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December 3, 2010

Via Electronic Mail

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

Re: Medicare Program: Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program (CMS-1345-NC)

Dear Dr. Berwick:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment on the Medicare Program: Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program (CMS-1345-NC).

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 understands the complexity of the process involved in establishing the parameters for the Accountable Care Organization (ACO) program and is pleased to offer comments on a number of the areas identified in CMS's information request. Our comments will address the following issues:

- Beneficiary attribution to ACOs
- Assessing beneficiary and caregiver experience of care
- Identifying and evaluating aspects of patient-centeredness
- Quality standards to determine performance
- Additional payment models

QUESTION: Attributing Beneficiaries to an ACO - The process of attributing beneficiaries to an ACO is important to ensure that expenditures, as well as any savings achieved by the ACO, are appropriately calculated and that quality performance is accurately measured. Having a seamless attribution process will also help ACOs focus their efforts to deliver better care and promote better health. Some argue it is necessary to attribute beneficiaries before the start of a performance period, so the ACO can target care coordination strategies to those beneficiaries whose cost and quality information will be used to assess the ACO's performance; others argue the attribution should occur at the end of the performance period to ensure the ACO is held accountable for care provided to beneficiaries who are aligned to it based upon services they receive from the ACO during the performance period. How should we balance these two points of view in developing the patient attribution models for the Medicare Shared Savings Program and ACO models tested by CMMI?

ACOs hold promise for improving the quality and efficiency of care. In particular, they offer an opportunity for savings and improved quality through better management of chronic disease, for more effective delivery of preventive services, and improved coordination of care. However, unless these new health care delivery systems are carefully designed, they could have the inadvertent effect of preventing some patients from receiving the care most appropriate to their needs. AdvaMed is particularly concerned that without proper safeguards, ACOs could put patient care at risk by creating incentives to stint on care.

Congress included provisions in the ACO program requiring the Secretary to develop quality performance standards to assess quality of care furnished by ACOs, but the law appears to depend on ACO reporting of standardized quality measures. This may not fully safeguard quality of care as many quality standards focus on short-term process measures, rather than long-term outcomes measures. Further, currently available measures do not cover all important areas of health care and make it difficult for CMS to assure beneficiaries that performance measure reporting alone will be a sufficient safeguard against inappropriate ACO actions motivated only by the desire to produce savings. Moreover, quality standards may not necessarily be linked to the methods for generating savings, so that a provider may generate savings in an area without any assessment on the quality of care for patients impacted by the specific changes in practice that generate the savings.

Without appropriate safeguards, patient access to the full array of treatment options could be compromised. Specifically, ACOs could compromise patient access to the most appropriate treatment or service or access to new technologies simply because they are focused on cost savings that can result from the use of older, less expensive, and less effective treatments or technologies.

Beneficiaries must understand the changes in health care delivery and incentives created by an ACO in which they are enrolled and must understand that they are free to opt-out at any time by using a provider that is not part of the ACO. This requires prospective attribution of patients, both so that beneficiaries can understand that they are potential participants and what the implications are of their participation in the ACO, and so that the ACO itself can have a reasonable basis on which to target management of care.

In light of these concerns, AdvaMed offers the following recommendations:

> ***Recommendation: Medicare beneficiaries should consent to be prospectively assigned to an ACO and be fully informed of the potential benefits and potential concerns with enrolling in ACOs. Such consent 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.***

Beneficiaries should be notified that their provider is participating in an ACO well in advance of patient care (i.e., prospective attribution). Such beneficiary notification should be balanced and fully explain the incentive structure of the ACO and the potential rewards to participating providers. Detailed information, including the shared savings arrangement that the ACO has with providers, should be provided to beneficiaries as soon as possible in advance of their consideration of participation in an ACO.

Moreover, for beneficiaries choosing to participate in an ACO, providing such notice in advance of each ACO encounter would keep patients and their families fully informed and could be used to provide up to date information on any change in provider participation. Prospective assignment of Medicare beneficiaries would also facilitate care coordination and ACO-beneficiary collaboration.

