

The need to collect data on global billing provides a good example of the problem and solution outlined above. Collecting data from physician practices could best be facilitated by offering compensation to

practices for reporting. This can either be done by soliciting a random sample of physicians to submit to cost studies, and paying for their participation costs, or by requiring all physicians to report certain data and compensating all of them for the increased cost. The compensation must be adequate to cover data collection and reporting costs and provide a reporting incentive. Compensating physicians for reporting can also increase data accuracy. For example, if you simply ask physicians to file unpaid claims which report information about the visits or other services that are incorporated in the global period, there is no incentive for physicians to undertake the necessary modifications to their IT systems and office processes in order to report. The reported data set is likely to be incomplete or inaccurate. If, however, you offer compensation adequate to cover costs plus a small return on the investment, more physician practices are likely to undertake the system changes and reporting that you have requested.

Improved Payment for the Professional Work of Care Management Services

We are pleased that you are once again considering the need to pay for services that may not be confined to the limited setting of a face-to-face visit. We would note that the kinds of extensive cognitive work that you have discussed in this rule can occur when a patient has complex diagnoses, atypical reactions to standard treatments, or a condition that is unusual or is difficult to diagnose. We urge you not to make the requisite rules and documentation administratively difficult or costly. As we noted above, adding more administrative cost burden can drive up total cost and decrease physician productivity by diverting time and resources from clinical care.

Establishing Separate Payment for Collaborative Care

We appreciate your intention to minimize burden on providers in developing payment rules for the new telephone/internet consultation codes. These services are subject to the same privacy, security and documentation requirements that apply to any other patient service. Since multiple communication modes are possible and new technical solutions may be developed, we see no reason to require the use of any particular technology. We also appreciate your recognition that beneficiaries may be confused or unhappy about coinsurance bills for these services and your willingness to consider waiving coinsurance, treating these services in the same way that preventive care is currently covered.

Advance Care Planning Services

It is important for patients to communicate with their physicians about their wishes for end-of-life care and we support the proposal to make this service available. Physicians need information about patient preferences and patients need explanations about treatment options in order to make informed decisions. Since illnesses and accidents can be unexpected, Texas patients increasingly make some of these decisions well in advance of any life-threatening illness and prepare advance directive documents to clarify their preferences. Healthy patients who are engaged in this planning process may wish to discuss these plans with physicians and physicians may wish to record information about patient preferences in the patient's medical record. Allowing physicians to be compensated for this service when patients initiate the discussion is prudent policy. We would also note that patient preferences often change over time, so the decisions and documents may need to be revisited on a regular basis.

Incident to Proposals

We strongly support the requirement that all incident to services must be provided in accordance with state law. Texas has clear laws and regulations governing scope of work and supervision requirements for clinical care providers that are designed to assure patient safety. We agree that Medicare payment rules should not nullify those regulations. We do not, however, support the proposal to require the billing physician to be the same physician who directly supervises the staff providing the service. Services such

as suture removal or other follow-up care do not require the direct supervision of the physician who originally treated the patient, as long as appropriate physician supervision is provided in accordance with Texas law and Medicare rules. Any effort to assure proper compliance with supervision requirements should take a different form.

Physician Compare Web Site

Your assertions that the proposed rules and measures are valid ignore the fact that most measures in current use are substantially affected by patient choices and behavior. Section 10331 of the Affordable Care Act requires that quality measures made public must be "statistically valid and reliable" and "provide a robust and accurate portrayal of a physician's performance". You previously acknowledge that validity "refers to the ability to record or quantify what it claims to measure", but that test cannot be met for most measures if the intent is to measure physician performance. For example, a measure that reflects whether a patient followed physician directions by getting certain screening tests or taking certain prescribed drugs is not necessarily measuring physician performance. It does not measure whether the physician ordered the care or what efforts the physician took to communicate the importance, or to remind the patient. If the patient's compliance is ultimately affected by barriers to care, such as transportation, financial limitations or family support systems or affected by cultural attitudes about health care and medicine, there may be nothing that the physician can do to can patient compliance. Measures that are affected in this way may be valid measures of patient behavior or preferences, but not of physician quality. Data which measures patient behavior, preferences or abilities does not provide a statistically valid portrayal of a physician's performance and should not be published.

