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AdvaMed
Advanced Medical Technology Association

Via Electronic Mail

Donald M. Berwick, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-P
Mail Stop C4-26-05
P.O. Box 8013
Baltimore, Maryland 21244-1850

Re: Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations (CMS-1345-P)

Dear Dr. Berwick:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment on the Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule (CMS-1345-P). AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed recognizes the importance of increasing quality and efficiency in the Medicare program and the broader health care delivery system. 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, 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.

AdvaMed appreciates the complexity of developing the new Accountable Care Organization (ACO) program and support the goals of increasing the quality of care and efficiency in health care delivery. However, AdvaMed is concerned that the proposed rule places a strong emphasis on reducing costs without sufficient means to assess the quality of care provided to beneficiaries. Most notably, as proposed, in the first year,

ACO participants could reduce costs below their calculated benchmark (or target) and distribute bonus "shared savings" payments to the participating physicians and other providers so long as they report on quality measures without assuring any level of quality of care provided to the Medicare beneficiaries. Likewise, the 65 quality measures are useful but are insufficient to assure quality care. They include relatively few outcomes measures, and provide no measures for assessing the quality of care provided to patients with a wide variety of serious illnesses affecting significant numbers of beneficiaries, including cervical, ovarian, endometrial, leukemia/lymphoma, pancreatic, skin, lung, esophageal, bladder and other cancers, neurological diseases, including Parkinson's disease, Alzheimer's disease, diverticulitis, glaucoma, macular degeneration, cataracts, osteoarthritis, rheumatoid arthritis, and gout.

AdvaMed recommends that additional safeguards in three areas be incorporated in the ACO final rule, in the recently announced "Pioneer" ACO program, and other Center for Medicare and Medicaid Innovation (CMMI) health care delivery reform initiatives to ensure that patients have access to the care that is appropriate to their health care needs. These safeguards are as follows:

I. **Stronger Oversight and Monitoring.** CMS should provide for stronger oversight of the ACO program, including use of an outside independent monitor to do an in-depth medical review or clinical audit of beneficiaries in ACOs, comparing their care and health outcomes to professionally recognized standards. AdvaMed recommends that this evaluation include a comparison of ACO and non-ACO beneficiary utilization of specific services, and a review of referrals to medical specialists. CMS can also use the proposed rule's application process and the written request for shared savings as vehicles for stronger oversight of the ACO program.

II. **Protecting Patient Access to Needed Care.** Medicare beneficiaries should be fully informed of the potential benefits and implications of new incentives under the ACO programs. The program should mitigate incentives for reducing costs at the expense of quality by requiring ACOs to distribute shared savings among participating physicians and other health care professionals on a per capita or other rational basis that is not related to savings generated by the individual provider. This would discourage incentives for individual providers to stint on care in an effort to increase their personal level of shared savings and would be consistent with the overall goal of the ACO program—a team effort to reduce costs through better systems of health care delivery. To the extent that CMS allows providers to be rewarded differentially for their performance in an ACO, it should be done on the basis of performance on quality measures and providing superior care.

III. **Protecting Medical Progress for Current and Future Patients.** CMS should adjust ACO spending targets and payment incentives to avoid penalizing providers who are early adopters of advances in medical technology. In addition, CMS should exclude, for a reasonable period of time, certain new treatments from ACO quality scores when existing quality measures do not reflect the new treatments available to patients.

AdvaMed's specific recommendations to address these three key issues are provided in detail below. An appendix includes additional recommendations on other important issues.

I. Stronger Oversight and Monitoring

For ACOs to achieve the goals of better care for individuals and better health for populations, beneficiaries must have confidence that the ACO delivery model will make available and provide the care and services appropriate for their condition. Incentives to reduce costs can lead providers to achieve savings by better management and coordination of care, elimination of unnecessary services, and higher quality care that reduces hospitalizations or avoids complications. Such incentives, however, have the potential to lead to stinting on care—denial of needed specialty referrals or higher cost tests and interventions, even when this is the most appropriate treatment for the individual patient.

AdvaMed supports CMS's plans to monitor care provided by ACOs, as enumerated in the proposed rule, and specifically a proposal to include among CMS monitoring activities analysis of specific financial and quality measurement data, site visits, and audits. However, the proposed rule can and should include additional and stronger safeguards and more rigorous oversight of patient care in the ACO model, both to encourage beneficiary engagement with the ACO model as well as to assure patients that CMS will be monitoring their care experiences for access to the treatments that are most appropriate for their individual needs.