> ***Recommendation: Medicare beneficiaries should be informed about the structure and function of the ACO, the shared savings arrangements the ACO has with its providers, other implications of the structure and function of the ACO for their care, and the rights they have in the event they are dissatisfied with their care. Similar notice should be provided prior to each ACO encounter.***

Patients should be informed about their assignment to an ACO, implications of that assignment for their care, the shared savings arrangements the ACO has with its providers, and the rights they have in the event they are dissatisfied with their care. Similar notice should be provided prior to each ACO encounter. Beneficiaries should have access to a timely appeals process, as well as instructions for seeking care from non-ACO participating professionals and providers. CMS should evaluate each ACO's

beneficiary protections in accordance with the relevant requirements specified in regulations for Medicare Advantage plans.

> ***Recommendation: For hospital admissions, hospitals and admitting physicians in ACOs should provide, at least 10 days prior to admission to the hospital, meaningful and effective prior written disclosure to patients affected by the shared savings program.***

Particularly for hospital admissions, meaningful prior written disclosure by the hospitals and physicians involved in shared savings is an important safeguard. AdvaMed recommends that such prior written notice or disclosure:

- Identify the hospital and physicians participating in the program;
- Disclose that participating physicians may receive payments for producing savings by taking specified actions;
- Describe in a written plan the shared savings program in a manner reasonably designed to inform patients about key elements of the program, including how savings, if any, are produced under the program, and any alternative treatment options, modalities, or choices that may not be included in the program, and where the patient may obtain such alternatives;
- Inform the patient that he or she may opt out of the shared savings program and seek alternative care; and
- Provide contact information for an individual within the hospital and the local Quality Improvement Organization, and inform patients that they may contact either or both of them if they have concerns about the quality of care being provided.

> ***Recommendation: AdvaMed further recommends that ACOs be closely monitored to ensure that they are not engaging in enrollment practices which discriminate against at-risk patients and to ensure that higher-risk, and potentially high-cost care beneficiaries, receive the care that is best suited to their individual medical needs.***

While AdvaMed believes that patient notification and consent is a critical safeguard to ensure that ACOs are truly patient-centered, patient notification and consent alone is not sufficient to protect patient access and quality of care. As noted elsewhere in these comments, AdvaMed recommends use of risk adjustment, independent monitoring, and limitations on compensation to protect Medicare beneficiaries against underuse of medically appropriate - and often life saving - care.

Finally, while we recognize that the Secretary may grant waivers of various legal requirements to ACOs in Medicare's shared savings program – including the physician self-referral law, the anti-kickback statute, and the civil monetary penalty laws - "as may

be necessary to carry out the provisions of this section" (Section 1899(f) of the Social Security Act), the policy concerns that gave rise to these laws still apply. Congress created these laws to protect against the risk of patient and program abuse that exists when physicians, hospitals and other Medicare providers are given financial incentives that skew judgment and health care decision-making that would otherwise be purely in the best interest of each individual patient. ACOs clearly implicate each of these strong legal protections and while the Secretary may choose to waive these legal requirements, the concerns about protecting against patient abuse still exist. AdvaMed recommends that the Secretary ensure there are strong safeguards in place to protect against patient and program abuse in the Medicare shared savings program.

QUESTION: How should we assess beneficiary and caregiver experience of care as part of our (CMS) assessment of ACO performance?

Assessing beneficiary and caregiver experience in ACOs is essential and should be part of a continuous process. If the Secretary chooses to use her new authority to waive laws designed to protect against the risk of patient and program abuse, it is critical that patient and caregiver experience is fully monitored. Fundamentally changing incentives within the health care delivery system will significantly impact beneficiaries and their caregivers. Patient and caregiver satisfaction surveys conducted by independent monitors are necessary but insufficient to fully assess ACO performance and patient and caregiver experience. Physicians and other professionals act both as agents on behalf of the patients and as the individuals who deliver care. AdvaMed recommends that the Secretary establish methods for independent monitoring of beneficiary access to appropriate care, including access to innovative medical technologies.

