AdvaMed
Advanced Medical Technology Association

POLICY RECOMMENDATIONS TO ADDRESS SELECTED HEALTH DELIVERY REFORMS

INTRODUCTION

The Patient Protection and Affordable Care Act (PPACA) includes provisions for the Medicare program to test and implement a variety of innovative payment and health delivery options. Two such provisions, the establishment of the Medicare shared savings program (Section 3022) and the payment bundling demonstration project (Section 3023) share several common elements:

- Establishment of provider-led organizations that are accountable for the costs and quality of care for a pre-defined population and/or range of services; [1]
- Payment reforms that emphasize risk- and reward-based quality improvements and cost containment; and
- Quality measurement and performance standards designed to protect Medicare beneficiary access to and quality of care.

A health care system organized around accountable care organizations (ACOs) or bundling of acute and post-acute payments for an episode of care has potential for improving the quality and efficiency of care. However, unless the new systems are carefully designed, they could have the inadvertent effect of discouraging medical progress and preventing some patients from receiving the care most appropriate to their needs. Problems can arise in several ways.

Medical Progress

Medical progress is dependent on a a physician or other provider's willingness to adopt new and better treatments and cures, whether the improvement is a new surgical technique or a new medical device. Such improvements are often initially developed in academic health centers or by medical device companies. In the medical device area, much of innovation comes from small companies dependent on venture capital investment. For these companies, the expectation of a financial return once the product receives regulatory approval is especially critical to maintaining the flow of financing during the research and development phase.

[1] This includes the establishment of groups of providers that are legally permitted to receive and distribute Medicare payments to participating providers.

Most typically, once a device is developed and receives regulatory approval, it is initially adopted by a small group of cutting edge physicians and medical centers. If it proves successful, it gradually diffuses until it becomes the standard of care. Under an ACO or bundled payment model, unless special provision is made for new treatments, this process of adoption and diffusion could be interrupted in several ways. First, to the extent that providers under ACOs or bundled payments are rewarded based on quality measures and these measures are based on process standards, physicians who are early adopters of a new treatment could be penalized by low quality scores. For example, if physicians' quality of care is measured by whether or not they give an aspirin after a heart attack and no special exception is provided for a new, alternative treatment, it will be difficult to find physicians who will be willing to be early adopters of an alternative medication, even if it works better than the aspirin. Or, those physicians willing to provide cutting edge care could receive inappropriately low quality scores.

Second, new treatments may be more costly than old treatments, particularly when they are first introduced, but may deliver much higher value. Moreover, alignment of incentives means that all providers will have incentives to minimize costs within the payment window, but this may discourage adoption of treatments that reduce long-term costs. A rigid system of rewarding physicians and other providers under ACO and bundled models for reducing the cost of care and penalizing them for higher costs could discourage adoption of more costly treatments before they become the standard of care, even if they are clinically superior and would reduce long-term costs.

Appropriate Treatment for Individuals

All individuals have unique attributes. While care for many patients with a specific illness may be fairly standardized and the efficiency of such care can be fairly measured and rewarded, for other patients, special factors—whether they are co-morbidities, patient preferences, individual reactions to treatment, or factors unknowable in advance--may mean that appropriate care will cost substantially more than the average. The reimbursement system should avoid discouraging providers from treating these higher cost patients or providing more costly but more appropriate treatments to them.

These issues can be addressed without undermining the goals of new delivery and payment models—with responsibility for care for across a longer period of time together with strong incentives for improved quality and greater efficiency through greater coordination and collaboration among providers

This report reflects a range of policy recommendations to ensure these new health care delivery system methods provide physicians and their patients with access to the full range of services to preserve and promote the health of our nation's elderly, including the best that medical technology has to offer.

MEDICARE SHARED SAVINGS PROGRAM/ ACCCOUNTABLE CARE ORGANIZATIONS (ACOs)

Section 3022 of PPACA requires that the Secretary establish a Medicare shared savings program not later than January 1, 2012. The program is intended to promote the establishment of groups of hospitals and physicians who are jointly responsible for the quality and cost of the full range of care for a pre-selected group of Medicare beneficiaries.

Background

Under the program, groups of providers and suppliers may establish and work together through accountable care organizations (ACOs) to provide care to Medicare fee-for-service beneficiaries. ACOs that meet pre-established quality performance standards are eligible to receive additional payments in the form of shared savings with the Medicare program.

The law specifies eligibility requirements for ACOs including the types of participating providers and groups, legal structure and governance issues, and required processes. To be eligible, an ACO must participate in the program for a period of not less than 3 years (referred to as the agreement period) and must have at least 5,000 beneficiaries assigned to it. The Secretary is responsible for determining a method whereby Medicare beneficiaries are assigned to an ACO, based on their utilization of primary care services.

The Secretary is required to establish appropriate quality measures, performance standards and reporting requirements necessary to assess the quality of care provided by ACOs. Provisions of the law also provide for the Secretary to monitor ACO avoidance of at-risk patients and to impose sanctions (including termination of agreements) for such behavior, or for failure to meet quality performance standards.

ACO providers and suppliers continue to receive Medicare fee-for-service Part A and B payments for services provided to beneficiaries assigned to the ACO. In addition, participating ACOs are eligible to receive shared savings payments, based on certain requirements, as discussed below.

Shared savings payments are determined based on the difference between the ACO's benchmark expenditure level and the actual ACO expenditures for a given year of the agreement period. The following factors are considered in determining the shared savings payment. (Note that terminology has been added for discussion purposes; these terms are not specifically referenced in the law.)

<u>Setting the Benchmark</u>

- A *benchmark baseline* is initially established for each ACO and reset at the start of a new agreement period. The benchmark baseline is determined using the

most recently available 3 years of per-beneficiary expenditures, for Parts A and B, for the panel of beneficiaries assigned to the ACO.

- *Adjustments to the benchmark baseline* are made to account for beneficiary characteristics and other factors, as deemed appropriate by the Secretary.
- Each ACO's benchmark baseline is updated annually by the projected absolute amount of growth in national per capita expenditures for Parts A and B. For purposes of discussion, this amount is referred to as the ACO's *annual benchmark amount.*

Determining Eligibility for Shared Savings Payments

An ACO is eligible to receive payments for shared savings based on two factors:

- First, the ACO must meet pre-determined quality performance standards.
- Second, the estimated average per capita Medicare fee-for-service Part A and B expenditures for the ACO panel of beneficiaries must be at least a specified percent below the applicable annual benchmark amount for that ACO. The Secretary determines this percent and may account for normal variation in expenditures, based on the number of beneficiaries assigned to an ACO.

Determining the Shared Savings Payment Amount

Subject to these eligibility requirements, an ACO's shared savings payment amount is determined as follows:

- First, the difference between the ACO's estimated average per capita Medicare expenditures in a year (adjusted for beneficiary characteristics) and the ACO's annual benchmark amount (as described above) is determined.
- The ACO receives a percentage of this difference as a shared savings payment. The remainder of the difference is retained by the Medicare program. The Secretary has discretion to determine the appropriate percent of shared shavings between ACOs and the program, as well as any limits on the total amount of shared savings that may be paid to an ACO.

Discussion

In general, the ACO model is intended to introduce incentives to constrain volume growth while maintaining or improving quality of care. The law includes a voluntary approach with a bonus-only design wherein providers continue to receive Medicare fee-for-service payments, but are also eligible to receive shared savings payments if they meet specified quality standards and achieve per-beneficiary spending reductions. Under this approach, providers have the potential for upside reward, while having virtually no downside risk.

While this model has the potential to encourage quality care and cost-effective practice, it does not provide explicit protections for beneficiaries or provisions designed to avoid discouraging adoption of beneficial new treatments and cures. If designed improperly, it

could limit patient access to medically appropriate care and slow medical progress. There is little experience to-date with shared savings programs through accountable care organizations and, in many respects, ACOs are still in their infancy. Caution must be exercised to ensure that payment incentives do not distort physicians' clinical judgment, inhibit beneficiary access to services and technologies, or discourage adoption of better treatments.

The recommendations that follow are designed to:

- Establish explicit protections for Medicare beneficiary access to medically appropriate care, including advances in medical technology, and to improved treatments and cures;
- Ensure that quality performance standards include measures of the full range of health outcomes attributable to technology;
- Support medical progress for current and future patients;
- Avoid penalizing ACO providers for spending growth due to random variation in costs beyond their control; and
- Provide for an open and transparent process for projecting expenditure targets, including amounts attributable to medical technology innovation.