> ***Recommendation #1a: Implement an Independent Clinical Care Monitoring Program--*** AdvaMed recommends that a comprehensive independent monitoring program be developed to provide the impartial analysis needed to assure beneficiaries that the model will improve their care outcomes. An independent monitor should be tasked with providing an in-depth medical review/clinical audit of beneficiaries in ACOs, comparing their care and health outcomes to professionally recognized standards. This evaluation would include analysis of patient medical records (not simply claims data), and a comparison of ACO and non-ACO beneficiaries' utilization of specific services, including a review of referrals to medical specialists and the inappropriate substitution of Part D prescription drugs, which are not included in the calculation of the benchmark for Part A or Part B treatments, for services which are included in the benchmark.[1] AdvaMed recommends that the independent monitor's first report be available to

[1] For an example of potential Part A or B substitution to Part D, see the discussion of heart rhythm medicines and radiofrequency ablation in AHRQ's publication entitled, "Radiofrequency Ablation for Atrial Fibrillation, A Guide for Adults" available at the following link: http://effectivehealthcare.ahrq.gov/ehc/products/51/348/RFA%20consumer.pdf

the public no later than 3 months after the close of the first year's reporting period. (Recommended amendment to §425.12)

The independent monitor should also survey ACO participating beneficiaries and providers. Provider surveys should include their assessment of the availability of products and services and changes in practice that have been implemented under the ACO model. Similarly, beneficiaries should be independently surveyed regarding their assessment of the care they received and the results should be compared to survey results from beneficiaries receiving care through the traditional fee-for-service Medicare program. These results should also be made public. This monitoring program could be implemented through a CMS-appointed independent monitor for each ACO or alternatively by using one monitor for several ACOs in the same general area. (Recommended amendment to §425.12)

Recommendation #1b: Require New Safeguards in ACO Applications and Clinical Expertise in Approving Each ACO Plan--ACO applications should include statements describing 1) detailed plans for preserving patient and physician clinical decision-making; 2) plans for fully informing patients about their full range of treatment options, including medical advances and emerging technologies, and those available only outside the ACO; and 3) processes for ensuring beneficiary access to specialists' care and advances in medical treatments and emerging technologies, including participation in clinical trials. In addition, CMS's evaluation of ACO applications for meeting these requirements and others proposed by CMS to be included in the final rule should include a review by, and input from, clinical experts. (Recommended amendment to §425.5(d)(15))

Recommendation #1c: Report on How ACO Achieved Shared Savings — The proposed rule requires that the ACO make a written request to CMS for payment of shared savings (or acknowledge the amount of shared losses) in a document that certifies compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted to CMS. Such request should include a complete description of how the ACO achieved savings (or incurred losses). This description should include data analysis on utilization of specific categories of services, referrals to specialists, utilization of new treatments and technologies, lengths of stay in facilities, changes in health status of patients, etc. The ACO's description of how it achieved shared savings (losses) should be made available to the public along with the release of the independent monitor's public report. (Recommended amendment to §425.5(d)(12))

II. Protecting Patient Access to Needed Care

A. Requiring Beneficiary Informed Consent to Receive Care from ACO Providers

While ACOs hold promise for improving the quality and efficiency of care, new incentives embedded in the ACO design could have the inadvertent effect of compromising patient access to the full array of treatment options. Medicare beneficiaries with conditions that require more expensive treatment options could be seeking care from providers who will have incentives to limit access in order to reduce costs and enhance the shared savings pool that would be available to them at the end of the year.

The ACO model, therefore, has significant implications for the care beneficiaries need and receive. Patients should be able to consider whether the model and its incentive structure are appropriate for their unique health care needs. Requiring that beneficiaries provide informed consent to receive care from an ACO participating provider is an appropriate step to ensure patient-centered care.

