February 28, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services

Patrick Conway
Deputy Administrator for Innovation and Quality
Center for Medicare & Medicaid Innovation

7500 Security Blvd.
Baltimore, MD 21244-1813

Re: Request for Information (RFI) on Evolution of Accountable Care organization (ACO) Initiatives

Dear Ms. Tavenner and Dr. Conway:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the RFI requesting comments on CMS/CMMI’s Accountable Care Organization (ACO) initiatives for encouraging greater care integration and financial accountability. AdvaMed has been a strong supporter of ACOs since their inception in the Affordable Care Act. We recognize the importance of the goals of ACO initiatives as they seek to improve both the efficiency and quality of health care in this country and we believe that our members’ technologies can play a critical role in assisting providers to achieve these goals. Our member companies are leading the way through advances in medical devices, diagnostics, and other advanced medical technologies. These products and services improve patient care quality and many improve efficiency by reducing the lengths of stay of patients in health care facilities, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

In this letter, we offer general comments that address beneficiary protections that we believe should be considered as CMS and CMMI explore new directions for ACOs to assume more financial risk for the cost of care. We have divided our comments into three major sections: First, our letter raises questions about the impact a transition to greater insurance risk for ACOs
could have on the broader health care marketplace and whether ACOs assuming full insurance risk and functioning more like Medicare Advantage plans raises competitive concerns. We also recommend that patient protections be incorporated into models that carry more financial risk for providers serving beneficiaries of the Medicare and Medicaid programs. The second section of this letter discusses specific recommendations that we offer to address concerns that the financial incentives underlying the ACO model can lead to stinting on care and compromised patient access to breakthrough treatments and technologies. We note that new ACO models including more financial risk for providers can increase the likelihood that beneficiaries may experience these problems. The final section of our letter recommends that CMS move beyond the 33 quality measures now used in ACO programs and incorporate additional measures from the robust range of measure areas available for application to the programs and asks that CMS consider two gap areas – among many that are possible – for future measure development and application to ACOs.

I. Transition to Greater Insurance Risk

The RFI is predicated on the notion that ACOs should take on more financial risk, expand their scope, involve multiple payers, and become a more common feature of the health care delivery system, even though there is relatively little evidence regarding the impact of currently configured ACOs on patients and other stakeholders. When the Medicare Shared Savings Program (MSSP) was implemented by CMS through final regulations, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) joined in a statement pertaining to antitrust enforcement policy regarding MSSP-participating ACOs. This statement identified an antitrust safety zone and offered ACOs a voluntary process for seeking expedited review of arrangements outside this safety zone. The statement also identified types of conduct that could raise competitive concerns. The two agencies also indicated their intent to closely monitor the competitive effects of ACOs.

We believe that CMS and CMMI should take a very guarded approach to expanding the reach of ACOs, especially since there is the potential for ACOs to have anti-competitive effects. We believe that more time is needed to assess the impact of current ACOs in various marketplaces and the nature of related anti-trust enforcement activities and findings. Such a measured approach will also provide an opportunity to assess the adequacy of the existing antitrust enforcement statement and related policies.

The RFI seeks input on the types of precautions that should be taken to protect beneficiaries if and when ACOs take on more insurance risk. First, AdvaMed believes that more balanced educational materials need to be prepared for beneficiaries potentially served by ACOs, including current ACOs. While beneficiaries, in theory, are not locked into an ACO and its providers, we believe that an ACO’s referral patterns and other actions may effectively have the result of locking beneficiaries into ACO providers. Increasing financial risk is likely to bring greater pressures to control health expenditures by steering beneficiaries only to ACO providers or delaying referrals to specialists. Beneficiaries should be clearly informed that they may seek care outside an ACO. Effectively, the ACO is analogous to a point-of-service (POS) option in a
Medicare Advantage (MA) plan. Medicare Advantage enrollees with a POS option must be given notice that they can seek care outside of the Medicare Advantage provider network (see the requirements in 42 CFR §422.105(d)(2) regarding the evidence of coverage document).