> ***Recommendation: In assessing the beneficiary and caregiver experience, the Secretary should ensure that patients have access to appropriate products and services (including new and improved innovative technologies) for their condition as determined by an independent medical expert.***

> ***Recommendation: The Secretary should further examine beneficiary and caregiver experience by health status (severity, risk), age, gender, and by sub-populations and other factors that may contribute to differences in individual patient needs.***

Improving quality and efficiency in the Medicare program are laudable goals. AdvaMed members develop innovative diagnostic tests and medical devices that improve patient care and increase efficiency by their earlier detection and diagnosis and improved treatment options available to patients and the providers who care for them.

QUESTION: The Affordable Care Act requires us to develop patient-centeredness criteria for assessment of ACOs participating in the Medicare Shared Savings

Program. What aspects of patient–centeredness are particularly important for us to consider and how should we evaluate them?

Patients will thrive in a patient-centered health care delivery system. A patient-centered health care system encompasses many factors, but most basic among these is recognition of the uniqueness of each individual patient and the need to deliver appropriate care for each patient's condition. In responding to this question, our recommendations focus on two key aspects—Ensuring Patient-Centeredness in ACO care and Monitoring Patient-Centered Care in ACOs.

Ensuring Patient-Centeredness in ACO Care

One of the primary goals of the ACO program is to lower overall growth in Medicare spending while maintaining or improving the quality of care received by beneficiaries. The ways in which ACOs will accomplish both of these objectives can have a significant impact on beneficiary health care. Congress mandated that ACOs demonstrate to the Secretary of HHS that they meet patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments and the use of individualized care plans. A patient-centered health care delivery program should include these features and others.

> ***Recommendation: Patient-centered health care should begin with an assessment of the patient's health and the development of an individualized care plan, both of which should include input from the patient and caregiver. The care plan should also reflect the preferences of the patient (and caregiver) and shared decision-making between patients and physicians to ensure patients are fully informed about their full range of treatment options, including medical advances and emerging technologies.***

ACO design features are critical for ensuring patient-centered care. For example, rigid ACO spending targets (benchmarks) and the prospect of shared savings may discourage providers from offering the medical advances and new treatments deemed appropriate for patients, especially when these are more expensive than older treatments. To ensure that patient-centeredness is at the core of clinical decision-making by ACO providers, ACO benchmarks should include adjustments that reflect the cost of new treatments that are more costly than average. We note that the statute gives the Secretary broad authority to adjust ACO benchmarks for "such other factors as the Secretary determines appropriate."

> ***Recommendation: ACO spending targets should be adjusted to avoid discouraging providers from adopting new treatments and medical advances for their patients. Participating entities should be required to establish protections for individual physicians and other providers that do not penalize them for being early adopters of new treatments or for participating in clinical trials.***

This recommendation can be implemented through several different mechanisms. One approach would be to allow a time-limited pass-through payment for new treatments that are more costly than average, applied both to payments received by participating organizations from Medicare as well as to incentive or shared savings payments received by individual providers from the participating organization. Specific examples of this approach exist in the Medicare program, such as add-on payments for the use of new technologies in the inpatient hospital setting and pass-through payments for new technology under the hospital outpatient prospective payment system. These policies, however, would have to be modified to provide more effective support for medical innovation.

Furthermore, financial incentives offered to ACO providers for reducing costs and sharing in savings should not interfere with their patient-centered clinical decision-making.

> ***Recommendation: ACOs should employ financial incentives that are reasonably limited in amount, and shared savings payments should be distributed to physicians in a physician group on a per capita basis.***

Limiting the financial incentives offered to physicians through, for example, caps on payment, is one way to limit the adverse impact on patient care that can result from financial incentives to limit items and services. In addition, payment on a per capita basis mitigates an individual physician's incentive to generate disproportionate cost savings by stinting on care in an effort to increase their personal level of shared savings. While some may argue that ACOs need to be given maximum flexibility in deciding how to allocate shared savings within the ACO, AdvaMed strongly believes that Medicare's ACO regulations should include a number of ground rules to limit incentives to stint on patient care.

