TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

December 3, 2010

Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

DELIVERED
ELECTRONICALLY

Re: Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Saving Program. File code CMS-1345-NC.

Dear Dr. Berwick:

The Texas Medical Association (TMA) appreciates this opportunity to provide comments upon the CMS Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program, published in the Federal Register, vol. 75, no. 221, pages 70165 to 70166.

TMA is a private voluntary, nonprofit association of Texas physicians and medical students. TMA was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its mission is to "Improve the health of all Texans." Its almost 46,000 members practice in all fields of medical specialization. It is located in Austin and has 119 component county medical societies around the state.

TMA appreciates the Centers for Medicare and Medicaid Services (CMS) efforts in collecting insight regarding small and solo physician practice participation in accountable care organizations (ACOs). TMA recognizes the difficult task placed before CMS on this important issue. TMA respectfully offers the following comments.

Policies and Standards to Ensure Active Participation

First, CMS solicits input as to the policies and standards that are necessary in order to ensure the active participation of small and solo physician practices in the Medicare Shared Savings Program and the ACOs tested by the Center for Medicare and Medicaid innovation (CMMI). To that end, TMA contends that it is imperative CMS work closely with the Federal Trade Commission (FTC) and Department of Justice (DOJ) to ensure that physicians are granted broad bright-line antitrust exemptions that will permit physicians to act together in a manner that is clearly anticipated by the Affordable Care Act ("ACA"). Such exemptions are critical to providing physicians with the flexibility necessary to create ACOs that will appropriately address local public health conditions and issues, as well as to clarify the application of otherwise nebulous antitrust law so that physicians have a level of certainty that their actions fall within the confines of law. The narrower

the antitrust exemption is for small and solo physician practices, the greater the obstacle to innovation in ACO structure.

The specter of antitrust enforcement hinders small and solo physician practice (hereinafter "small practices") participation in ACOs as it is recognized that cooperative action must be taken for the implementation of ACOs, yet the government has previously expressed distrust of coordinated physician activities. As acknowledged in CMS' Request for Information, small practices have limited resources and those resources should be devoted to creating health care delivery systems and protocols that will achieve the goals of ACOs, rather than having to dedicate capital to legal representation and ongoing compliance programs. The current FTC series of advisory letters upon antitrust and clinical integration that may allow practices to avoid enforcement (via a rule of reason analysis) is complex and unworkable for small practices seeking to participate in or establish an ACO. Indeed, it is widely acknowledged (even by the government itself) that "what constitutes clinical integration is still uncertain." (Remarks of J. Thomas Rosch, Commissioner, US Federal Trade Commission, Sept. 3, 2008). Given the coordinated goals of ACOs and Congress' intent for broad-reaching physician participation in ACOs, this uncertainty must be eliminated. The creation of a common sense bright-line *physician-specific* exception will facilitate coordination among physicians and provide certainty which encourages physician participation.

Furthermore, to encourage the establishment and investment in ACO organizations by small practices, any broad bright-line antitrust exception must also be applicable to physician activity in the private insurance market. Discernment of which patient carries which type of coverage is a distraction to medical care and will introduce, at least, inefficiencies through administrative processes or be entirely impractical – thereby acting as an impediment to participation. Also, appropriate care, provided at the right time, in the right place of service is an objective that government should encourage in all professional interactions, in government programs as well as private insurance arrangements.

Hospitals or hospital systems need not be included in a physician bright-line exception from antitrust. The ACA expressly permits the establishment of ACOs by physicians *only* and, TMA argues, this is an expression of the Congress' preference for physician practice ACOs. Hospitals are permitted to participate in the Shared Savings Program, but only in concert with physicians. Given that: (1) physician-led ACOs with hospitals are likely to enjoy greater resources and (2) hospital systems have a much larger presence in their market, hospital-participating ACOs do not need the same level of antitrust consideration as ACOs established solely by physicians, especially physicians in small practice. Hospitals simply do not face the same operational challenges and coordination challenges as physicians. This distinction should be recognized by the government.

<u>ACOs must be Physician-led</u>

Next, in order to ensure active participation of physicians in the Medicare Shared Savings Program as well as ACOs tested by CMMI, it is critical that CMS properly acknowledge the integral role physicians play in determining an ACO's success and the attendant need for physician leadership in ACO development and implementation.