> ***Recommendation #2a: Require Beneficiary Informed Consent through Notification and Acknowledgement***--Medicare beneficiaries should be fully informed of the potential benefits and concerns associated with receiving care from ACO participating providers. Such information should be balanced and fully explain the opportunities for increased coordination of care and the implications of the incentive structure and rewards to participating providers. Beneficiaries should indicate annually that they have been fully informed of these benefits and concerns and are choosing to seek their care from a primary care physician and other providers who are participating in an ACO. The patient form should include a statement that the beneficiary is entitled to all Medicare covered Part A and B benefits outside the ACO, including services from specialty providers outside the ACO. In addition, the beneficiaries should receive clear information about two distinct decisions they must make about ACOs. First, whether they will see an ACO participating primary care physician and other providers or move to another primary care doctor and second, whether they will decline to share their identifiable claims data with their ACO-participating primary care physician or other ACO providers. (Recommended amendment to §425.6 and 425.19(d)(4))

B. Require Shared Savings to be Distributed on an Equal Per-Capita or Other Rational Basis

AdvaMed supports CMS's decision to include proposed rules that would require ACOs to describe in their applications their criteria for sharing savings among providers and how they plan to use shared savings and achieve the goals of the program. However, the proposed rule needs to go beyond these application descriptions to include significantly stronger safeguards to ensure the amount of savings is calculated appropriately and to safeguard against stinting on care.

ACO law requires that CMS define shared savings as those realized by the Medicare program, rather than those that accrue to providers but do not produce savings for Medicare. For example, some CMS gainsharing demonstrations have provided financial incentives to physicians for confining choices of particular devices for surgeries or other procedures to those on a preferred list (a practice known as "device standardization"). This practice simply reduces options and generates savings within a diagnosis-related group or other payment bundle and does not create savings for Medicare. Consequently, such practices would not be permitted under the shared savings program.

With respect to the distribution of savings, AdvaMed disagrees with CMS's assertion that it does not have the authority to specify how shared savings are to be distributed. The ACO statute does not speak to the direct question of how shared savings should be distributed within an ACO. As a general principle of administrative law, where a statute is not clear on its face, the Secretary has discretion to interpret the statute. Requiring that shared savings be distributed on a per capita or other rational basis is consistent with the goals of the program to promote accountability for a patient population while discouraging stinting on care, and to ensure that ACOs meet quality performance standards. Moreover, as noted in the proposed OIG rule, the distribution of shared savings implicates the Physician Self Referral ("Stark") law and the Civil Monetary Penalty law. Savings can not be distributed without waiving these statutes and the Secretary has discretion as to the scope of the waiver.

> ***Recommendation #2b: Distribute Savings Based Solely on Team Effort or Other Rational Basis and Quality***— ACOs should be required to distribute shared savings among participating physicians and other health care professionals on an equal per capita or other rational basis that would discourage physicians from generating disproportionate cost savings by stinting on care in an effort to increase their personal level of shared savings. This recommendation is consistent with OIG Advisory Opinions on similar matters. Moreover, it is consistent with the general concept behind ACOs—savings can be achieved from team collaboration among ACO providers working together to streamline and coordinate processes of care and to better manage chronic disease, and not from reducing or limiting appropriate care. To the extent that CMS allows providers to be rewarded differentially for their performance in an ACO, it should be done on the basis of performance on the designated quality standards and providing superior care. (Recommended amendment to §425.5(d)(11))

III. Protecting Medical Progress for Current and Future Patients

A. Adjusting the Benchmark and Performance Year Expenditures to Protect Medical Progress for Current and Future Patients

Medical progress generally occurs when leading physicians and institutions adopt new treatments that gradually diffuse until they become the standard of care. As currently proposed, ACOs would be rewarded for cost savings in the short term and for achieving a limited set of quality measures, most of which are not outcome-based. This creates

disincentives for using innovative treatments that represent improvements in care if they are more costly. In fact, it may even discourage adoption of less costly treatments that deliver lower costs outside the ACO annual performance timeframe, such as an implant that lasts longer and requires no, or less frequent replacement.

CMS's proposed ACO regulation should be modified to include significantly stronger safeguards to ensure that medical progress continues to thrive and patient care continues to improve. AdvaMed strongly recommends that the final rule incorporate a process for adjusting both benchmark and performance year expenditures to protect medical progress for current and future patients.

