AMA
AMERICAN
MEDICAL
ASSOCIATION

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Donald M. Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Room 314G
Washington, DC 20201

Dear Administrator Berwick:

I am writing on behalf of the American Medical Association (AMA) to share our thoughts with you regarding ways that CMS can increase the likelihood of success for the program to create accountable care organizations (ACOs) established under the Affordable Care Act (ACA). The AMA appreciated the opportunity to participate in the special open door forum that the Centers for Medicare and Medicaid Services (CMS) convened on June 24th to discuss ACOs and our comments are reflected in the transcript of the call which CMS released on July 29th. We were also pleased to be included in the discussion at the White House regarding ACOs and antitrust issues, as well as the second CMS listening session at the Humphrey Building. We look forward to working with you to successfully implement this and other key payment and delivery reforms included in the ACA.

Promoting Participation by a Variety of Physician Practices

In order to achieve the goal of higher quality and more efficient service delivery for the Medicare program envisioned by Congress, we believe it is essential that the regulations implementing Section 3022 of the ACA enable the majority of U.S. physicians, including those who are in solo or small group practices, to participate effectively. We recognize that many physicians will need to change their organizational structures and processes of care in order to participate effectively, and toward that end, the AMA has been working to educate physicians about how new payment models, including ACOs, can help them deliver better care to their patients and how their practices may need to change in order to succeed under these new models. The AMA engaged Harold Miller of the Center for Healthcare Quality and Payment Reform to develop a white paper, "Pathways to Physician Success Under Healthcare Payment and Delivery Reforms," that we distributed to member physicians, and which Margaret Garikes has provided to you. The AMA is also conducting webinars and regional continuing medical education seminars for physicians featuring Mr. Miller and physician leaders involved in new payment models. We continue to inform physicians of new developments on payment reform and opportunities to improve health care delivery through communication vehicles such as *American Medical News* and our weekly electronic newsletter on health reform, *HSR Insight*. Information on these and other AMA resources for physicians can be found at www.ama-assn.org/go/paymentpathways.

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We have received a very enthusiastic response from physicians to these educational materials and programs. It is clear that many physicians want to play a leadership role in creating a healthcare delivery system that will allow them to deliver high quality and efficient care to their patients. In drafting the ACA, Congress wisely allowed for a range of different organizational models to serve as ACOs, including physicians in "group practice arrangements" and "networks of individual practices" of physicians, because in most of the nation, patients receive their care from physicians in small, independent practices, not from large health systems. There are many examples of physician groups and independent practice associations across the country that take accountability for the overall cost and quality of care for their patients without having to deliver every service, including hospital care, for those patients. We urge that CMS, in preparing the regulations to implement Section 3022, do everything possible to facilitate participation by all the provider structures authorized in the law, and not inadvertently bias participation in favor of large health systems and hospital-dominated networks.

Antitrust and Anti-Kickback Safe Harbors Needed

The ACA explicitly authorizes the Secretary to waive requirements under the Civil Monetary Penalty statute, the Anti-Kickback statute, and the Ethics in Patient Referrals (Stark) law, and we urge you to establish a full range of waivers and safe harbors that will enable independent physicians to use existing or new organizational structures to participate as ACOs. In addition, we would urge you to work with the Federal Trade Commission to provide explicit exceptions to the antitrust laws for ACO participants. The AMA has argued throughout the debate on payment and delivery reform that physicians cannot completely transform their practices only for their Medicare patients, and antitrust enforcement could prevent them from creating clinical integration structures involving their privately insured patients. In addition, there needs to be provisions for continuing these waivers and safe harbors beyond the end of the initial agreement between the ACO and CMS (as defined in Section 1899(b)(2)(B)) so that any new organizational structures that are created to participate in the program do not suddenly become illegal simply because the shared savings program does not continue. To begin with, the AMA recommends that the government take the following steps:

- Establish a safe-harbor (from a presumption of anticompetitive market power) for independent physicians who join together to achieve the minimum scale necessary to participate in the Medicare shared savings programs, i.e., primary care professionals sufficient to treat a beneficiary population of 5,000 beneficiaries. In many communities, an ACO of this size would be viewed as having a large or dominant market share.