In addition, beneficiaries should be informed about the full array of incentives that apply to ACOs, including those that could prove detrimental to beneficiary interests. CMS-prepared educational materials should not imply that ACOs can have only positive consequences for patients when so little is actually known about their impact on access to and the quality of care. In the Medicare Advantage program, for example, beneficiaries are entitled to information regarding physician compensation (see 42 CFR §422.111(c)).

Second, AdvaMed recommends that CMS and CMMI incorporate a broader range of patient protection provisions in ACO programs, especially if ACOs take on more financial risk, expand the scope of their responsibilities to additional items and services, and begin to resemble Medicare Advantage plans. At a minimum, these patient protections should include requirements that ACOs have grievance and appeals processes identical to the Medicare Advantage program. In addition, ACOs should provide options for their assigned beneficiaries to participate in clinical trials. We believe that granting beneficiaries such rights if and when ACOs transition to greater insurance risk would be preferable to only giving beneficiaries the choice of walking away from an ACO with which they have concerns about care or other grievances.

The beneficiary protections mandated for the MA program in Section 1852 of Medicare law were created to address concerns similar to the concerns that surround ACOs – ensuring beneficiary choice of providers and coverage, and ensuring that beneficiaries receive appropriate care in the face of pressures on providers and plans to reduce costs. One such basic protection is the requirement that MA organizations have a robust grievance process in place that provides beneficiaries an opportunity for resolving issues involving the provision of health care services where, for example, the beneficiary believes he or she has not received items or services to which he or she is entitled.

Having such recourse is far less burdensome and blunt than disenrolling from a plan and enrolling into another plan. CMS’ regulations (see 42 CFR §422, Subpart M) require MA organizations to establish and maintain a formal grievance procedure, a procedure for making timely organization determinations, and appeal procedures that meet robust regulatory requirements regarding timeliness, responsiveness, and transparency by the MA organization. In certain cases, a member may be able to receive an expedited determination and reconsideration or response. Together, the grievance regulations amount to a meaningful review process for beneficiaries, with potential review by an independent review entity, an administrative law judge, the Medicare Appeals Council, or even judicial review. This creates opportunities for beneficiaries to challenge the plan in which they are enrolled on a variety of matters. AdvaMed believes these provisions should be incorporated into any future ACO models.
CMS also ensures that beneficiaries who are members of an MA plan and choose to enroll in a clinical trial are not required to pay additional cost sharing for the services in the trial, beyond the applicable cost-sharing in the MA plan for similar services provided in-network (see Medicare Managed Care Manual, Ch. 4, §10.7.1). MA plans are required to reimburse the difference between the cost-sharing paid by the beneficiary to receive services in the clinical trial and the cost-sharing that is otherwise applicable had the services been delivered as in-patient services within the plan. MA plans cannot limit the clinical trials in which a beneficiary can participate for this policy, and must reimburse the difference even if the member has not yet paid the clinical trial provider. This protection allows beneficiaries seeking innovative therapies to participate in clinical trials without facing financial barriers. We believe this protection is important for ACO beneficiaries, as well, and will become increasingly important as CMS contemplates expanding its ACO initiatives and requires ACOs to take on more financial risk. As we will discuss below, such changes may increase the potential for beneficiaries to have reduced access to innovative therapies.

As the number of ACOs approved for participation in the program has grown and beneficiaries assigned to them has expanded to the point that ACOs are now serving approximately 10 percent of total Medicare enrollees, the need for beneficiary protections similar to those in the MA program has become more apparent. We also believe these protections are necessary given the absence of detailed information about the steps CMS is taking to monitor care provided to beneficiaries in these programs. Including these beneficiary protections in the requirements for ACO participation in the program, as well as others discussed below for countering unintended consequences of the financial incentives of the program, would ensure that the proliferation of ACOs does not impinge patients’ options and treatment.

II. Ensuring Patient Access to Appropriate Care

As noted above, AdvaMed has supported delivery reform models, such as ACOs, and their goals to achieve lower cost and higher quality health care. At the same time, we are concerned that the financial incentives in these and other delivery reform models, such as the Bundling Initiative, can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above “benchmark” thresholds—we refer to this as stunting, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run.

