February 6, 2015

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1461-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1813

Re: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations—Proposed Rule

Dear Administrator Tavenner:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the proposed rule published in the Federal Register December 8, 2014. 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 do so 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 comments on a number of issues and questions raised in the proposed rule for the Medicare Shared Savings Program (MSSP):

I. Ensuring Patient Access to Appropriate Care [Comments related to Section II.F.7—Shared Savings and Losses: Seeking Comment on Technical Adjustments to the Benchmark and Performance Year Expenditures]

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 stinting, 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. The potential negative impact of the financial incentives of these models is magnified by the short payment windows used in the programs to compare actual spending against benchmarks in order to determine the level of savings that may be shared among providers. Many medical devices and technologies provide benefits over a long period of time spanning multiple years.

Data analysis by one of our member companies points to the potential impact the financial incentives in the ACO model and the relatively short timeframes for measuring savings can have on care received by Medicare beneficiaries in these models. The specific data analysis done by our member company focused on utilization rates for several interventional treatment options for arterial procedures and utilization rates of these options for Medicare beneficiaries served by ACOs. The analysis showed an increase in utilization of a lower cost procedure option and a decrease in utilization of a higher cost alternative procedure for patients served by ACOs. The increase in utilization of the lower cost option could mean more frequent re-interventions for patients in the future, with the result that higher savings for ACOs in the short-term could also mean higher long-term spending for the Medicare program in the subsequent years.

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 allow ACOs and other delivery reform models to assume more risk for the cost of care.

AdvaMed notes that CMS has recently acknowledged the impact a higher cost innovative technology can have on providers’ ability or interest in using that technology in patient care when they participate in delivery reform models, specifically in CMMI’s Bundled Payments for Care Improvement (BPCI) Initiative. In this instance, CMMI has decided to remove an IPPS new technology add-on payment (NTAP), approved last year by CMS, from a BPCI project’s actual spending total for an episode of care. We understand that CMMI is also considering whether to remove NTAP amounts for other approved technologies as well. This policy change will go a long way in removing disincentives providers would face in using the recently approved new technology awarded NTAP status while at the same time ensuring that Medicare beneficiaries have access to new technologies. It is a good example of how the cost reduction
incentives in certain delivery models can have an enormous impact on whether beneficiaries have access to the best that American medicine has to offer.

We have also learned recently from CMMI that physicians in Pioneer ACOs have asked to be able to use a new and more effective pneumococcal pneumonia vaccine instead of an older vaccine that is specified in a process quality measure used for both the MSSP and Pioneer programs. The problem that physicians in these ACOs face is a reduction in their quality scores if they do choose to use the new vaccine, simply because this particular measure does not yet reflect a new standard of care and because no special exception is allowed for physicians to use the innovation. Patients may not be harmed by the old vaccine but they are not, at the same time, provided the benefits of the new product. This is another good example of how a technical adjustment in ACO programs can provide Medicare beneficiaries the benefits of innovations in health care without undermining the overarching goals of the program.

Our specific recommendations for payment and quality score adjustments follow:

**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. **AdvaMed also recommends that at the present time, the final rule for the MSSP program should, at a minimum, incorporate the BPCI policy for removing the new technology add-on payment from an MSSP ACO’s actual expenditure total that is compared to its benchmark for determining shared savings for the ACO.**

**CMS Review of New Treatments and Process:** CMS should establish a process for manufacturers or developers to identify breakthrough technologies/treatments meeting the criteria below. This process could 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 spending that would result from each use of each an approved treatment. 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 should 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 should 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; or
- 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 should 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; or
- 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 should 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.

## II. Beneficiary Protections [Comments related to Section II.G. – Additional Program Requirements and Beneficiary Protections]

### A. 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 add to the new requirements for an ACO’s website at §425.308 information about shared savings received by individual practitioners participating in the ACO to protect Medicare beneficiaries access to all of the treatment options available for their conditions. This would complement the proposed new requirement that ACOs disclose aggregate shared savings or shared losses and the proportion of shared savings used to advance the three-part aim, including the proportion distributed among ACO participants.

B. 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 2011 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.

With the proposed rule encouraging greater ACO participation in the MSSP program, AdvaMed is concerned that CMS will be proceeding with a significant expansion of the program before we have a clear understanding of the impact currently configured ACOs are having on patients and other stakeholders. We recommend that CMS undertake a rigorous evaluation of care received by beneficiaries in ACOs.

C. Additional Beneficiary Protections

AdvaMed continues to believe that beneficiaries need additional educational materials to assist them in understanding the implications ACOs have for the care they receive. 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 for ACOs, as proposed in the rule, 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)(4).

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 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’s 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 that similar 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. 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.

III. Billing and Payment for Telehealth Services [Comments related to Section II.F.4—Shared Savings and Losses: Seeking Comment on Ways to Encourage ACOs Participation in Performance-Based Risk Arrangements]

Telehealth (including but not limited to remote patient monitoring technologies) is generally recognized as fundamental tools for improving the efficiency and quality of health care. As the proposed MSSP rule suggests, ACOs, with their emphasis on care coordination and collaboration among providers, are a potentially ideal delivery model for realizing the benefits telehealth and related technologies can bring to improving the efficiency and quality of care.