Monitoring Patient-Centered Care in ACOs

AdvaMed has several recommendations regarding patient-centeredness as an important issue for assessing, monitoring, and evaluating ACO performance. Our specific recommendations include development and implementation of a comprehensive independent monitoring program to assess beneficiary and caregiver experience of care, monitoring appropriate beneficiary access to care within an ACO including access to innovative medical technologies and specialists, comparing ACO models of care to non-ACO models, surveying participating beneficiaries and caregivers, and establishing an appeals and grievance system as described in more detail below.

> ***Recommendation: AdvaMed recommends that beneficiary and caregiver experience of care be monitored via an independent monitoring program.***

AdvaMed recommends that a comprehensive independent monitoring program be developed and charged with the responsibility of overseeing health care delivery within ACOs. This program could be implemented in a number of ways including assignment of a government-appointed independent monitor to each ACO (or alternatively, one monitor for several ACOs in the same general area), creation of an organization to monitor and provide oversight of ACO programs throughout the country, or assessment by an existing national review body. Monitoring should continuously assess the performance of an ACO including the ACO's performance on meeting patient-centeredness criteria, quality standards, improvements in beneficiary outcomes, and access to appropriate treatments and services, among other factors. Monitors should also assess whether ACOs have adequate provider networks, as well as specialists, to ensure access to appropriate care, services, and medical advances.

AdvaMed also recommends that independent monitors survey ACO participating beneficiaries and providers regarding the quality of services available within their ACO. Provider surveys should include their assessment of the availability of products and services, their continued ability to make medically appropriate decisions on behalf of their patients, and changes in practice that have been implemented under the ACO model. Similarly, we recommend that beneficiaries be anonymously surveyed regarding their assessment of the care available to them through the ACO as compared to their care experience in other Medicare payment models, as well as their overall impression of the quality of care they are receiving through the ACO. AdvaMed would recommend that the initial surveys be conducted shortly after enrollment to assess the disclosure of ACO information provided to beneficiaries, one year after the roll-out of the ACO program, and on a periodic basis thereafter.

> ***Recommendation: AdvaMed recommends that ACOs monitor appropriate beneficiary access to care, including access to innovative medical technologies and specialists. All monitor findings regarding access to care and quality should be made available to the public.***

Patient-centered care requires that each patient be assessed based on their unique condition and that physician clinical decision making be preserved. Implementing a patient-centered approach to care within the ACO model will require ACOs to maintain appropriate beneficiary access to care. This will involve taking steps to ensure that patients and their providers have continued access to the products and services that are best suited to the treatment of the patient's individual condition including access to innovative medical technologies and to services provided by specialists. Ensuring appropriate access to care will require ACOs to have plans in place to accommodate participation by specialists and will also require them to implement policies and procedures to address situations where the best course of treatment for a patient may involve the use of higher cost and/or newly developed technologies and services.

> ***Recommendation: AdvaMed recommends that ACO care performance be measured by comparing ACO models of care to non-ACO models of care.***

Comparison of ACO models of care to non-ACO models is an important tool for assessing ACO performance. These assessments can be used to, among other things, examine utilization trends in an effort to determine if practice patterns differ among the various settings and, if so, whether the patterns found within ACOs have resulted in higher, lower, or the same quality of care for beneficiaries. They can also be used to assess the rate of technology diffusion within the different settings. AdvaMed would recommend that this comparison be performed within one year of the roll-out of the ACO program and on a periodic basis thereafter. The results of these comparisons should be made available to the public.

> ***Recommendation: AdvaMed recommends that each ACO establish an appeals and grievance system.***

AdvaMed recommends that each ACO have an appeals and grievance system to allow patients and their physicians to seek recourse when appropriate access to care is compromised. Information regarding the outcome of appeals and other deliberations related to product selection and access should be made available to the independent monitors to enhance that program's effectiveness.

QUESTION: What quality measures should the Secretary use to determine performance in the shared savings program?

AdvaMed has long been a strong advocate for the development of quality of care measures and well-conceived and executed value-based purchasing programs. To this end, AdvaMed is a member of both NQF and the AQA and plays an active role in these organizations' discussions of principles that underlie measure development as well as specific measures being developed for care provided in various health care settings.