In addition, quality standards used for ACOs could discourage early adoption of new and better alternative treatments simply because the quality measures do not reflect breakthrough and innovative treatments. If a new approach to care is developed that may be superior to standard practice, and no special exception is provided for the new alternative treatment, physicians or hospitals may avoid adopting it because it will lower the ACO’s quality score and, in turn, reduce shared savings.
These negative impacts can be avoided without undercutting the goals of the new payment and delivery systems by incorporating certain technical adjustments in the programs and by adopting other patient protection measures. We believe that these technical adjustments and patient protections become even more important for beneficiaries if CMS and CMMI proceed with implementing new ACO models that allow ACOs to assume more risk for the cost of care.

**AdvaMed Recommendations for Addressing Patient Access to Innovative Care Through Payment and Quality Score Adjustments**

Our recommendations would provide adjustments for a limited number of innovative treatments or diagnostics that are first reviewed and approved by CMS after meeting certain criteria. These adjustments would be used for a limited period of time to allow time for these treatments and diagnostics to be reflected in new benchmarks or incorporated in quality measurement to the extent they become the standard of care. For purposes of payment for innovative treatments, the cost of approved innovative treatments would be removed from the calculation of benchmarks and Medicare expenditures when calculating savings or losses. Where the barrier to adoption is a quality standard, quality measurement would exclude the case with the new treatment from the provider or physician quality score. With these adjustments, the disincentives to use an innovative treatment or diagnostic would be neutralized and ACO providers would make decisions purely on medical grounds.

**CMS Review of New Treatments and Process:** CMS would establish a process for manufacturers or developers, to identify breakthrough technologies/treatments meeting the criteria below. This process would be similar to the one now used by CMS for New Technology Add-On Payments. Manufacturers and developers would provide CMS the estimated incremental increase in expenditures that would result from each use of the treatment in a given year. They would also provide CMS the data and methodology for such estimates as part of the application process to assist CMS in determining whether a treatment or technology warrants special accommodation and what adjustments would be made. If approved by CMS, the adjustments would apply to use of the technology across all ACOs.

CMS would also allow individual ACOs/bundled payment awardees to request an adjustment if they were to adopt breakthrough/high cost treatments in advance of other providers. The adjustment could be applied to the individual awardee or all awardees using the treatment.

**Recommended Eligibility Criteria for Payment Adjustments:** CMS would establish the following criteria to authorize adjustments to benchmarks and calculations of Medicare expenditures:

- New technologies/treatments/diagnostics that offer substantial clinical improvements and represent a higher cost to the awardee than use of current therapies;
• Existing treatments or diagnostics that offer significant therapeutic advances for new populations or conditions and that represent a higher cost to the awardee(s) than existing treatments for those populations.

**Recommended Eligibility Criteria for Quality Measurement Adjustments:** CMS would establish the following criteria to authorize adjustments to calculations of Medicare’s individual quality scores:

• The new treatment, service, or diagnostic test is potentially a superior clinical substitute for the current treatment, service, or diagnostic test used for quality measurement.

• The treatment, service or diagnostic test is clinically equivalent to existing treatment, service, or diagnostic test but provides advantages for patients or providers, such as ease of administration or reduced discomfort.

**Length of Adjustment Period:** At the time of qualification, CMS would determine the length of a payment and/or quality adjustment period based on a reasonable assumption of the time needed for the product to be reflected in benchmarks. Generally, this would be a period of three to five years from the time of designation. In the case of an alternative quality measure, the adjustment period would end if a consensus quality standard body determined that a new quality measure should be developed or the new treatment or diagnosis should replace the existing one.

**Making Public Provider Financial Rewards Received under ACO Programs**

Incentives for reducing costs have the potential to lead to stinting on care, denying specialty referrals or higher cost tests and interventions, or selecting cheaper technologies, even when the specialty referrals or higher cost tests and interventions are the most appropriate treatment for the individual. Furthermore, the limited payment window used to evaluate costs and calculate shared savings in ACO programs provides significant disincentives to treat patients with interventions that demonstrate long-term value. This may lead to focus on short-term cost savings even when this is not in the best long-term interest of the patient.