Small practices are independent by choice. In Texas, 58% of all physicians practice in groups of one to three physicians. Seventy-two percent (72%) of all Texas physicians practice in groups of one to eight physicians. When Texas physicians were asked about the factors they considered when entering practice for the first time or when changing their practice setting 74% and 60% of those physicians, respectively, chose "personal control of clinical decisions" as a very important factor in their decision.[1] These physician perspectives on medical practice should be acknowledged by and incorporated into the framework developed by CMS in order to encourage viable ACO development and to achieve the ACA's stated goal of "patient-centeredness."

ACOs must be physician-led so that the physicians within the ACO are properly empowered to develop and implement the clinical goals and protocols pursuant to which care is provided. Physician leadership will encourage greater physician participation in ACOs by granting physicians control over clinical decisions, which TMA's survey demonstrates is often one of the paramount concerns of small practices. Additionally, it will ensure that the quality and health goals of CMS' triple aims are satisfied (rather than solely focusing on the cost reduction aim).

Furthermore in the development of exceptions from antitrust and fraud and abuse laws, preference should be granted to ACOs where physicians comprise a majority of the controlling board positions. When one surveys the common examples for ACOs, such as the Cleveland Clinic[2] or Mayo Clinic[3], one will note they are systems that began first with physician groups that then decided to establish hospitals. If these organizations are the template, then physician leadership is a given and institutional leadership (hospital governing boards comprised of non-physicians) should be disfavored. In any event, physicians' personal choice to practice in a small setting should be respected by the government.

Access to Capital

Next, CMS solicits input regarding any potential mechanisms for accessing capital that could be utilized to encourage physician participation in ACOs. TMA appreciates CMS' acknowledgement of the resource constraints facing physicians. To address this concern, TMA urges CMS to work with other federal agencies to facilitate the issuance of ACO-related grants and loans to physicians. A successful ACO—especially an ACO with components comprised of small practices—will likely require investments in information technology to aid in the satisfaction of quality performance data reporting and care coordination. Consequently, CMS should also consider (in coordination with other federal agencies) dedicated grants, loans, and technical services for IT infrastructure.

Additionally, TMA encourages CMS to alleviate small practices of some of these IT capital costs by providing data to physician-led ACOs so that they may assess and analyze the services patients are receiving, as well as the costs associated with each. Many small practices may not have fully implemented electronic medical record systems. IT assistance and ongoing access to that data from CMS will facilitate and encourage small practice participation in ACOs and the Shared Savings Program.

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[1] Source: Texas Medical Association 2010 Survey of Texas Physicians.
[2] According to the Cleveland Clinic website, "Cleveland Clinic was founded in 1921 by four renowned physicians with a vision of providing outstanding patient care based upon the principles of cooperation, compassion and innovation."
[3] The Mayo Clinic was established by Drs. Mayo (William Mayo and his two sons), Dr. Stinchfield, Dr. Graham, Dr. Henry Plummer, Dr. Millet, Dr. Judd, and Dr. Balfour.

Informing the Beneficiary and Transparency

Next, CMS solicits input regarding beneficiary attribution and transparency. As a starting point, it is important that CMS note that the basis of the patient-physician relationship is trust. Patients disclose personal information to physicians and submit to examinations with the trust that the physician will utilize his or her professional skill for the patient's benefit. The AMA Council on Ethical and Judicial Affairs, in Opinion 10.01, states that patients are to be granted "courtesy, respect, dignity, responsiveness, and timely attention to his or her needs."

To that end, patients who are beneficiaries in the Medicare program must not only be informed of assignment to an ACO for the coordination of his or her care, but should also be given the opportunity to opt-in by CMS. The ACA contains provisions for "shared decision-making" in regard to medical treatment.[4] That principle should extend to participation in an ACO. Thus, patients should be offered the opportunity to join an ACO rather than involuntarily be assigned to an ACO. The managed care backlash, which has diminished the presence of HMOs in the Texas private insurance market, was a product of the lack of access to personal physicians, not lack of transparency.[5]

If patients are afforded the opportunity to opt-in to ACOs, then it logically follows that attribution to an ACO must be prospective. Prospective attribution of patients will aid ACO-participating physicians to analyze how to work and modify the patient case management component of the ACO as the endeavor moves forward. It will also aid in the review of how patients generally move between sites of care. Importantly, this also ensures you have an ACO that *is aware it is accountable* for the patient's care. The move to true ACOs is a delivery paradigm shift and obstacles will undoubtedly arise. Prospective attribution provides additional information to aid in physician decision-making.