- Establish a safe-harbor for nonexclusive ACOs, i.e., those that do not prohibit their members, in law or in fact, from contracting with payers apart from the network.

- Recognize that an ACO may have a legitimate need to engage in exclusive dealing in order to eliminate free riding. Developing clinical integration programs is expensive and requires substantial investment to create and maintain the program. Once physicians are trained and have access to the necessary infrastructure, however, payers and physicians have incentives to "free ride" by cutting out the organization creating the clinical integration program. Exclusive dealing is a common method of preventing free rider problems and should be considered.

- Establish a safe harbor for innovative care delivery practices, such as physician practices offering additional services to patients in an effort to improve the quality and efficiency of the care they

receive, or other arrangements aimed at improving care coordination, quality and efficiency.

- Establish a safe harbor for gainsharing arrangements that meet criteria similar to those identified in the OIG Advisory Opinions on such arrangements. Features common to the permitted arrangements to date include:

    - specific, identifiable, and transparent cost saving actions and verifiable cost savings from those actions;
    - a ceiling on how much of the realized savings participating physicians could receive;
    - arrangements of fixed duration;
    - a floor on the minimum permissible use of certain services and materials, set in accordance with objective evidence;
    - provisions for participating physicians to make a patient-by-patient determination of necessary care and other patient-care safeguards;
    - disclosures to patients about the hospital and physician participation in cost-saving efforts;
    - equal distribution of cost savings among all participating physicians; and
    - reliance on third-parties to develop and monitor the gainsharing arrangement.

Multiple Payment Models and Transitional Approaches

It is important that payment changes be tailored as much as possible to support the specific changes in care delivery that will improve quality and control costs. Contrary to popular belief, physicians are willing to make changes that will result in higher-value care, but in many cases current payment systems do not give them the ability to do so or actually penalize them when they do. For example, physicians may be able to reduce the rate of hospitalizations and readmissions for chronic disease patients by employing nurse care managers to provide patient education and self-management support, but Medicare does not cover these care management services. The solution is not merely to give the physician a financial "incentive" to reduce hospitalizations, it is to provide the patient support resources the physician needs to do so.

A serious problem with the shared savings model in Section 3022 of the law is that it does nothing to provide physicians with the upfront resources and flexibility they need to reduce overall healthcare costs. Even if an improved program of care would ultimately reduce total costs and result in a shared savings payment that would cover the upfront costs of the program, many physicians cannot afford to make the upfront investment.

Moreover, particularly during the initial years of operation of an ACO, even if the ACO makes a significant impact on many aspects of care, it could fail to receive any shared savings payments if there are increases in the cost of the portions of care that it has not yet brought under control. This could discourage even large providers from making investments to improve portions of care delivery and transitioning to full accountability over time.

Fortunately, the final version of Section 3022 allows CMS to use partial capitation and "other payment models" to support an ACO in addition to the shared savings model. We urge CMS to implement the other payment models authorized by the ACA in order to support physician practices which need upfront resources and flexibility to transform care, and to support physician practices which could transition to full accountability over a period of several years. Innovative and flexible policies will benefit the

Medicare program by enabling more physicians to participate in the ACO program and to allow physician practices to take transitional steps toward better care coordination without making a sudden leap to a completely new delivery model. For example, physicians may want to offer a "warranty" on a particular set of services that they provide, hire care managers and accept comprehensive care payments for patients with a particular condition, or redesign care processes in other ways to improve quality and lower costs. Any of these actions would benefit the Medicare program and should be encouraged rather than discouraged.

Performance Measurement and Reporting

Congress clearly intended for the physician group practice (PGP) demonstrations to inform the ACO program, and the PGP projects do provide some important lessons, especially with regard to quality reporting:

- Patient selection and attribution methodologies are a major issue. The AMA understands that the patient assignment methodology used in the PGP demonstration was at times problematic, as beneficiary assignment was based on the plurality of care to any provider type regardless of specialty. It is hard to imagine that data precision and information sharing are going to evolve to such a degree in the next couple years that it will be possible to accurately assign all beneficiaries who may come in contact with one or more physicians affiliated with an ACO or to accurately attribute all the care that they receive. This will need to be a major CMS focus.