Recommendations

Recommendations Protecting Patient Access to Appropriate Care

- **Recommendation 1A: Participating ACOs should be required to provide processes that preserve physician clinical decision making and protect beneficiary access to the most appropriate services and medical advances. ACOs should ensure that (i) individual physicians participating in the shared savings program made a patient-by-patient determination of the most appropriate service, procedure or item[2] and the availability of the full range of services, procedures or items was not compromised by any aspect of the shared savings program; and (ii) individual physicians still have available the same selection of services, procedures or items after implementation of the shared savings program as before, and that the economies gained through the ACO resulted from inherent clinical and fiscal value and not from restricting the availability of services, procedures or items.**

Ensuring that a patient-by-patient determination was made regarding the determination of the service, procedure or item needed for each patient, and that the same selection of items and services are available to physicians will serve as a safeguard against limitations on access and adverse effects on the quality of care.[3]

[2] The term "item" includes any device or supply.

[3] This safeguard was included in the HHS Office of Inspector General (OIG) advisory opinions on gainsharing.

ACOs also should be required to provide a beneficiary appeals process, as well as an internal appeals process for physicians. Appeals should be monitored and published.

- **Recommendation 2A: Patients should be notified about their assignment to an ACO and rights if they are included in an ACO. 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.**[4]

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.

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 informs patients that they may contact either or both of them if they have concerns about the quality of care being provided.

- **Recommendation 3A: The Secretary should establish methods for independent monitoring of beneficiary access to appropriate care, including access to innovative medical technologies.**

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[4] In light of the need for prior written notice, services provided to patients in emergent situations should not be included in the gainsharing or shared savings program.

The full impact of shared savings incentives on ACO adoption and use of high cost, high value technologies is unknown. Standards should be developed that address patient access to critical medical advances. These may include measures of selected service use for the ACO prior to and during the agreement period, as well as requiring ACOs to establish and document processes to ensure appropriate evaluation and adoption of critical technologies. The evaluation on beneficiary access to the full array of technologies should include baseline use of services for the conditions subject to shared savings, and comparing utilization to that provided under the shared savings program.

- **Recommendation 4A: ACOs should employ financial incentives that are reasonably limited in duration and 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 caps on payment and limiting the term of the arrangement) is one way to soften the risk that financial incentives to limit items or services can adversely impact patient care. In addition, payment on a per capita basis mitigates an individual physician's incentive to generate disproportionate cost savings.[5]

Recommendations to Address Quality Performance Standards

- **Recommendation 5A: 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 be incorporated into performance standards used to assess the quality of care provided by ACOs.**

PPACA clause (b)(3)(A)(iii) requires the Secretary to determine appropriate measures of the quality of care furnished by ACOs, including measures of utilization. Such measures should be developed to detect under-utilization of services and technologies to ensure patient care is not compromised.

- **Recommendation 6A: Quality performance standards developed by the Secretary should incorporate measures of health outcomes and be risk-adjusted.**

The Secretary should require that any program of shared savings be tied to quality improvement, adherence to clinical protocols, and achieving high performance on quality measures. Robust quality measures are needed to offset financial incentives to reduce the volume and intensity of care. ACO quality is best measured through outcomes of care, where feasible. Outcome measures should reflect the full range of

[5] These safeguards were included in the OIG advisory opinions on gainsharing.

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-hospitalizations 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 7A: 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 the National Quality Forum (NQF).

- **Recommendation 8A: Assessment of the quality of care furnished by ACOs should incorporate a mechanism for evaluation of ACO initiatives by an independent medical expert to determine whether quality of patient care will be adversely affected, and for independent verification of compliance with quality standards.**

Review by an independent third party medical expert is an important safeguard against potential adverse effects on patient care. Before beginning any new ACO initiatives, such initiatives should be evaluated by an independent medical expert to determine whether patient care may be adversely affected. Moreover, CMS should not rely solely on self-reporting as a method for determining an ACO's compliance with quality of care standards. CMS should also review the care provided to a case-mix stratified sample of patients served by the ACO. Further, CMS should survey specialist physicians to determine whether they have concerns regarding patient access to advanced technologies that may be costly.

<u>Recommendations Supporting Medical Progress for Current and Future Patients</u>

- **Recommendation 9A: Spending targets should be adjusted to avoid discouraging adoption of new treatments. 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 that are more costly than the standard of care 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 in outpatient hospital care. These policies, however, would have to be modified to provide more effective support for medical innovation. Important modifications for the policy applying to the inpatient hospital setting include:

1) Lowering the current cost threshold required to trigger the add-on payment, since the provider base against which costs are measured under the ACO will make the new treatment a smaller percentage of the total cost of care provided to an individual patient, but the cost of the new treatment could still be a very significant factor affecting payments to individual physicians. Moreover, the new emphasis on reducing costs will reduce the willingness of providers to cover higher costs for new treatments by internal cost shifting.
2) Increasing the amount of the add-on payment recognized for purposes of reimbursement. As noted above, the new sensitivity to costs will reduce providers' willingness to cost shift among patients or treatments.
3) Allowing major incremental improvements in technologies (e.g., a battery that lasts 10 years rather than 5) to meet the test that the technology is new.
4) Allowing a broader range of evidence to be considered in assessing whether a new technology meets the test of providing substantial clinical improvement over an older technology.
5) Providing flexibility to the test that a new technology meets the substantial clinical improvement test by allowing new technologies to meet this test by demonstrating that there is substantial likelihood that clinical improvement will result. This should not be unreasonable, given the fact that conclusive evidence would not necessarily be available in the short period of time for which an add-on payment would be available (e.g., 3 years).

Alternative approaches to add-on payments for new technologies include:

1) a carve-out approach employed by some private payers, which allows separate and additional payments for implantable and other high-cost technologies; or
2) building expected expenditures for add-on or pass-through payments into overall budget targets for ACOs and adjust them periodically based on experience. This approach would still require, however, protection for individual providers within the ACO who are early adopters of new treatments.

Those services characterized by low frequency and high cost should be excluded from the spending targets initially. These services represent special problems for beneficiary access.

- **Recommendation 10A: 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 lead to stinting on appropriate care. Providers that are early adopters of new treatments that have not yet become the standard of care should not be penalized for using these treatments in lieu of more established methods of care unless robust outcome measures show poorer results.

Recommendations to Address Random Spending Variation

- **Recommendation 11A: The Secretary should adjust the ACO benchmark baseline amount and the ACO's yearly average per capita Medicare expenditures to account for differences in beneficiary health status (severity, risk), age, gender, and other factors that may contribute to expenditure variations beyond the ACO's control. The Secretary should commit to an ongoing process of reviewing and refining its risk adjustment methodologies to assure their accuracy, adequacy, and appropriateness.**

The benchmark baseline amount and yearly average ACO expenditures are critical determinants of eligibility for and level of shared savings payments for the agreement period. These amounts should be normalized to account for factors that can differentially affect the rate of increase in expenditures from year to year, and that are beyond the control of an ACO. Risk adjustment requires constant attention because clinical data change and improve and because a risk adjustment that is continually adapting makes it more difficult for providers to focus on serving only the most profitable patients.

- **Recommendation 12A: For purposes of determining eligibility for and the amount of shared payment, the Secretary's estimation of an ACO's yearly average per capita Medicare expenditures should be adjusted to account for extremely costly cases.**

The increased incidence of extremely costly cases can skew an ACO's per capita expenditures to a degree that will not be reflected in the ACO corresponding benchmark amounts. Particularly vulnerable are ACOs enrolling relatively small panels of patients. With a panel of 5,000 beneficiaries, for example, an ACO may be unable to adequately spread the cost of such cases.[6] ACOs should not be penalized for treating these catastrophic cases. Such an adjustment would be analogous to Medicare's current treatment of outlier cases in the MS-DRG system.

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[6] Considerable attention has been given to the appropriate minimum number of patients comprising an ACO panel; further research is required. Recently, McClellan et al noted that "initial actuarial analyses suggest that, for reliable measurement of spending patterns, an accountable care organization will need to serve a primary care population of at least 5,000 Medicare beneficiaries…further analysis is warranted." (*Health Affairs*. 2010; 29(5):w 982-990.)

- **Recommendation 13A: ACOs should not be penalized for beneficiaries assigned to it going outside the ACO for care.**

Patients are unique and may require treatments or services that are not available to them within the network of ACO providers. Neither the beneficiary, her physician, nor the ACO should penalized when such care is provided.