Payment Models

Next, CMS seeks input regarding the payment models that it should consider under ACA. TMA strongly urges CMS to utilize rewards—not penalties—in ACO programs. Further, CMS must ensure that those rewards are sufficient in scope to cover any additional work and practice expense incurred by physicians as a result of program participation.[6] TMA encourages CMS to pay for services, such as telephone or email consultations with established patients, patient education, and care coordination, which allow small practices to better manage care while lowering overall costs. Research demonstrates that such interventions can contribute to fewer emergency room visits as well as fewer hospitalizations, particularly for patients with chronic conditions. Without payment for these services, it will be difficult for small practices to implement these effective interventions.

[4] Section 3506 of the Accountable Care Act.
[5] Texas Medical Association expressly disagrees with the Medicare Payment Advisory Commission assertion that "…providers, many of whom were losing revenue due to managed care, were more than willing to feed patient concerns that savings from managed care were being produced at the expense of the quality of care…" as insurance carriers did indeed impose medical policies and other measures that impeded the provision of appropriate medical care.
[6] Texas Medical Association House of Delegates Policy 265.017. Pay-for-Performance Principles and Guidelines.

In addition, TMA expressly opposes the assertion in the Medicare Payment Advisory Commission letter of November 22, 2010 (upon this request) that "the two-sided risk model should become the dominant or *the only [payment] model available.*" (emphasis added). Contrary to MedPAC's assertion, downside risk which would penalize certain ACOs is *not* necessary for the Medicare Shared Savings Program to meet its potential. Improvement of patient care is always a goal of the medical profession; thus, two-sided risk is not needed to create an incentive to avoid poor medical outcomes.

Congress did not think two-sided risk is necessary and did not *require* the Shared Savings Program in Section 3022 of the ACA to provide for such risk taking.[7] The typical description of an ACO is a local entity established by physicians, including primary care physicians and specialists, which can be held accountable for the cost and quality of care delivered to a defined subset of traditional Medicare program beneficiaries or other defined populations. The alignment between these typically separate physician practices comes from the creation of a single goal to work toward – a shared savings bonus, for instance. Achievement of the goal is measured through quality and efficiency assessment. The addition of "down-side" risk does not add any dimension to the ACO model other than to possibly introduce a temptation to withhold services that would have otherwise been provided.

The more risk that is thrust upon an ACO, the greater the scrutiny must be to ensure the financial stability of the entity. Financial stability of health insurers is an area of traditional state regulatory activity. Introducing risk upon ACOs (if CMS does not limit ACO risk to professional or management risk) will require the federal government to develop financial solvency monitoring that it has not previously undertaken. TMA recognizes some entities may be willing and able to bear insurance risk, however, we urge the Secretary to be very cautious in the imposition of downside risk as insolvency would undoubtedly disrupt care to patients. TMA would suggest that capitation or other insurance risk sharing should *not* be a dominant model or the exclusive model for ACO programs.

Quality Measures

Finally, CMS seeks input regarding the quality measures the Secretary should use to determine performance in the Shared Savings Program. TMA agrees that quality measures *developed by physicians* are necessary for appropriate monitoring of ACO marketplace conduct. Quality measures used in the program must be defined prospectively and developed collaboratively across physician specialties. Practicing physicians with expertise in the area of care in question must be integrally involved in the design, implementation, and evaluation of any quality measurement program. Quality measures should also have the following characteristics:

- They 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;
- They must be subject to the best available risk adjustment for patient demographics, severity of illness, and comorbidities;
- They must be kept current and reflect changes in clinical practice, but, except for evidence-based updates, the quality measures should be stable for two years; and
- They must be selected for clinical areas that have significant promise for improvement.

[7] Sec. 1899(i) does grant discretionary authority to provide for other payment models, but does not require them.

Given the cost involved in collecting and reporting data on the measures, CMS should be flexible in implementation of quality measurement and initially limit the number of quality measures based upon which bonuses are awarded. Furthermore, as ACOs are to be locally oriented, the ACO should have the flexibility to utilize quality measures specific to its population and its local public health concerns.

Furthermore, TMA encourages CMS to establish a technical assistance learning laboratory where ACOs led by small physician practices can regularly exchange best practices relating to patient care management, cost containment, community partnerships, and improving population health.

Conclusion

Thank you for the opportunity to provide you with these comments upon ACOs and the participation of small practices. TMA supports physician-led ACOs as they offer an opportunity to better enable physicians to provide the right care at the right time. If you have any questions, please feel free to contact Mr. Lee Spangler, Vice President, Medical Economics at 512-370-1300 extension 1315.

Sincerely

Susan R. Bailey, MD
President

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