The patient-controlled variables might not be of concern if the factors that relate to non-compliance or poor outcomes were evenly distributed among the patient population or were uniformly amenable to modification by provider intervention, but that is not the case. 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 intensive care and resuscitation at end of life.[3]

Alternatively, the validity of the measures could be enhanced if the patient preference and compliance variables were 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 which includes factors related to educational attainment, race, ethnicity, or religion, and a better factor to measure poverty. Furthermore, efforts should also 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. Although data on patient income, education and other factors is not available to CMS, population estimates based on geographic location should be used to

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[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

improve the risk adjusters. If CMS is not able to appropriately risk-adjust for patient preference and compliance variables, none of the measures affected by those factors are statistically valid and none should be published.

Another alternative that could improve validity would be to compare physicians to a baseline comprised only of other physicians with comparable patient populations, based on socioeconomic and cultural variables, but that is not what is proposed here. By proposing a national, unadjusted benchmark, the proposed rule creates a statistical disadvantage for physicians whose patient populations tend to be more resistant to compliance or who face barriers to care created by local conditions such as transportation distances. We oppose the use of national benchmarks used to score physicians who practice in very different patient care settings with dissimilar patient pools.

When measures are published on the Physician Compare web site in a way that is transparent about the nature of the measure, we believe that most patients can intuitively understand the data limitations outlined above. 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 meaningless in measuring the quality of care that physicians provide. However, using stars or checks instead of actual measures is not transparent and tends to obscure the actual meaning of the specific measure. We oppose all uses of stars or checks because they may tend to imply greater significance to the data than is warranted. Any 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. Stars and checks will tend to be misleading, and should not be used.

Physician Quality Reporting System

TMA appreciates efforts made by CMS to align the PQRS requirements with other quality reporting programs. However, the complexity of the program still remains and many physicians have expressed great difficulty learning about how to participate in PQRS and staying abreast of the ever-changing measures, annual reporting requirements, and submission deadlines. This issue has resulted in negative payment adjustments for some physicians and we urge you to re-evaluate your communication methods and outreach to educate physicians on successful participation. We further urge you to streamline the process in accessing feedback reports and to increase your efforts on educating physicians on how to interpret their feedback reports to improve their quality performance.

We do not agree in mandating the requirement of the CAHPS for PQRS surveys for group practices of 25 or more eligible professionals. It would be unfair to physicians to be required to conduct CAHPS for PQRS surveys and bear the burden of those costs merely for selecting one reporting mechanism over another. TMA suggests that participation in the surveys remain optional for physicians that determine that the survey data is beneficial to their practice and patient care.

We strongly urge you to simplify the PQRS program to reduce the burden on physicians who are in good faith trying to comply with program requirements and striving to improve their quality of care for their patients.

Electronic Clinical Quality Measures and Certification Criteria and Electronic Health Record Incentive Program-Comprehensive Primary Care (CPC) Initiative

We appreciate that CMS is placing the appropriate responsibility on the Certified EHR Technology vendors to have the ability to report CQMs electronically to CMS. In reviewing the various CEHRT vendors, it is noted that many vendors only certify to electronically submit some CQMs to CMS. This limitation has the unintended consequence of steering physician users to report on CQMs that may not be

optimal for their specialty or patient demographic. TMA suggests that CMS work closely with CEHRT vendors to increase the number of CQMs that can be submitted electronically to 100 percent by certified vendors. This will vastly improve the quality reporting efforts that CMS desires.

When physicians participate in a Comprehensive Primary Care initiative and choose the group reporting option, first-year EHR incentive program participants should be permitted to use a 90-day CQM reporting period. It is unfair to require eligible providers to report on full-year CQMs rather than aligning the required CQM reporting with the meaningful use attestation period of 90 days. If CMS maintains the full-year requirement, it will continue to alienate physicians who are attempting to comply with rules that have become increasingly more complex. CMS should seek ways to simplify the program, and aligned reporting periods would be a step in the right direction.

The Merit-Based Incentive Payment Systems (MIPS)

TMA appreciates the opportunity to propose clinical practice improvement activities under the new MIPS. The reporting requirements to demonstrate participation in these activities should not require extensive documentation, certification, or entail a burdensome process. In addition to the existing examples under each subcategory, we propose expanded practice access, such as extended hours; population management and care coordination activities, such as providing chronic care management services; and beneficiary engagement, such as the consideration of Choosing Wisely recommendations.