Recommendations for Projecting Expenditure Targets

- **Recommendation 14A: The ACO benchmark should be updated annually throughout the agreement period in order to reflect the most recent data and trends in per capita expenditures for Medicare fee-for-service Parts A and B.**

Under this approach, benchmark amounts would better reflect revisions to practice patterns and changes in input prices, including technology prices.

- **Recommendation 15A: The methods and data used to determine the ACO benchmark for the agreement period (based on the Secretary's projection of the absolute amount of growth in per capita expenditures for Medicare fee-for-service Parts A and B) should be transparent and subject to public comment. Projections should account for advances in patient care and medical technology that may not be captured adequately in the data used to establish the projections.**

This approach would ensure that increased costs associated with ACO adoption of new cost-increasing, quality-enhancing technologies and therapies are adequately reflected in the determination of shared savings benchmark levels and payment amounts.

PAYMENT BUNDLING

Section 3023 of the law establishes a national 5-year pilot program on payment bundling. The program is designed to develop and evaluate bundled payment for a range of services including inpatient and outpatient hospital, physician, and post acute care (including home health, skilled nursing, inpatient rehabilitation, and inpatient services furnished by a long-term care hospital).

Background

An entity comprised of providers including a hospital, a physician group and post-acute care providers and suppliers may apply to participate in the bundling pilot. Bundled payment, based on a method determined by the Secretary, would be made to the participating entity for a given episode of care.

Bundled payments would encompass an episode of care that begins three days prior to admission and spans to 30 days following discharge, although the Secretary is given discretion to establish an alternative period. The pilot will focus on ten clinical conditions, to be selected by the Secretary based on a variety of criteria. In developing the pilot, the Secretary is required to determine the patient assessment instrument to be used to determine the most clinically appropriate site(s) for the provision of post-acute care.

The Secretary is required to develop payment methods for the pilot program, which may involve bids from entities. The payment is to be comprehensive, covering the costs of all services furnished during the episode.

The provision requires the Secretary to develop quality measures for use in the pilot program for episodes of care and for post-acute care. These measures are to include a range of factors such as functional status improvement and other patient outcomes. Participating entities are required to submit data on quality measures during each year of the pilot program.

The pilot program is to be implemented by January 2013, with an independent evaluation starting two years following implementation. If the program meets goals of improving or maintaining quality and reducing spending, the law calls for the Secretary to develop a plan for expanding the pilot program by January 2016. Expenditures under the pilot are to be budget neutral.

Discussion

Bundling payment for services around a hospitalization creates incentives for providers to seek the appropriate care setting, provide care more efficiently and coordinate care more effectively. At the same time, bundling can be challenging due to factors such as variation in clinical practices and site of care, current lack of integration between individual providers of care, and limitations of systems and mechanisms needed to track care and related costs across settings over time. Moreover, there exists wide variation in the provision of post acute care services and related spending in the post-discharge period.

Approaches to bundling have been explored on a limited basis in the past.[7] This demonstration suggests a very broad payment bundle, including not only hospital and physician services during an inpatient stay (the focus of previous and current demonstrations), but also all post-acute care within a 30-day post-discharge window. In this regard, there has been virtually no broad-scale experience with including post-acute services in payment bundling demonstration projects to-date. Moreover, there is the potential for extreme variation in these services with respect to provider, patient characteristics and cost.

The law provides little detail regarding the establishment of the bundled payment method for participating entities, giving considerable discretion to the Secretary. Past MedPAC deliberations may provide insight on potential approaches, however. One option considered by the commission is that of "virtual bundling" wherein individual providers in the participating entity continue to receive Medicare fee-for-service payments, but those payments are adjusted based on providers' relative efficiency across an episode of care. Another variation considered by MedPAC is "hybrid bundling" wherein hospitals and physicians receive bundled payment for the hospitalization, and virtual bundling (fee-for-service with an adjustment) is provided for post-acute care services related to the episode.

Given the nature, breadth and complexity of PPACA's episode of care bundling pilot, extreme caution needs to be exercised in establishing the program so as to preserve quality, achieve spending objectives, assure continued patient access, and avoid unnecessary risk to Medicare beneficiaries and providers. In contrast to the shared savings plan discussed previously, the bundling approach contemplated by this section of the law places far greater risk of loss on a participating entity (albeit this risk is confined to pilot program participating entities). Furthermore, unlike a demonstration initiative, this pilot program can be expanded by CMS without further legislation, thereby requiring that additional caution be exercised in the initial design.

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[7] For example, there has been limited experience with bundling of hospital and physician services for an inpatient stay for selected conditions.

The recommendations that follow are designed to:

- Establish explicit protections for Medicare beneficiary access to medically appropriate care, including advances in medical technology;
- Ensure that quality performance standards include measures of the full range of health outcomes attributable to medical technology;
- Support medical progress for current and future patients;
- Avoid penalizing providers for spending growth due to random variation in costs beyond their control; and
- Provide for an open and transparent process for estimating and updating bundled payment amounts, including updates attributable to medical technology innovation.

Recommendations

Recommendations Protecting Patient Access to Appropriate Care

- **Recommendation 1B: Participating providers should be required to provide processes that preserve physician clinical decision making and protect beneficiary access to the most appropriate services and medical advances. Bundling participants should ensure that (i) individual physicians participating in the pilot program made a patient-by-patient determination of the most appropriate service, procedure or item[8] and the availability of the full range of services, procedures or items was not compromised by any aspect of the pilot program; and (ii) individual physicians still have available the same selection of services, procedures or items after implementation of the pilot program as before, and that the economies gained through the pilot program resulted from inherent clinical and fiscal value and not from restricting the availability of services, procedures or items.**

Ensuring that a patient-by-patient determination was made regarding the determination of the service, procedure or item needed for each patient, and that the same selection of items and services are available to physicians will serve as a safeguard against limitations on access and adverse effects on the quality of care.[9]

Bundling pilot participants also should be required to provide a beneficiary appeals process, as well as an internal appeals process for physicians. Appeals should be monitored and published.

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[8] The term "item" includes any device or supply.

[9] This safeguard was included in the HHS Office of Inspector General (OIG) advisory opinions on gainsharing.

- **Recommendation 2B: Patients should be notified about their inclusion in a bundled payment system and their rights in the new system.**

Patients should be informed about their participation in a bundled payment system and the implications of new incentives for their care and the rights they have in the event they are dissatisfied with their care.

- **Recommendation 3B: The Secretary should establish methods for independent monitoring of beneficiary access to appropriate care, including access to innovative medical technologies.**

The full impact of bundling arrangements and use of high cost, high value technologies is unknown. Standards should be developed that address patient access to critical medical advances. These may include measures of selected service use by providers under the bundled arrangement prior to and during the agreement period, as well as requiring providers to establish and document processes to ensure appropriate evaluation and adoption of critical technologies. The evaluation on beneficiary access to the full array of technologies should include baseline use of services for the conditions subject to bundling, and comparing utilization to that provided under the bundling pilot program.

Recommendations to Address Quality Performance Standards

- **Recommendation 4B: In assessing the quality of care furnished by providers participating in a bundled payment system, the Secretary's quality measures should ensure that patients have access to appropriate products and services (including new and improved innovative technologies) for their condition. These measures should be incorporated into performance standards used to assess the quality of care provided by these providers**

Measures of utilization should be developed to detect under-utilization of services and technologies so as to ensure patient care is not compromised.

- **Recommendation 5B: Quality performance standards developed by the Secretary should incorporate measures of health outcomes and be risk-adjusted.**

The Secretary should require that bundled payment systems be tied to quality improvement, adherence to clinical protocols, and achieving high performance on quality measures. Robust quality measures are needed to offset financial incentives to reduce the volume and intensity of care. Quality is best measured through outcomes of care, where feasible. 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. As discussed previously, applying a quality measure to patients undergoing hip or knee replacement that reflects only re-hospitalizations 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 6B: 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 the National Quality Forum (NQF).

- **Recommendation 7B: Assessment of the quality of care furnished by providers participating in a bundled payment program should incorporate a mechanism for independent verification of compliance with the standards.**

CMS should not rely solely on self-reporting as a method for determining compliance with quality of care standards. CMS should also review the care provided to a case-mix stratified sample of patients served by providers participating in a bundled payment program. Further, CMS should survey specialist physicians to determine whether they have concerns regarding patient access to advanced technologies that may be costly.