The rule points out that some ACOs are using telehealth services to improve care for their beneficiaries. The problem, however, is that Medicare’s fee-for-service coverage and payment rules restrict the ability of ACOs to realize the full benefits these technologies offer for improving care delivery because the program limits the type of technologies that may be covered, the site of service where beneficiaries may receive care and the geographic area where they must reside. A similar problem exists for remote monitoring services, with only limited reimbursement for these services, such as for cardiac trans-telephonic monitoring of pacemakers, or remote monitoring of patient physiological data as part of new billable chronic care management services for beneficiaries with multiple chronic conditions. To the extent telehealth services are not covered by Medicare, the proven benefits of many telehealth technologies, the
upfront investment and ongoing implementation costs of telehealth create a disincentive to use these technologies at a time when cost pressures and restricted budgets limit the ability of ACOs to do so.

AdvaMed supports CMS’s proposal to add a new eligibility requirement for ACOs to describe how they will encourage and promote the use of enabling technologies, including remote patient monitoring and other forms of telehealth services. AdvaMed also supports CMS waiving current Medicare coverage and payment restrictions for telehealth services provided by ACOs. In fact, we recommend that CMS use its waiver authority to define a more global approach to expanded telehealth and remote patient monitoring benefits than that discussed in the proposed rule.

Specifically AdvaMed recommends that CMS use each of the tracks of the MSSP program to assess: (1) coverage and payment for a more comprehensive set of technologies that today are understood to encompass telehealth technologies, and (2) coverage and payment for a broader range of services for conditions that are known to benefit from telehealth and remote monitoring connection with patients. With the MSSP program CMS has an excellent vehicle for assessing the specific services and circumstances under which telehealth and related services can be demonstrated to improve the quality and efficiency of care. Given the underlying cost control mechanisms in the MSSP program, we believe that it is appropriate to assess the potential for improved quality and efficiency of telehealth across each of the tracks of risk that will be an option for ACOs in 2016. Without more experience, it is premature to limit expanded coverage and payment to specific tracks. CMS, however, could limit waivers to those ACOs who demonstrate in their applications for participation in the MSSP program that they will most effectively encourage and promote the use of these technologies.

Today telehealth technologies are commonly thought to embrace a wide variety of different modes of technologies for patient care diagnosis, treatment, and monitoring. Coverage should not be limited to technologies that substitute for face-to-face services or procedures. Rather, they should include the use of remote sensors, communications and data processing technologies that focus on the patient and involve dynamic interaction with providers in real time or near real-time, resulting in improved clinical outcomes, lower costs, and greater satisfaction. CMS should use its waiver authority to cover services provided in connection with these various technologies, including the use of bi-directional audio/video, physiologic and behavioral monitoring, engagement prompts, remote monitoring, store and forward technologies, and/or point-of-care testing. Telehealth programs utilize remote teams of physicians, nurses, pharmacists, social workers and health coaches supported by this enabling technology to provide the highest quality health care.

With its waiver authority, CMS could allow ACOs to define the specific technologies, conditions, and services that they would use in the provision of care and CMS would then evaluate which services improved care delivery efficiency and quality.

The MSSP program provides a unique opportunity to assess expanded telehealth health services and their impact on population health across at least two different models of risk and CMS should move forward with waivers to cover these services as quickly as possible.
IV. Establishing, Updating, and Resetting the Benchmark [Comments related to Section II.F.6(b)—Factors to Use in Resetting ACO Benchmarks and Alternative Benchmarking Methodologies]

The proposed rule seeks comment on a number of different methodologies it might consider in the future for resetting ACO benchmarks. With our concerns about cost reduction incentives contained in the ACO model that could lead to stinting on care and compromised patient access to innovative technologies, AdvaMed generally supports approaches that would reduce inappropriate pressure on ACOs to continue generating shared savings as their benchmarks fall. We would therefore support options, such as equal weighting of the three benchmark years in a previous agreement period and adding back shared savings to benchmarks, as ways to lower more gradually the benchmarks of ACOs that performed well in their first agreement period, with the understanding that these methodologies would protect patient access to all appropriate care options regardless of cost. In this regard, AdvaMed is especially concerned about the impact expanded telehealth service coverage in ACOs would have on benchmark calculation in a second 3-year agreement period, when spending reductions that would occur as the result of an expansion of telehealth services under waivers, ACOs would face falling benchmarks that would make it difficult for ACOs to continue generating savings. We do not believe that ACOs should be penalized in future benchmarks for savings they have been achieved through use of expanded telehealth services.

We thank you again for this opportunity to comment on the proposed rule for the MSSP program. If you have questions, please contact Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

/S/

Don May
Executive Vice President, Payment and Health Care Delivery