Value-Based Payment Modifier

We continue to be concerned that the proposed value-based payment modifier will selectively penalize physicians that serve disadvantaged populations and those that practice in areas where the physician supply or patient access to care is poor. If physicians face financial penalties for patient choices, the incentives that are created are not in the public interest. Even in cases where poor patient compliance can be and is improved through various interventions, physicians who treat less-compliant populations will be, in effect, financially penalized due to the higher cost of the additional intervention efforts.

If measures used in the PQRS and value-based payment program are related to patient demographic characteristics and cannot be adequately risk-adjusted for demographic differences 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. We are particularly concerned about proposed measures that depend on outcomes such as lowered cholesterol levels. Outcomes such as these are highly dependent on patient lifestyle and the patient's effort or ability to follow physician instructions. These measures should not be used unless new methods of risk adjustment are identified that recognize socioeconomic and cultural differences in patient populations. Measures must be based on factors within physician control, not those that are the results of patient choices. Because cultural and socioeconomic differences sometimes vary regionally, poorly designed value-based purchasing 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 the value-based purchasing initiative. An incentive system that penalizes physicians who care for some types of patients could have dire effects on access to care for Medicare beneficiaries.

We are also concerned about the effect of poor physician supply on local cost and performance measures. In local 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 continue to analyze the effect of the proposed value-based payment reductions for 2016 to determine whether there will be adverse impact to physicians who serve patients who live in poverty or those who live in areas where there are physician shortages or other barriers to care. Physicians who serve disadvantaged populations should be immediately exempted from downward adjustments. Then we urge you to act quickly to revise the risk adjustment methods used in the calculations of both cost and quality to adjust for the effect of the factors listed above.

Physician Self-Referral Updates

TMA appreciates the guidance and proposed changes to promote consistency, reduce regulatory burdens, and improve clarity regarding application of the physician self-referral law. TMA is optimistic that the proposals and comments providing clarification on certain technical aspects of the law and applicable regulations, including documentation requirements, signature noncompliance, one-year terms and holdovers, will be helpful in lessening compliance burdens for physicians and other providers and reducing the number of potential violations submitted via the self-referral disclosure protocol. That being said, TMA welcomes additional comments and explanation in order to assist physicians and other providers avoid technical violations and comply with applicable regulations, especially when considering participation in integrated health care delivery models that enhance patient care and promote coordination of patient care.

For example, regarding the documentation requirements discussed in the proposed rule, TMA notes that the preamble states that, depending on the facts and circumstances, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the requirement in certain exceptions that arrangements be set out in writing. (80 FR 41915) In other words, the regulations do not require that, for example, an office lease arrangement be documented in a single formal contract in order to meet the writing requirement under 42 CFR §411.357(a)(1). While TMA appreciates this clarification, additional guidance and/or examples of scenarios where a "collection of documents" or "contemporaneous documents evidencing the course of conduct between parties" would meet the writing requirement would be helpful.

TMA supports the proposal to consider new exceptions allowing physicians to work with other community providers to provide care through, for example, timesharing arrangements and increasing access to primary care services for physician's patients through employment of non-physician practitioners. In regard to future rulemaking, TMA believes that additional guidance or clarification on the regulations relating to physician compensation, including but not limited to, indirect compensation arrangements and the indirect compensation arrangements exception under 42 CFR §411.357(p) would be helpful. Similarly, we welcome additional guidance regarding the "volume or value" and "other business generated" standards to promote increased understanding among physicians and providers attempting to comply with the applicable regulations—particularly in relation to participation in health care delivery systems that promote coordinated care, clinical and financial integration, shared savings, or alternative payments models.

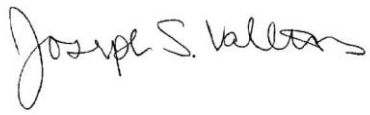
Medicare Opt-Out

The recent provision in MACRA that removed the requirement for renewal every 2 years was designed to eliminate the necessity to continuously track a renewal date. The proposed provisions in this rule that make a cancellation only effective on a renewal date defeats that purpose. An opt-out election should be

effective for a minimum of two years but should be cancellable at any time after that initial period with a 30 day notice. A physician who cancels an opt-out election then later choses to opt-out again, would again be subject to an initial 2-year minimum period. These standards should be sufficient to prevent abuse without requiring the perpetual monitoring of two-year renewal dates.

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

Sincerely,



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