<u>Recommendations Supporting Medical Progress for Current and Future Patients</u>

- **Recommendation 8B: Payments should be adjusted to avoid discouraging adoption of new treatments. The Secretary should establish protections for individual physicians and other providers so as not to penalize them for being early adopters of new treatments that are more costly than the standard of care 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 providers from Medicare. 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 in outpatient hospital care. These policies, however, would have to be modified to provide more effective support for medical innovation. Important modifications for the policy applying to the inpatient hospital setting include:

1) Lowering the current cost threshold required to trigger the add-on payment, since the provider base against which costs are measured will make the new treatment a

smaller percentage of the total cost of care provided to an individual patient, but the cost of the new treatment could still be a very significant factor affecting payments to individual physicians. Moreover, the new emphasis on reducing costs will reduce the willingness of providers to cover higher costs for new treatments by internal cost shifting.

2) Increasing the amount of the add-on payment recognized for purposes of reimbursement. As noted above, the new sensitivity to costs will reduce providers' willingness to cost shift among patients or treatments.

3) Allowing major incremental improvements in technologies (e.g., a battery that lasts 10 years rather than 5) to meet the test that the technology is new.

4) Allowing a broader range of evidence to be considered in assessing whether a new technology meets the test of providing substantial clinical improvement over an older technology.

5) Providing flexibility to the test that a new technology meets the substantial clinical improvement test by allowing new technologies to meet this test by demonstrating that there is substantial likelihood that clinical improvement will result. This should not be unreasonable, given the fact that conclusive evidence would not necessarily be available in the short period of time for which an add-on payment would be available (e.g., 3 years).

Alternative approaches to add-on payments for new technologies include:

1) a carve-out approach, which allows separate and additional payments for implantable and other high-cost technologies; or

2) building expected expenditures for add-on or pass-through payments into bundled payments and adjust them periodically based on experience. This approach would still require, however, protection for individual providers who are early adopters of new treatments.

Those services characterized by low frequency and high cost should be excluded from the bundling initially. These services represent special problems for beneficiary access.

- **Recommendation 9B: Bundled Payment 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 bonus based on quality, where measurement of quality is based on measuring conformity to established processes of care must recognize new treatments and technologies.**

Quality standards are essential to assure that the financial incentives under bundling arrangements do not lead to stinting on appropriate care. Providers that are early adopters of new treatments that have not yet become the standard of care should not be penalized for using these treatments in lieu of more established methods of care unless robust outcome measures show poorer results.

Recommendations to Address Random Spending Variation

- **Recommendation 10B: The Secretary should adjust the bundled payment amounts to account for differences in beneficiary health status (severity, risk), age, gender, and other factors that may contribute to expenditure variations beyond the control of the participating providers. The Secretary should commit to an ongoing process of reviewing and refining its risk adjustment to assure their accuracy, adequacy, and appropriateness.**

The bundled payment amounts are critical determinants for ensuring appropriate payments. Risk adjustment requires constant attention because clinical data change and improve and because a risk adjustment that is continually adapting makes it more difficult for providers to focus on serving only the most profitable patients.

- **Recommendation 11B: A bundled payment system should include adjustments to account for extremely costly cases.**

The increased incidence of extremely costly cases can skew expenditures. Providers should not be penalized for treating catastrophic cases. Such an adjustment would be analogous to Medicare's current treatment of outlier cases in the MS-DRG system.

Recommendations for Updating Bundled Payment Amounts

- **Recommendation 12B: Bundled payments should be updated annually in order to reflect the most recent data and trends in per capita expenditures for Medicare fee-for-service Parts A and B.**

With annual updates, bundled payments would better reflect revisions to practice patterns and changes in input prices, including technology prices.

- **Recommendation 13B: The methods and data used to determine bundled payments should be transparent and subject to public comment. Payment updates and adjustments should account for advances in patient care and medical technology that may not be captured adequately in the data used to establish the payments.**

This approach would ensure that increased costs associated with certain new quality-enhancing technologies and therapies are adequately reflected in the bundled payment amounts.

GAINSHARING

Section 3027 of the law provides for the extension of the existing gainsharing demonstration project that was originally authorized in the Deficit Reduction Act of 2005 (DRA). The law extends the demonstration period from December 31, 2009, to September 30, 2011. It applies to projects that are in operation as of October 1, 2008.

Background

Under current law, hospitals are unable to share gains derived from improved quality and greater efficiency with physicians who practice in those hospitals. The DRA gainsharing demonstration allows arrangements between a hospital and physician(s) wherein the hospital provides payment to the physician that represents a share of the savings accrued as a result of collaborative efforts to improve quality and efficiency.

The current DRA demonstration establishes up to six projects, each consisting of one hospital, and seeks to test a variety of gainsharing models. According to the demonstration solicitation, CMS intends to "focus on short-term improvements in quality and efficiency relative to the hospital stay and up to thirty days following the episode of care." CMS also requires that each project provide measures to monitor quality and efficiency under the demonstration. Total costs to Medicare under the demonstration are to be budget neutral or produce savings. CMS will monitor the demonstration throughout and will contract with an independent evaluator to conduct a formal assessment of program results.

Discussion

Gainsharing provides physicians with financial incentives to lower costs. Although this approach has the potential to improve the quality and efficiency of care provided, it also may threaten patient access to innovative and quality-enhancing technologies and therapies. The short-term focus of cost savings under gainsharing (defined as pertaining to a particular hospital stay) fails to adequately capture costs, efficiencies, and health benefits accruing over an entire episode of care or the life of the patient.

The CMS solicitation for the DRA Medicare Hospital Gainsharing Program makes it clear that the focus of gainsharing programs is on establishing the relationship between *financial* performance and gainsharing payments: "Improvements in quality and efficiency which lead to improved operational and financial hospital performance must be achieved to justify physician gainsharing payments." It is understandable that CMS seeks to limit incentive payments to physicians based on productivity improvements achieved, rather than other factors such as patient referral. However, this sole focus on financial performance raises concerns about the potential for ignoring other critical aspects of patient care for the sake of efficiency gains. Measures are needed to protect patient access to existing and new technology innovations that are threatened by the financial incentives imposed by gainsharing arrangements.

The recommendations that follow are designed to:

- Establish explicit protections for Medicare beneficiary access to medically appropriate care, including advances in medical technology, and to improved treatments and cures.
- Ensure that quality performance standards include measures of the full range of health outcomes attributable to technology
- Provide a mechanism, or "safety valve" to allow for clinically appropriate utilization of medical products and high value technologies;
- Avoid penalizing providers for spending growth due to random variation in costs beyond their control; and
- Provide for an open and transparent process for projecting expenditure targets, including amounts attributable to medical technology innovation.

Recommendations

Recommendations for Ensuring Patient Access to Appropriate Care

- **Recommendation 1C: Participating providers should be required to provide processes that preserve physician clinical decision making and protect beneficiary access to the most appropriate services and medical advances. Gainsharing demonstration projects should ensure that (i) individual physicians participating in the gainsharing or shared savings program made a patient-by-patient determination of the most appropriate service, procedure or item[10] and the availability of the full range of services, procedures or items was not compromised by any aspect of the gainsharing or shared savings program; and (ii) individual physicians still have available the same selection of services, procedures or items after implementation of the gainsharing program as before, and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of services, procedures or items.**

Ensuring that a patient-by-patient determination was made regarding the determination of the service, procedure or item needed for each patient, and that the same selection of items and services are available to physicians will serve as a safeguard against limitations on access and adverse effects on the quality of care. This safeguard was included in the HHS Office of Inspector General (OIG) advisory opinions on gainsharing.

Gainsharing arrangements also should be required to provide a beneficiary appeals process, as well as an internal appeals process for physicians. Appeals should be monitored and published.

[10] The term "item" includes any device or supply.

- **Recommendation 2C: The independent evaluation of existing and future gainsharing demonstration projects should include both review by an independent medical expert to evaluate beneficiary access to the full array of appropriate medical devices and technologies.**

The full impact of gainsharing incentives on adoption and use of high cost, high value technologies is unknown. Standards should be developed that address patient access to critical medical advances. These may include measures of selected service use for the provider prior to and during the agreement period, as well as requiring providers to establish and document processes to ensure appropriate evaluation and adoption of critical technologies. Review by an independent third party medical expert was a safeguard in the OIG gainsharing advisory opinions and is critical as a safeguard against potential adverse effects on patient care. The evaluation on beneficiary access to the full array of technologies should include baseline use of services for the conditions subject to gainsharing, and comparing utilization to that provided under the demonstration program.