- The data collection tool used in the PGP demo was helpful in capturing and sharing data with CMS. The AMA urges that this tool also allow practices to verify the accuracy of their data prior to and after CMS makes incentive calculations. Further, CMS should explore making the data collection tool a secure web-based application rather than free-standing at each practice.

- The standards that may be appropriate for a pilot program in the Bronx may differ markedly from the standards for measuring results of a program serving patients in rural Texas. CMS should consult with measure developers like the AMA-convened Physician Consortium for Performance Improvement (PCPI) as it seeks to define "performance results," including whether this information is determined by a national benchmark or derived from individual group practice quality improvement that compares yearly progress.

The law does not require public reporting of ACO performance information, and we would urge that CMS approach both the collection and any reporting of such information thoughtfully to avoid having unintentional adverse consequences for patients. For example, neither physicians nor ACOs should be penalized for delivering care to individuals who are at higher risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or who have economic and cultural characteristics that make them less adherent with established protocols, or literacy problems that make it difficult to comprehend basic medical information.

In setting up the quality measurement standards for ACOs, CMS should consider that the Physician Quality Reporting Initiative program includes only a small number of "intermediate" outcomes measures related to diabetes, chronic kidney disease, end-stage renal disease, and eye care. These focus on short-term outcomes, whereas true "outcome" measures are longitudinal and population-based. Additional resources and time are necessary to gather an evidence base, assess methodologies for risk-adjustment,

and test the measures for feasibility and reliability prior to broad based implementation across health care settings.

The AMA remains concerned about the low reliability of efficiency measures used in determining physician ratings or scores. Incorrect reporting of physician performance can mislead patients, disrupt patient/physician relationships, unfairly damage physician reputations, inappropriately redistribute physician compensation, and potentially generate negative unintended consequences for patient access to care. Currently, no single risk adjustment methodology is appropriate across a spectrum of conditions or episodes of care.

The success of any payment model for ACOs hinges on the use of an effective risk adjustment methodology. Successful ACOs will likely attract sicker patients (since they will receive better and more efficient care), and it is critical that those ACOs not be penalized for this. Development of a risk adjustment methodology must adequately address the complexities which arise from the multiple chronic conditions of the typical patient population. The process of risk adjustment model selection should be based on physician and other expert input and transparent to all stakeholders. It is essential that the risk-adjustment methodology be improved and standardized before savings targets are calculated and before any performance data is publicly reported.

The PCPI has long advocated for the use of measure sets. Reporting on a measurement set, as compared to a single measure in a set, provides a more comprehensive picture of the care being provided. Measure sets should include intermediate and long-term outcome measures based on a patient population.

ACOs should be allowed to report on a hybrid of nationally and locally focused quality measures related to their particular patient population, such as asthma measures if providing care in a region with poor air quality, or measures for a population where the ACO is explicitly seeking to reduce overutilization of services. Especially at this early stage when there is so much we do not yet know about ACOs, a one-size-fits-all approach would be a mistake.

Although the ACOs will need to report quality measures using health information technology, specifying quality measures for use in electronic health records is a complex, detailed process that requires the development of new specification sets. Measure developers, including the PCPI, are working on these specifications now, but they will need to be tested to ensure physicians can consistently use their electronic health record to accurately report quality measures.

Timely Provision of Performance Data

One of the biggest challenges that any physician organization will face in successfully serving as an ACO is getting recent data on the utilization of services by their current patients and getting rapid feedback on utilization of services during the course of the agreement period, particularly for services delivered by providers who are not part of the ACO organization. It is essential that CMS make such data available to providers well in advance of the initiation of the program, and that it provide timely performance information beginning with the first month of actual implementation. In addition, the AMA urges CMS to devote resources to providing technical support to small, independent physician practices and others who need to better develop the capabilities to be able to gather, analyze, review and act on data on their patients' care.

We look forward to working closely with CMS on these issues as the rulemaking process moves forward. Please do not hesitate to contact Margaret Garikes, Director of Federal Affairs, at 202-789-7409 or margaret.garikes@ama-assn.org if you have any questions or wish to discuss any of the topics we have raised.

Sincerely,

Michael D. Maves, MD, MBA