The Congress mandated that the Secretary determine appropriate measures of the quality of care furnished by ACOs, including measures of clinical processes and outcomes, patient and caregiver experience of care, and utilization. We are pleased that CMS is seeking comments in its RFI about quality measures. Quality standards are essential to assure that the quality of care improves (or at a minimum is maintained) and that the financial incentives under ACOs do not lead to stinting on appropriate care. AdvaMed has a number of specific recommendations in this area.

> ***Recommendation: Incentive systems designed to reward quality care should not inappropriately penalize providers that use new treatments and technologies. This could be achieved by a time-limited carve-out of patients***

> ***receiving the new treatments from calculation of reimbursement penalties or bonuses based on quality, where measurement of quality is based on measuring conformity to established processes of care or on incomplete measures of outcomes.***

Quality standards are essential to assure that the financial incentives under ACOs do not discourage providers from offering appropriate care, including new treatments. Providers who are early adopters of new treatments should not be penalized for using these treatments in lieu of more established methods of care unless robust outcome measures show poorer results.

> ***Recommendation: Quality care measures should keep pace with advances in medical treatments and technologies. In calculating bonuses or penalties for meeting quality standards, certain cases should be excluded for a reasonable period of time when existing quality measures do not reflect the new treatments available to patients.***

Physicians who are early adopters of a new treatment should not be penalized by low quality scores that are the result of quality measures that reflect a standard of care at an earlier point in time. This low quality penalty could have been the case when coronary angioplasty with stents were first being used as an alternative to no treatment and/or drug therapy. Failure to adopt revised standards would have discouraged physicians from becoming early adopters of this alternative treatment which has since become the standard of care. Quality measurement should not freeze medical practice in place or erect barriers to medical innovation and improved patient care. Rapid updating of measures will help, but is not a complete solution to the problem.

> ***Recommendation: In assessing the quality of care furnished by ACOs, the Secretary's measures should ensure that patients have access to appropriate products and services, including new and improved innovative technologies, for their condition. These measures should attempt to capture the long-term benefits of various interventions, since many new technologies provide long-term outcomes and savings that would not be captured using measures of procedure/treatment effectiveness at 30-days or longer periods post discharge.***

As noted above, Congress directed the Secretary to incorporate measures of utilization in quality measures for ACOs. We recommend that such measures consider not only utilization but under-utilization of services and technologies to ensure that patient care is not compromised.

> ***Recommendation: Quality performance standards developed by the Secretary for ACOs should incorporate measures of health outcomes and be risk-adjusted.***

Robust quality measures are needed to offset financial incentives to realize short-term savings by reducing the volume and intensity of services, even when an individual patient's condition requires both more services and more expensive services than the average. In addition, ACO quality is best measured through outcomes of care, where feasible. These outcome measures should be linked to care processes where the ACO achieves cost reductions, in order to assure that savings do not come at the expense of patient health. In addition, outcome measures should reflect the full range of outcomes, rather than relying solely on a single measure that may reflect only one dimension of quality. This is especially important in the case of treatments to restore or maintain function or to treat chronic disease. For example, applying a quality measure to patients undergoing hip or knee replacement that reflects only re-hospitalization or 30-day mortality would not capture either the functional restoration that is the purpose of the surgery or the durability of the artificial joint, which can only be measured over a period of many years or inferred from other data sources on the expected functioning of the device.

> ***Recommendation: Quality measures should be developed through a transparent process.***

The process for developing quality measures should include opportunities for all affected stakeholders to provide input into their form and content. Measures should also be endorsed by NQF.

> ***Recommendation: Assessment of the quality of care furnished by ACOs should incorporate a mechanism for evaluation of ACO initiatives by an independent medical expert, board, or panel to determine whether quality of patient care has been adversely affected, and for independent verification of compliance with quality standards.***

CMS should not rely solely on self-reporting as a method for determining an ACO's compliance with quality of care standards. Review by an independent third-party medical expert, board, or panel is an important safeguard against potential adverse effects on patient care. This independent monitor should also evaluate beneficiary access to advances in medical treatments and technologies, and access to specialist care, by comparing the experience of beneficiaries inside and outside the ACO. Further, CMS should survey specialty physicians to determine whether they have concerns regarding patient access to advanced technologies that may be costly.