- **Recommendation 3C: The hospitals and admitting physicians in gainsharing demonstration projects should provide, at least 10 days prior to admission to the hospital, meaningful and effective prior written disclosure to patients affected by the gainsharing program.**[11]

Prior written disclosure by the hospitals and physicians involved in a gainsharing arrangement was also a safeguard included in the OIG gainsharing advisory opinions. While disclosure may not in itself prevent against the risk of patient abuse, meaningful disclosure offers some protection against abuses of patient trust. 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 gainsharing or 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 gainsharing or shared savings program and seek alternative care; and
- Provide contact information for an individual within the hospital and the local Quality Improvement Organization, and informs patients that they may contact either or both of them if they have concerns about the quality of care being provided.

[11] In light of the need for prior written notice, services provided to patients in emergent situations should not be included in the gainsharing or shared savings program.

- **Recommendation 4C: Gainsharing demonstration projects should employ financial incentives that are reasonably limited in duration and amount, and gainsharing payments/profits should be distributed to physicians in a physician group on a per capita basis.**

Limiting the financial incentives offered to physicians (through caps on payment and limiting the term of the arrangement) is one way to soften the risk that financial incentives to limit items or services can adversely impact patient care. In addition payment on a per capita basis mitigates an individual physician's incentive to generate disproportionate cost savings. These safeguards were included in the OIG advisory opinions on gainsharing.

Recommendations to Address Quality Performance Standards

- **Recommendation 5C: In assessing the quality of care furnished by providers in gainsharing arrangements, 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 be incorporated into performance standards used to assess the quality of care provided by providers.**

Quality measures should be developed to detect under-utilization of services and technologies to ensure patient care is not compromised.

- **Recommendation 6C: Quality performance standards in gainsharing arrangements should incorporate measures of health outcomes and be risk-adjusted.**

Any gainsharing program should be tied to quality improvement, adherence to clinical protocols, and achieving high performance on quality measures. Robust quality measures are needed to offset financial incentives to reduce the volume and intensity of care. Quality is best measured through outcomes of care, where feasible. 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-hospitalizations 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 7C: 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 the National Quality Forum (NQF).

- **Recommendation 8C: Assessment of the quality of care furnished by providers in gainsharing arrangements should incorporate a mechanism for evaluation of the gainsharing arrangement by an independent medical expert to determine whether quality of patient care will be adversely affected, and for independent verification of compliance with quality standards.**

Review by an independent third party medical expert is an important safeguard against potential adverse effects on patient care. Before beginning any new gainsharing initiatives, such initiatives should be evaluated by an independent medical expert to determine whether patient care may be adversely affected. Moreover, CMS should not rely solely on self-reporting as a method for determining a gainsharing provider's compliance with quality of care standards. CMS should also review the care provided to a case-mix stratified sample of patients served by the provider. Further, CMS should survey specialist physicians to determine whether they have concerns regarding patient access to advanced technologies that may be costly.

Recommendations for New and Improved Technology Safety Valve

- **Recommendation 9C: Future gainsharing demonstration projects should require that participating hospitals establish a "medical technology access" mechanism to permit physician utilization of technologies that provide patient benefit, but at increased costs for the episode under study.**

A "safety valve" mechanism would help ensure that physicians and their patients have the right to choose technology and services that, in the professional judgment of the physician, are most appropriate to meet the medical needs of the patient. Such cases would include those warranting the use of medical products that are outside of the gainsharing arrangement, or requiring the use of new cost-increasing, quality enhancing technologies.

Such a process might include establishment of case carve outs, based on a pre-determined process, wherein certain cases would be exempt from gainsharing arrangements and related financial determinations. Cases eligible for carve out would be determined by an autonomous group of individuals within the entity consisting of clinicians and administrators, who would review and authorize the use of services, products and technologies that may not be reflected in or whose costs may be prohibitive under gainsharing arrangements. Additional financial mechanisms may also be considered, such as establishment of reserve accounts to fund use of certain items or high-value medical technologies.

Importantly, entities participating in the demonstration should be provided flexibility to design safety value mechanisms that best complement their unique gainsharing arrangement, while ensuring an outlet for physician and patient access to the most appropriate technologies.

Recommendations to Address Random Spending Variation

- **Recommendation 10C: The baseline benchmark amount in a given gainsharing arrangement and the provider's yearly average per capita Medicare expenditures should be adjusted to account for differences in beneficiary health status (severity, risk), age, gender, and other factors that may contribute to expenditure variations beyond the provider's control. The Secretary should commit to an ongoing process of reviewing and refining its risk adjustment methodologies to assure their accuracy, adequacy, and appropriateness.**

The baseline benchmark amount and yearly average expenditures are critical determinants of eligibility for and level of gainsharing payments for the agreement period. These amounts should be normalized to account for factors that can differentially affect the rate of increase in expenditures from year to year, and that are beyond the control of a provider and the physicians in the gainsharing arrangement. Risk adjustment requires constant attention because clinical data change and improve and because a risk adjustment that is continually adapting makes it more difficult for providers to focus on serving only the most profitable patients.

Recommendations for Projecting Expenditure Targets

- **Recommendation 11C: The baseline benchmark should be updated annually throughout the agreement period in order to reflect the most recent data and trends in per capita expenditures for Medicare Part A.**

Under this approach, benchmark amounts would better reflect revisions to practice patterns and changes in input prices, including technology prices.

- **Recommendation 12C: The methods and data used to determine the baseline benchmark for the agreement period should be transparent and subject to public comment. Projections should account for advances in patient care and medical technology that may not be captured adequately in the data used to establish the projections.**

This approach would ensure that increased costs associated with adoption of new cost-increasing, quality-enhancing technologies and therapies are adequately reflected in the determination of gainsharing baseline benchmark levels and payment amounts.

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Accountable Care Organizations (ACOs) and Medical Progress

The Health Reform law requires the Secretary of Health and Human Services (HHS) to establish under Medicare a new delivery and payment program known as Accountable Care Organizations (ACOs). Under this program, provider-led organizations, such as physicians and hospitals, become accountable for the costs and quality of care for a defined group of Medicare beneficiaries, and are eligible for shared saving bonuses if they achieve quality standards and spending reductions for that population. ACOs have the potential to improve the quality and efficiency of health care through incentives that encourage greater coordination among providers and better management of chronic conditions. However, safeguards should be included so that ACOs do not have the unintended effects of preventing some patients from receiving the care most appropriate for their needs and discouraging medical progress.

Ensuring Patient Access to Appropriate Care. Some individual patients with unique medical needs may require different medical interventions. While care for 90 percent of patients with a specific illness may be fairly standardized and the efficiency of such care can be fairly measured and rewarded, for the other ten percent, special factors—co-morbidities, patient preferences, individual reactions to treatment, or other unknown factors--may mean that appropriate care will cost substantially more than the average.

In addition, while ACOs hold the promise of transforming the payment system from rewarding volume to rewarding quality, there is a risk that the pendulum could swing too far and incentivize some providers to limit necessary care in order to achieve greater shared savings. Greater financial incentives to reduce costs could also lead to inappropriate standardization of products, making it more difficult for patients and providers to utilize specific treatments that may be more appropriate for a patient's needs.

Recommendations: ACOs should include safeguards to ensure patients continue to have access to the treatments that are appropriate for their individual needs, even if those treatments are more expensive.

- ACO financial incentives for providers should be limited in amount (e.g., through the use of caps) and determined on a per capita basis. This approach will preserve the financial incentive for providers to work together to reduce overall costs to the ACO and at the same time mitigate an individual physician's incentive to generate disproportionate savings by inappropriately reducing care. This recommendation is consistent with OIG Advisory Opinions on similar matters.
- Independent monitors should assess and provide oversight regarding beneficiary access to appropriate care including:
    - ACO processes for preserving patient and physician clinical decision-making to ensure beneficiary access to the most appropriate services and medical advances.
    - Patient and physician engagement in determining the availability of appropriate diagnostics and treatments within the ACO.
    - Beneficiary access to advances in medical treatments and technologies by comparing the experience of beneficiaries inside and outside the ACO.

  - All monitors' findings should be publicly disclosed.
- ACOs should notify patients of their assignment to an ACO and their rights. In addition, ACOs should have an appeals program that allows physicians and patients to request permission to have available treatments that are deemed medically necessary for a patient's condition.