AdvaMed recommends that the Secretary use her authority under section 1899(d)(l)(B)(ii) and section 1899(i) to make the adjustments recommended below and other necessary adjustments.[2] The process that AdvaMed recommends for incorporating the adjustments into the calculation of benchmarks and actual expenditures should include the following elements:

Recommendation #3a: Remove Medicare Payments for New Technology from Benchmarks and Actual Expenditures--First, CMS should exclude certain Medicare payments made for new technology from its ACO-related calculations, including add-on payments for new services and technology under the inpatient prospective payment system (IPPS), pass-through payments for certain devices, drugs and biologics under the hospital outpatient prospective payment system (OPPS), payments for covered services involving clinical trials of medical technologies, and other special payment categories such as teaching (IME) and disproportionate share hospital payments (DSH). These exclusions would apply to both the benchmark and actual ACO expenditure calculations and take the affected expenditures off the table for purposes of determining whether an ACO has produced shared savings. (Recommended amendment to §425.7)

Recommendation #3b: Establish a New Process for Excluding High Cost or High Volume Break-Through Technologies from Shared Savings (Losses)--Second, CMS should create an annual process under which stakeholders could identify certain

[2] AdvaMed argues that in giving the Secretary under section 1899(d)(l)(B)(ii) explicit authority to adjust ACO benchmarks for "such other factors as the Secretary determines appropriate," Congress also provided authority to the Secretary to make the same or similar adjustments to actual ACO expenditures. Otherwise, "one-sided" adjustments would make valid comparisons impossible, yielding "apples to oranges" comparisons.

Furthermore, section 1899(i) essentially authorizes "any [ACO] payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under [Medicare]." In the proposed rule, CMS itself acknowledges that section 1899(i) provides very broad authority. For example, although section 1899(d)(1)(B)(ii) states that the ACO benchmark shall be "updated by the projected absolute amount of growth in national per capita expenditures," CMS states in the proposed rule that section 1899(i) would permit CMS to adopt an "alternative" under which the ACO benchmark would be updated by "the lower of the national projected absolute amount of growth in national per capita expenditures or the local/State projected absolute amount of growth in per capita expenditures."

high cost or high volume, break-through treatments and diagnostics for which a special accommodation is required in order to obviate incentives to discourage providers from providing these treatments and diagnostics to their patients. While this special accommodation would vary from case to case, it would typically involve excluding certain Medicare expenditure data from an ACO's shared savings or shared loss calculations. Examples of authorized exclusions would include:

- novel technological approaches to treatment or diagnosis;
- new technologies that potentially provide substantial clinical improvements, including major incremental changes to existing technologies;
- existing technologies determined appropriate for new populations or conditions; or
- an increase in the volume of procedures with higher costs as advances in innovation migrate from cutting edge early adopters to greater numbers of medical professionals.

As part of the consideration process, AdvaMed recommends that CMS ask developers or manufacturers applying for special designation of a new technology, treatment, or drug to estimate the Medicare expenditures that would result from the technology's use in a given year and provide the data and methodology for such estimates, to assist CMS in determining whether a treatment or technology warrants special accommodation under the ACO program and what specific adjustment(s) to the usual ACO shared savings or shared loss calculation are needed. AdvaMed also recommends that the exclusions apply for an appropriate period (e.g. 5 years) depending on the unique factors of the breakthrough treatments or technologies. AdvaMed further recommends that this new process be handled through the annual ACO-related rulemaking cycles. The end result would be a national decision regarding the treatment of certain new technologies that would apply across-the-board to all ACOs participating in the Medicare Shared Savings Program. (Recommended amendment to §425.7)

Recommendation #3c: Allow Individual ACO Requests for Adjustments to Benchmark and Actual Expenditures--Third, CMS should provide a process under which individual ACOs could petition for adjustments to their benchmark and/or actual expenditures to take into account other circumstances that might be relevant for some, but not all ACOs. This might, for example, include the need to adjust for an ACO's accelerated use of new, high impact technologies in advance of most other health care providers and suppliers (e.g., because the ACO includes one or more nationally recognized centers of excellence), a documented variance between the historic utilization rates used in the calculation of the ACO's assigned population's expenditures benchmark and higher utilization rates that reflect adherence to consensus-based clinical practice guidelines, a local disaster affecting health care expenditures in the ACO's service area, or the relatively unique capabilities or expertise of an ACO or its participants. (Recommended amendment to §425.7)

B. Adjustments to Quality Measures for Advances in Technology

AdvaMed strongly supports efforts to increase health care quality and is actively engaged in the National Quality Forum (NQF) and other quality organizations and initiatives. As noted above, new devices, diagnostics, and other advanced medical technologies improve patient care quality and many improve efficiency by reducing the lengths of stay, 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. Often these benefits, which may be long term in nature, may not be captured in the proposed measures, which only address short-term outcomes.