QUESTION: What additional payment models should CMS consider in addition to the model laid out in Section 1899(d), either under the authority provided in 1899(i) or the authority under the Center on Medicare and Medicaid innovation? What are the relative advantages and disadvantages of any such alternative payment models?

With the ACO program, Medicare's fee-for-service program will embark on a new model for care delivery under which physicians and hospitals will provide care with aligned incentives for reducing costs, improving quality, and sharing savings. The model has potential for increasing collaboration and coordination among providers and eliminating care fragmentation, waste, and duplication that many Medicare beneficiaries now face. However, the model also contains incentives for minimizing costs that could result in stinting on care and compromised patient access to care and treatments that may be more expensive but more appropriate and more effective in the short and/or long term for their conditions. AdvaMed recommends that CMS consider the following before moving forward with risk-sharing models as contemplated by 1899(i).

> ***Recommendation: CMS should proceed cautiously in implementing the ACO program and focus initially only on the basic model outlined in Section 1899(d) of the ACO authority.***

The law's basic model envisions groups of providers being paid their usual fee-for-service reimbursements from Medicare, and sharing in savings if the group provides care to assigned beneficiaries for less than a benchmark spending target while also meeting specified quality standards. No penalties would be incurred for spending above the benchmark target. Under this model, the ACO and its providers assume no risk related to either the amount they receive for the care they provide or for the total cost of medical services provided. While the providers under this model are not at risk for reduced revenues, patients, on the other hand, may see significant changes in the care they are provided. While the changed financial incentives under which providers in the ACO operate can lead to improved care outcomes, they can just as easily result in diminished patient access to treatments that are appropriate for their particular care needs. Since we have little information regarding how providers might respond to these incentives and their impact on patient care, CMS should first thoroughly test the basic model, before authorizing other risk-sharing models--such as withholding some portion of fee-for-service payments for distribution at a later point in time, or capitated models.

> ***Recommendation: Before authorizing the use of greater risk-sharing models under the ACO program, the Secretary should first thoroughly evaluate changes in patient care, including patient access to new treatments and technologies, under the model specified in 1899(d).***

Little evidence exists regarding how providers will respond to new financial incentives and how patients' health care outcomes will change under the ACO model. CMS should use an independent evaluator to assess patient care outcomes under the model. The evaluator's assessment should compare the experience of beneficiaries inside and outside of ACOs, the adequacy of quality standards used in ACOs, and patient access to appropriate care and new treatments and technologies.

> ***Recommendation: The Secretary should require, through regulations, that risk-sharing ACO models incorporate, at a minimum, an analogous set of beneficiary protections included in Medicare regulations for Medicare Advantage plans, if not otherwise addressed by the preceding AdvaMed recommendations.***

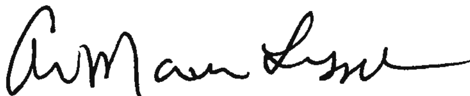
Given the similarity of incentives contained in risk-sharing ACO models to those of Medicare Advantage (MA) plans, and the potential consequences these incentives have for patient care in both delivery systems, the risk-sharing model should be required to offer, at a minimum, an analogous set of beneficiary protections as required for MA plans. The MA regulations address a wide range of issues, including plans having to cover all Medicare Part A and B benefits, disclosing the plan's performance, and grievance and appeals procedures.

Conclusion

AdvaMed greatly appreciates the opportunity to comment on the impending rulemaking for the ACO shared savings program and potential CMMI models and urges CMS to consider and incorporate our recommendations into the proposed rules for the ACO program and any regulatory or administrative actions taken with respect to the new CMMI. We also urge CMS to give consideration to comments from AdvaMed members and others who will be providing detailed recommendations regarding these matters.

We would be pleased to answer any questions regarding these comments. Please contact Richard Price, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7227 or DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if you require further assistance.

Sincerely,



Ann-Marie Lynch
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