Supporting Medical Progress for Current and Future Patients. The ACO model focuses on creating incentives for providers to reduce costs during the course of a year, in order to generate a savings pool that would be shared at the end of the period (assuming the ACO providers also met specified quality standards). AdvaMed supports the goal of reducing health care costs in the long term and believes that medical technology is a key component in achieving this goal. However, AdvaMed is concerned that an emphasis on cost savings in the short term will create barriers to physicians using innovative and more costly treatments that represent improvements in care, but deliver lower costs outside the ACO incentive timeframe.

ACOs should be designed with the process of innovation in mind – whereby cutting edge physicians and institutions are the early adopters of new technologies that, if proven successful, gradually diffuse until they become the standard of care. Failure of ACOs to account for this process – which results in innovative new therapies for patients – could discourage physicians from utilizing new, innovative technologies, and discourage innovators and venture capitalists from investing in them, out of concern that new products will have difficulty entering the market.

AdvaMed is also concerned that the quality measures available today do not measure the long-term benefits of many treatments and services. To the extent that the ACO and its providers are rewarded based on quality measures that reflect a standard of care at a point in time, physicians who are early adopters of a new treatment could be penalized by low quality scores. This would have been the case at the time when implantable cardioverter defibrillators (ICDs) were first being used as an alternative to anti-arrhythmic drugs for patients at risk because they have life-threatening arrhythmias. 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.

Recommendations: It is critical that ACOs and their providers not be penalized for adopting innovative treatments and technologies. To ensure beneficiary access to medical innovations appropriate for their care needs, AdvaMed recommends that:

- ACO benchmark spending targets and shared savings pools should keep pace with advances in medical treatments and technologies by including adjustments for a reasonable period of time during which a new innovation is diffused and becomes the new standard of care. CMS would determine which advances would qualify. Adjustments would be modeled after those used in the Medicare program today for inpatient and outpatient hospital care.
- Similarly, quality care measures should keep pace with advances in medical treatments and technologies. In calculating bonuses or penalties, certain cases should be excluded for a reasonable period of time when existing quality measures do not reflect the new treatments available to patients.

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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.

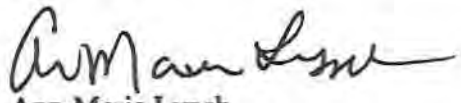
Given the similarity of incentives contained in risk-sharing ACO models to those of Medicare Advantage (MA) plans, and the potential consequences these incentives have for patient care in both delivery systems, the risk-sharing model should be required to offer, at a minimum, an analogous set of beneficiary 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,



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AdvaMed
Advanced Medical Technology Association

September 27, 2010

Attn: ACO Legal Issues
Mail Stop C5-15-12
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws

To Whom It May Concern:

I am writing on behalf of the Advanced Medical Technology Association (AdvaMed) in response to the Federal Trade Commission (FTC), U.S. Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS), and HHS Office of Inspector General (OIG) Federal Register notice of the "Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty Laws." 75 Fed. Reg. 57039 (September 17, 2010). AdvaMed appreciates the opportunity to comment on these legal and policy issues related to accountable care organizations (ACOs).

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. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the decision of FTC, CMS, and OIG to conduct the October 5th workshop on the legal issues that are raised by formation and operation of Accountable Care Organizations (ACOs). In order to inform AdvaMed's comments and the government's approach to the creation of ACO's, AdvaMed commissioned from Foley Hoag a brief, preliminary legal analysis of potential issues raised by ACO's. Please find this legal memorandum attached for your information.

The comments below focus on the following areas: (1) quality of care and patient access; (2) antitrust law considerations and market stability; (3) scope of the Secretary's waiver authority; and (4) creation of a new Stark exception and anti-kickback safe harbor.

I. Quality of Care and Patient Access

AdvaMed strongly supports initiatives to improve the quality of patient care and to ensure patient access to high quality care. AdvaMed's commitment to quality improvements includes participation in the National Quality Forum (NQF), the AQA, and other organizations operating in this arena.

AdvaMed notes that the statutory requirements of the Medicare Shared Savings Program[1] are geared toward promoting enhancements in infrastructure and redesigned care processes that will foster better coordination of, and accountability for, patient care. AdvaMed is concerned, however, that the law provides little detail about how to ensure protection of beneficiaries and their access to medically appropriate care, including critical life-saving medical innovations. We are concerned that without explicit protections for Medicare beneficiaries, restructuring the financial incentives in the health care system could inadvertently compromise patient care. AdvaMed therefore urges CMS to give this issue special attention as it develops implementation policy.

Moreover, there is little experience, nor thorough independent evaluation to date, with shared savings programs through ACOs. While potentially promising in several respects, ACOs are still in their infancy. Caution must be exercised to ensure that payment incentives do not distort physicians' clinical judgment or inhibit beneficiary access to services and technologies. AdvaMed believes that safeguards and protections can and should be built into the Program to protect Medicare beneficiaries especially given the fact that ACO benchmark updates will not reflect the unique aspects and utilization of services of the Medicare beneficiaries enrolled in ACOs.[2] Such safeguards should include, but should not be limited to, the following:

- Explicit protections for Medicare beneficiary access to medically appropriate care, including advances in medical technology, through such mechanisms as adjustments in spending targets to avoid discouraging adoption of new treatments and technologies;
- Avoiding penalties imposed on ACO providers for spending growth due to random variation in costs beyond their control;

[1] Section 1899 of the Social Security Act (enacted by section 3022 of the Patient Protection and Affordable Care Act, Public Law 111-148 (Mar. 23, 2010)).

[2] ACO benchmarks will be updated by projected growth in national per capita Medicare Parts A and B for the fee-for-service program as a whole and not growth in spending for a group of beneficiaries comparable to those served by the ACO

- Annual updating of the ACO benchmark throughout the agreement period in order to reflect the most recent data and trends in per capita expenditures for Medicare fee-for-service spending;
- Providing an open and transparent process for projecting expenditure targets, including amounts attributable to medical technology innovation;
- Development of robust quality measures for the care provided by ACOs to offset financial incentives to reduce the volume and intensity of care, including measures that ensure that patients have access to appropriate products and services (including new and improved innovative technologies) for their condition;
- Development of quality measures that monitor utilization in order to detect under-utilization of services and technologies to ensure that patient care is not compromised;
- Ensuring that quality performance standards include measures of the full range of health outcomes attributable to devices, diagnostics, and other medical technology; and
- Independent monitoring of beneficiary access to appropriate care, including access to innovative technologies using such methods as measures of selected service use for the ACO prior to and during the agreement period.

AdvaMed recognizes that the October 5th workshop is intended to focus on the legal issues associated with developing ACOs and plans to provide CMS specific, robust policy recommendations regarding the overall design of the Shared Savings Program to CMS at a later date.

II. Antitrust Law Considerations and Market Stability

As stated above, AdvaMed supports the increased emphasis on improving the quality of care provided to patients in the U.S. health care system. The FTC has emphasized in its enforcement of the antitrust laws identifying indicia of "clinical integration" sufficient to indicate that an ACO is likely to enable participating providers to improve quality of care. The FTC has considered clinical integration as a factor in determining whether joint price negotiation is reasonably necessary to achieve quality improvement and overall efficiencies.

AdvaMed supports the FTC's emphasis on quality improvement and encourages the development of meaningful quality performance standards that incorporate measures of health outcomes, not just process measures. Health outcomes are the most appropriate measure of quality. An ACO that is geared toward achieving appropriate measures of health outcomes will encourage true clinical integration that is patient-centered. Moreover, quality performance measures should capture the full range of outcomes, rather than relying solely on a single measure that may reflect only one dimension of quality. This is particularly important in 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 only reflects 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 many years.

We note that currently available performance measures are often limited and inadequate to assess and safeguard quality of care. Not all areas of care are addressed in the measures available to date, and even in areas where there are performance measures, there are often gaps. For example, a physician or provider might meet a process measure but perform poorly on other process measures not yet incorporated (or have poor patient outcomes).

Notwithstanding the importance of appropriate quality measures and the FTC's analysis of clinical integration, AdvaMed has concerns about the overall market power that an ACO may wield, to the exclusion of competitive forces in the health care marketplace. An ACO that encompasses every hospital, physician, and post-acute care provider in a given geographic area would permit no competition, skewing market power to the detriment of health care purchasers. There also may be anti-competitive impact if an ACO has a supermajority, a majority or even the largest minority share of providers in that area. AdvaMed is most concerned about the impact on patients of having little or no choice in the health care services and items available to them.