In assessing patient care quality, CMS proposes to use 65 measures. These measures reflect quality goals at a certain point in time. It is imperative that quality measures be updated or modified frequently to keep pace with advances in medical technology. Without proper adjustments to the quality measurements used for calculating an ACO's shared savings, physicians could be penalized for being early adopters of new technologies and providing their patients the best options.

> ***Recommendation # 3d: Adjust Quality Scores to Keep Pace with Advances in Medical Technology.*** In determining an ACO's shared savings bonuses or penalties on the basis of meeting quality measures, certain new treatments or diagnostics should be excluded from the measure's numerator and denominator when assessing a provider's performance on the measure. Such adjustment would be necessary until the existing quality measure is refined or replaced by a new measure that reflects the improved treatment or diagnostic available for patients. These adjustments will avoid freezing medical practice in place and penalizing providers who provide innovative healthcare to their patients. Treatments or diagnostics should be eligible for this adjustment through an application by stakeholders to CMS. (Recommended amendment to §425.10)

Additional comments on Coordinating with other Federal Agencies

AdvaMed recognizes the importance of increasing quality and efficiency in the Medicare program and the broader health care delivery system and appreciates the complexity of developing the new ACO program. AdvaMed also appreciates CMS's close coordination with other agencies in the Federal government on the disparate legal and regulatory issues that ACOs raise. Each of the agencies that have provided guidance--the HHS Office of Inspector General (OIG), the Internal Revenue Service, and the Federal Trade Commission (FTC) and Department of Justice Antitrust Division (DOJ) – has purview over laws and regulations that exist for important public policy reasons. Coordinating CMS's Shared Savings Program proposed rule with the notices from these other agencies has enabled all stakeholders to understand the universe of requirements (at the Federal level) to participate in the Shared Savings Program. AdvaMed is submitting comments in response to the OIG/CMS waiver notice and the FTC/DOJ antitrust statement.

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AdvaMed supports CMS's proposed approach toward coordinating the Medicare Shared Savings Program application process with the antitrust agencies' review as a means to preserve the benefits of competition for Medicare beneficiaries by precluding newly formed ACOs with market power from participating in the Shared Savings Program.[3] AdvaMed supports CMS's consideration of the impact of competition (or lack thereof) on quality of care and access to care. Making CMS approval of a Shared Savings Program application dependent on a favorable review from the antitrust agencies in circumstances where market power is a concern will help to protect Medicare beneficiaries from the negative effects of excess market power.

Thank you again for the opportunity to comment on these important matters related to the new Medicare Accountable Care Organization/Shared Savings Program. Should you or your staff have any questions, please contact me at (202) 434-7203 or ALynch@AdvaMed.org.

Sincerely,

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery Policy

[3] 76 Fed. Reg. 19629-31.

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APPENDIX

AdvaMed's key recommendations in the main comment letter focus on stronger oversight of the new ACO program, protecting Medicare beneficiaries' access to needed care, and protecting medical progress for current and future patients. The following recommendations provide additional strategies for meeting these goals.

Recommendation AX-1: List of Participating ACO Providers—ACOs should be required to provide beneficiaries with a list of their participating providers through the internet or other means. CMS should also develop a listing of ACO-participating and non-participating providers, by county, MSA, or other geographic market and make that information available on its website for use by beneficiaries who may decide to terminate their relationship with their ACO-participating primary care physician. (Recommended amendment to §425.6(c))

Recommendation AX-2: Ensure ACOs Address Beneficiary Access to Innovative Treatments and Technologies—An ACO should be required to describe to CMS and to beneficiaries the processes it will have in place for ensuring that assigned beneficiaries have access to innovative treatments and technologies. (Recommended amendment to §425.5(d)(15))

Recommendation AX-3: Designate a Specific ACO Ombudsman and 1-800 Number-- CMS should establish a specific ACO ombudsman office with a dedicated 1-800 number to receive and investigate complaints from patients and providers about ACO provision of care, including problems getting referrals to medical specialists and access to appropriate services and treatments. This office could be modeled after the program CMS has established for monitoring beneficiary problems under the competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies. (Recommended amendment to §425.12)

Recommendation AX-4: ***Ensure a Timely Grievance Process--*** Beneficiaries should have access to a timely grievance process, as well as instructions for seeking care from non-ACO participating professionals and providers and providing their medical record information to such providers. CMS should evaluate each ACO's beneficiary grievance process in accordance with the relevant requirements specified in regulations for Medicare Advantage plans. (Recommended amendment to §425.5(d)(15))