One way to monitor for a connection between suspiciously high financial gains by individual physicians and the withholding of the most appropriate treatments and technologies due to cost would be to publicize the amount of shared savings or gainsharing rewards that physicians receive as a result of their participation in an ACO. This information could then be coupled with data on the treatments and technologies that the beneficiary who is assigned to the ACO receives. AdvaMed strongly urges CMS to create and implement policies that would allow for such disclosure and transparency that will protect Medicare beneficiaries and uphold quality in the Medicare program. To this end, AdvaMed recommends that CMS and individual ACOs make available to the public both aggregated data and individual physician shared savings and gainsharing rewards received by practitioners participating in these programs.
Rigorous Monitoring of Care Received by Beneficiaries Assigned to ACOs

CMS recognizes that quality measurements currently applied under ACO programs are not adequate to avoid many forms of stinting on care. While the agency announced in the final MSSP rule that it would be conducting monitoring and oversight activities to guard against stinting, it is not clear at present what specific form these activities have taken. AdvaMed recommends that monitoring activities not be limited to claims data analysis, but also include medical record audits of beneficiaries in ACOs. Evaluations should also compare the care and health outcomes of beneficiaries assigned to ACOs with professionally recognized standards, as well as to non-ACO beneficiaries’ utilization of specific services, including a review of referrals to medical specialists.

III. Future Quality Measures

The RFI asks for comments on additional quality measures that should be considered for ACO programs if an ACO becomes responsible for all covered lives in a geographic area. AdvaMed supports the alignment, harmonization and implementation of quality measures in ACO programs. However, the current list of the 33 required quality measures that are part of the ACO quality performance standard do not reflect the robust range of measure areas potentially available for development across all CMS reporting and performance programs, including ACOs. We look forward to CMS adopting in the near future an expanded list of quality measures that would apply to ACO programs. In the short term, AdvaMed recommends that CMS consider the following two gap areas—among many that are possible-- for future measure development and application to ACO programs: (1) Malnutrition; and (2) Wounds.

Although evidence shows that the decline in nutritional status and wounds across all care settings impacts patient outcomes, resource use and costs, there are currently no quality measures to address gaps in management of malnutrition and wounds through screening, assessment, nutritional intervention, execution of nutritional /wound care (treatment) plan, and care coordination in any CMS program. While CMS has acknowledged the impact of undernutrition (and obesity) on patient outcomes with the implementation of a body mass index (BMI) quality measure in the Medicare Shared Savings Program, patients may be malnourished regardless of BMI as they may be deficient in the macro- and micro-nutrients needed to help promote healing and reduce medical complications. Malnutrition and wound care quality are benchmarks of an effective integrated care delivery system.

Summary

In summary, AdvaMed recommends that CMS and CMMI incorporate several patient protection policies into the existing structure of ACO programs implemented to date. These would include payment and quality score adjustments to neutralize disincentives that might discourage
providers from using innovative treatments and diagnostics that are appropriate for the condition of a particular patient but are more expensive than existing alternative treatments and/or not yet reflected in quality measures used in the programs. We also recommend that ACOs provide beneficiaries more complete information about the implications of the financial incentives that undergird the ACO program and that CMS and ACOs make available to the public both aggregated data and individual physician shared savings and gainsharing rewards received by practitioners participating in these programs. These patient protections, together with rigorous monitoring of care received by beneficiaries assigned to ACOs, will help ensure that beneficiaries receive high quality of care, especially if CMS and CMMI proceed with allowing ACOs to assume more risk for the cost of care. In this regard, we believe that more time is needed to assess both the impact of current ACOs in various marketplaces and the adequacy of the existing antitrust enforcement statement and related policies. At a minimum, ACOs assuming greater financial risk for the cost of care should be required to follow Medicare coverage policies, have grievance and appeals processes identical to the Medicare Advantage program, and be required to allow patient participation in clinical trials. Finally, AdvaMed recommends that CMS move beyond the 33 quality measures now used in ACO programs and incorporate additional measures from the robust range of measure areas available for application to the programs and asks that CMS consider two gap areas – among many that are possible – for future measure development and application to ACOs.

Thank you for your consideration of our comments. If you have any questions, you may contact me at dmay@advamed.org or 202-434-7203 or Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

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