AdvaMed is pleased that the FTC will be discussing ways to foster formation of multiple ACOs to encourage competition in any given geographic market. Recent health policy discussions at MedPAC have focused on whether the threshold in the ACA of 5,000 beneficiaries is sufficient to form an effective ACO. While that consideration may be legitimate, it is also important to consider at what point an ACO may be too large. This consideration will require an analysis of each relevant market. Such analysis is critical to protect and preserve health care marketplace competition for patients, employers and payers.

To ensure careful consideration of these and other antitrust issues, AdvaMed recommends that the FTC conduct an antitrust analysis for each individual ACO. AdvaMed appreciates the FTC's specialized and extensive expertise for conducting such analysis. AdvaMed supports a case-by-case analysis to ensure full consideration of the impact on both privately insured patients and Federal health care program beneficiaries. We note that ACOs are likely to change over time, potentially making structural and process adjustments as the organizations mature. ACOs should request updated analysis from the FTC as any such changes occur.

III. Scope of the Secretary's Waiver Authority

The Secretary of HHS possesses the authority to waive such requirements of section 1128A and 1128B and title XVIII of the Social Security Act as may be necessary to carry out the provisions of section 1899 of the Social Security Act (the Medicare Shared

Savings Program). This waiver authority is broad and includes the anti-kickback statute, the physician self-referral law, and the civil money penalty laws.

There may be multiple ways in which these three authorities would be implicated. For example, for the incentive payment or "gainsharing" arrangements that may be used in ACOs, such arrangements cannot fit within any of the following five existing physician self-referral law compensation exceptions for: academic medical centers, employment, personal services, fair market value compensation, or indirect compensation arrangements. Any broad program has numerous problems complying with each of these exceptions.

The fundamental failing of physician incentive payment arrangements is that directly or indirectly virtually all such programs compensate physicians to some extent based on the profitability of the business they generate for the hospitals. In other words, these programs are exactly the kinds of compensation arrangements that the physician self-referral statute is intended to prohibit.

Specifically, all five of these exceptions to the physician self-referral law prohibit any compensation to a physician that reflects or takes into account directly or indirectly the value or volume of any Medicare business generated by the physician (in the case of the employment exception) or any business at all, including commercial and private pay (in the case of the other exceptions). But such arrangements necessarily reflect the "value" of business generated by the participating physicians. The savings in such programs is the reduction in costs for patient care, which in turn increases their "value" to the hospital. Incentive payment programs that include cost reductions raise similar self-referral law issues, as do incentive payment programs for physicians that promote physician actions that qualify hospitals for higher payments from third parties since the physician payments will reflect the higher value of their patients.

Several of the exceptions have other conditions, with which incentive payment programs have difficulty complying.

The employment exception (42 CFR § 411.357(c)). Under the employment exception the payments must be fair market value for "identifiable services" provided by the employed physician and the payment cannot take into account directly or indirectly the volume or value of any Medicare or Medicaid referrals by the physician. Accordingly, any payment must be for services provided by the individual and no pooling of payments is permitted. In addition, we note that in the Medicare Shared Savings Program there are likely to be physicians who are not employees of the ACO or the hospital.

Personal services exception (42 CFR § 411.357(d)). As with the employment exception, the personal services exception only protects direct payments to physicians that are set in advance and may not take into account the value of any business, including commercial or private pay business, generated by the physician. In addition, the services may not

involve the counseling of an unlawful business arrangement. As discussed above, the requirement that payments be fair market value for the individual's personally performed services prohibit any payments based on group efforts or pooled savings or distributed on a per capital basis. The prohibition on services that involve the counseling of an unlawful business arrangement would disqualify any arrangement that would violate the civil money penalty prohibiting hospital payments to physicians for reducing or limiting clinical services to federal health care patients.[3]

As mentioned above, however, the Secretary may use her waiver authority. That waiver is to be used only "as may be necessary to carry out" the Program. In light of this condition in law, AdvaMed recommends that the scope of arrangements covered by the waiver be tailored so that only those ACOs arrangements that coordinate care, improve quality, and increase efficiency in the delivery of care should be eligible for a waiver. As a result, arrangements between the ACO and third parties, or between providers or parties subsumed within the ACO, that are either existing or new but unrelated to coordinating care should not be covered by the waiver.

For example, AdvaMed has received information about a number of arrangements between hospitals and physicians that are not meant to improve quality and coordination of care. The following are two examples:

> (i) hospitals subsidizing physician office leases or administrative support staff expenses in exchange for physician use of the lowest cost device without regard to quality or individual patient needs; and
>
> (ii) hospitals and physicians entering into co-management agreements or other joint venture arrangements that enable profit-sharing, in exchange for physician use of the lowest cost device without regard to quality or individual patient needs.

These examples are indicative of the legal and patient care risks attendant in expanding the waiver authority. These legally problematic arrangements serve only to reduce cost to the detriment of patient care. There are many ways health care entities and physicians could potentially structure their financial relationships to enhance profit margins without regard to quality improvement and coordination of care. Expanding the waiver authority would open the door to activity that presents a significant risk of patient abuse.

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[3] The analysis above applies only to gainsharing as a possible component of ACOs and how it might implicate the physician self-referral law. Although the anti-kickback statute and civil money penalty law are implicated, we have not provided an extensive review here. We would be pleased to provide a more detailed analysis if CMS or OIG would be interested in such analysis.

IV. Creation of a Stark Exception and Anti-kickback Safe Harbor

At present, the full scope and nature of possible ACO formations is unclear and therefore it is impossible to predict their full impact. This lack of clarity is one of the very reasons for holding the workshop on October 5th. However, even with public input about ACOs that are likely to be created and included in the Medicare Shared Savings Program, without experience and independent evaluation of the impact these ACOs may have, it is simply impossible to ensure that there will be adequate Medicare beneficiary protections to safeguard quality of care and access to care. AdvaMed is particularly concerned that gainsharing arrangements that are likely to be built into ACOs will put patient care at risk by fundamentally changing the physician-patient relationship without adequate analysis and understanding of the short-term and long-term impact on patient care. The following are three key factors to consider in evaluating the impact of ACO on patient care:

First, an offer of payment to physicians based on a percentage of hospital (or other provider) cost savings will create a clear motivation to generate those cost savings. If the arrangement is structured to generate those cost savings through reductions or limitations in patient care items or services, those reductions or limitations put necessary patient care at risk. Although section 1899 of the Social Security Act requires the development of quality performance standards to assess quality of care furnished by ACOs, the law appears to depend on ACO reporting alone. We are concerned that these elements alone may not fully safeguard patient care quality. The use of health information technology and specifically electronic health records (EHRs) for reporting clinical information may provide a mechanism for more objective assessment and monitoring of quality of care provided by ACOs, but EHRs alone are insufficient for ensuring patient care quality.

Second, because ACOs will likely have a significant impact on physician incentives regarding the provision of treatments and services, ACOs in the Shared Savings Program should not be permitted to restrict patient access to the full array of treatment options. Moreover, without appropriate design requirements, ACO's could compromise patient access to new technologies in the future. A hospital could potentially offer physicians payment based on the cost savings that would result from the use of older and potentially less effective technology. This offer of payment is powerful and is likely to skew the physicians' incentives to offer new technology that may be more appropriate for the patient.

Third, patients treated by providers participating in an ACO should be provided notice well in advance of patient care. Such beneficiary notification should include possible adverse effects on his or her care resulting from incentives to limit the items or services available to him or her. Providing such notice in advance of each ACO encounter would keep patients and their families fully informed and would provide up to date information on any change in provider participation.

In sum, there is a high risk of significant negative short-term and long-term impacts on patient care that results when an ACO, hospital, or other provider offers remuneration to induce a physician to reduce or limit beneficiary care. While AdvaMed supports efforts to improve the quality of care Medicare beneficiaries receive, a new shared savings/incentive payment exception to the physician self-referral law and a new anti-kickback safe harbor poses significant risks of patient abuse as hospital and/or other ACO-related payments to physicians raise the risk of skewing physician incentives and patient care is likely to suffer as a result.