Recommendation AX-5: Adjust for Patient Characteristics--An ACO's actual expenditures during a performance year should reflect the actual risk score for the population assigned to it during that year. Not adjusting expenditures for changing beneficiary characteristics could encourage ACOs to avoid high-risk patients. In the proposed rule, it was noted that CMS chose not to adjust performance year spending for beneficiary characteristics in order to protect the program from higher costs due to greater diagnosis coding intensity. To address this problem, AdvaMed recommends that CMS compare changes over time in the risk scores of patients assigned to the ACO with changes in risk scores for patients outside the ACO (in the same MSA or some other contiguous geographic area) and recognize at a minimum the average of the risk scores for beneficiaries not in the ACO. (Recommended amendment to §425.7)

Recommendation AX-6: Require Quality Performance Measurements in Each Year-- CMS should require meeting specific quality performance targets – not just reporting of quality measures – starting with the initiation of the ACO Program. Requiring ACOs to solely report quality data in the first year of the ACO program significantly undermines the strategic purpose underlying the ACO program. At the very least, attaining a *minimum quality* performance level should be implemented in the first year of the ACO program. (Recommended amendment to §425.10)

Recommendation AX-7: Clarify Interaction of ACO Performance Measures with Hospital Inpatient Quality Reporting (IQR) and other Quality Programs--CMS should provide a detailed explanation of how the measures proposed in the ACO rule will act in synergy with performance measure sets included in other CMS programs such as the IQR program, the Hospital Value-Based Purchasing Program, and other initiatives. (Recommended amendment to §425.11)

Recommendation AX-8: Provide ACO Performance on Each Element of Composite Measures--Among the 65 proposed quality measures is a "composite" measure (#24) that includes several elements addressing different health care acquired conditions. These include central line associated blood infections, blood incompatibility, and an AHRQ patient safety indicator which is a composite measure. In other words, there is a composite measure within a composite measure. AdvaMed has long supported efforts to reduce Health Care Acquired Conditions. Using composite measures, and/or composite measures within composite measures will be confusing for individuals seeking information about a provider's quality of care. AdvaMed recommends that CMS present performance information on each one of the elements within the composite measures in an understandable format to ensure adequate information is provided to patients. (Recommended amendment to §425.9)

Recommendation AX-9: Improve CAHPS by Assessing Referral to Specialists and Ancillary Services--AdvaMed supports and understands the value of surveying patients regarding their health care experiences and believes it is an important tool for improving patient-centered care. AdvaMed recommends that CMS enhance the proposed CAHPS surveys or develop a new survey to assess key issues including: 1) how patients were

informed about all treatment options including new technologies, and 2) the timeliness of Medicare beneficiary referrals to specialists and/or utilization of ancillary services for appropriate diagnosis, surveillance and treatment (e.g. labs, imaging, etc.). (Recommended amendment to §425.9)

Recommendation AX-10: Include Rigorous Outcome Measures and Seek Feedback via Notice-and Comment Rulemaking-- CMS should emphasize the use of outcome measures, in conjunction with process measures, to ensure better patient delivery of care. AdvaMed strongly recommends that CMS include rigorous outcome measures specifically ensuring that specialty care is not in any way inappropriately limited, or denied. AdvaMed also strongly suggests that CMS, in the future, only propose and implement quality measures in the ACO program that have been endorsed by NQF. Additionally, CMS should avoid using a subregulatory process to propose new or retire existing quality measures in the ACO program. AdvaMed believes that all stakeholders should have the occasion to comment — via formal notice-and-comment rulemaking — on whether such domains/measures are appropriate to include in the ACO program, retirement of domains/measures, and adjustment of the weights of domains and modules over time. AdvaMed feels that this feedback is critical to the success of the ACO program. (Recommended amendment to §425.9)

Recommendation AX-11: Encourage Transparency Regarding Quality and Cost Measures--CMS requires that ACOs describe in their applications the processes they will use for monitoring internal costs and quality and how they intend to use these processes to meet the needs of the Medicare population they serve. CMS also expects ACOs to make changes to improve these processes on the basis of information they gather. AdvaMed strongly encourages CMS to require ACOs to make public 1) their internal quality metrics and processes for monitoring quality and costs and 2) the changes made to these processes to achieve their cost and quality objectives. This transparency of information is critical as quality measures and the methods for implementing them will differ from one ACO to another ACO. (Recommended amendment to §425.12 and §425.23)