Moreover, there is no reasonable basis on which CMS or the Secretary can conclude that a self-referral law exception poses no risk of program or patient abuse from a legal standpoint. Gainsharing arrangements that involve product standardization in particular present a clear and present risk of patient abuse. These arrangements implicate the anti-kickback statute, § 1128B(b) of the Social Security Act (hereinafter the "Act") and the physician self-referral prohibition, § 1877 of the Act. More importantly, the OIG has repeatedly acknowledged that gainsharing arrangements violate the civil money penalty law prohibiting hospitals from offering remuneration to physicians for limiting medical care to their patients, § 1128A(b) of the Act ("CMP"). The CMP is an important protection for Medicare patients.[4] The OIG has stated that "gainsharing arrangements pose a high risk of abuse." OIG, Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, July 1999.[5]

AdvaMed believes that it would be impossible to satisfy the requirements of section 1877(b)(4) of the Social Security Act absent a requirement in the exception prohibiting payment from an ACO, hospital or other provider to a physician to induce a reduction or

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[4] As the House Committee Report that accompanied the CMP provision stated: "[t]he Committee believes that such incentive payments may create a conflict of interest that may limit the ability of the physician to exercise independent professional judgment in the best interest of his or her patients." H.R. Rep. No. 99-727, at 441 (1986).

[5] The only federal district court to address such arrangements reached the same conclusion. In Robert Wood Johnson University Hospital, Inc v. Tommy Thompson, 2004 WL 3210732 (D.N.J. April 15, 2004),, the court stated:

> [T]he same concerns Congress held in 1986 when the CMP was enacted and the OIG had in 1999 when the OIG Bulletin was released necessarily remain today – "no combination of features could guarantee that such plans would not be subject to abuse." Although the Secretary now "guarantee[s] that the quality of patient care [will] not [be] adversely affected by the financial incentives designed to promote cost-efficiency', such a guarantee was previously found by Congress as untenable.

Importantly, the gainsharing arrangement rejected by the court in Robert Wood Johnson University Hospital, Inc. was significantly more protective of patients than CMS's proposed exception because it was subject to independent monitoring by a consultant selected and paid by CMS.

limitation in items or services furnished to Medicare or Medicaid beneficiaries under the physician's direct care.[6]

AdvaMed notes that the Secretary may grant waivers under § 1899(f) of the Act ("as may be necessary to carry out the provisions of this section"). However, for purposes of determining whether to create a *permanent* regulatory exception to the physician self-referral law, AdvaMed recommends that the Secretary apply the standard in section 1877(b)(4) of the Act, which makes clear that the exception can pose "no risk of program or patient abuse." If this standard is waived pursuant to section 1899(f) of the Act, then AdvaMed recommends that the Secretary provide a clear explanation of why any risk of program or patient abuse might be appropriate within the Medicare Shared Savings Program.

* * *

Finally, we note that AdvaMed's comments have focused on considerations relating to the antitrust laws, the "Stark" physician self-referral law, the Federal anti-kickback statute, and the civil monetary penalty laws. As noted in the legal memorandum from Foley Hoag that is attached, there are many other legal considerations that will be important for ACOs, including, but not limited to, Federal income tax law and various state laws (such as state fraud and abuse laws and state corporate practice of medicine laws). AdvaMed recommends that the Secretary also take into consideration these legal requirements, in addition to those that are the subject of the October 5th workshop, as she implements section 1899 of the Act.

AdvaMed appreciates the opportunity to comment in advance of the FTC-CMS-OIG workshop. We would also like to make a statement in person at the afternoon listening session on October 5th.

Should you have any questions, please contact me or Teresa Lee (tlee@advamed.org or (202) 434-7219).

Sincerely,

Ann-Marie Lynch

Attachment

[6] Please note that AdvaMed submitted more extensive comments to CMS on February 17, 2009 in response to the 55 questions CMS posed related to a gainsharing or "shared savings" exception to the physician self-referral law. The comments provided herein are abbreviated, but AdvaMed encourages CMS and OIG to refer to those public comments for more detailed analysis on these issues.

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Memo

Date: September 27, 2010

To: Ann Marie Lynch
Executive Vice President of Payment and Health Care Delivery
Advanced Medical Technology Association

From: Thomas R. Barker, Partner

Regarding: Accountable Care Organizations –Considerations for AdvaMed Members

I. Introduction

Section 1899 of the Social Security Act, 42 U.S.C. § 1395jjj, was enacted by section 3022 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (March 23, 2010) (hereafter, the Affordable Care Act). Section 1899 authorizes the Secretary of Health and Human Services (HHS) to establish a "shared savings program" within the Medicare program. Under the shared savings program, groups of health care providers and suppliers "may work together to manage and coordinate care for Medicare … beneficiaries through an accountable care organization [ACO]." Id. at subsection (a)(1)(A). In addition, ACOs that meet quality criteria established by the Secretary can receive payments from the Medicare trust fund for "shared savings." Id. at subsection (a)(1)(B).

You have asked us to review the statutory language that created the ACO program. In particular, you have asked us to analyze the various waivers that the Secretary of HHS is authorized to grant to implement the program. In particular, you would like to know how broadly these waivers extend. You would also like to know what relevant provisions of the Social Security Act the Secretary was not permitted to waive, and you have asked us to analyze the implications of these provisions of law that remain in effect, such as the tax and antitrust implications of the ACO model.

We understand that you need this information in order to prepare for a Workshop to be held at the Centers for Medicare & Medicaid Services (CMS) on October 5. At this meeting, CMS, the HHS Office of Inspector General (OIG), and the Federal Trade

Commission (FTC) will solicit input, and address questions, from the public on the ACO model. See 75 Fed. Reg. 57039 – 42 (Sept. 17, 2010) (hereafter, the CMS-OIG-FTC Notice). As part of this session, CMS, OIG, and the FTC intend to "focus on whether and, if so, to what extent any safe harbors, exceptions, exemptions or waivers from" the antitrust laws, the prohibitions on physician self-referrals, the federal civil monetary penalty and anti-kickback statutes will be needed to implement section 1899. See id. at 57040. Because CMS, OIG, and the FTC have asked for public comment, you have asked us to prepare this analysis in order to better inform the comments that you will be submitting in advance of the Workshop.

In this memorandum, we first describe our understanding of how the ACO model will be structured under section 1899 of the Social Security Act. We then explain the scope of the waivers granted by the statute, explain why those waivers might be viewed as necessary for the successful operation of the ACO model, and identify provisions of the Social Security Act and other laws that were not waived. We also explain the policy implications of these provisions for AdvaMed's members. Next, we identify the federal income tax issues that may arise in the context of the ACO model, at least where some participants in ACOs may be exempt from federal income tax under section 501(c)(3) of the Internal Revenue Code of 1986. Last, we raise antitrust considerations that may, and likely will, be addressed by the FTC at the October 5 meeting.

II. The ACO Model

The ACO model has been advanced by health policy scholars as a means of addressing a central criticism of the American health care system: that no one health care provider is accountable for the overall cost and quality of health care.[1] To address this criticism, the ACO model envisions that multiple providers – hospitals and physicians, as well as other providers and suppliers – will band together and jointly assume accountability for the care provided to Medicare beneficiaries. Key design elements of the model include: (1) formation of a distinct legal entity capable of receiving shared savings; (2) identifying the Medicare beneficiaries to be assigned to the ACO; (3) establishing spending benchmarks for ACOs; (4) identifying and measuring quality and performance; and (5) distributing shared savings that would be split among participants in the ACO.[2] At least initially, the ACO would not bear risk.[3]

Under the statute, the Secretary of HHS is required to establish a shared savings program through ACOs beginning not later than January 1, 2012. Any entity that is eligible to be an ACO can apply for designation; it is anticipated that HHS will issue a proposed rule in the Fall of this year describing the application process and ACO program requirements.

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[1] Fisher and McClellan *et al*, "Fostering Accountable Health Care: Moving Forward in Medicare," 28 Health Affairs 2 (Jan. 27, 2009) at 219. Hereafter, "Fisher and McClellan."

[2] See Fisher and McClellan at 223 – 24.

[3] McClellan and McKethan *et al*, "A National Strategy To Put Accountable Care Into Practice," 29 Health Affairs 5 (May, 2010) at 982, 983.

Entities eligible to function as ACOs must "establish[] a mechanism for shared governance," Social Security Act § 1899(b)(1), and be able to receive and distribute shared savings, id. at subsection (b)(2)(C). Thus, the statutory model tracks very closely with the model envisioned by health policy scholars in the journal articles referenced above.

Both the statute and the journal articles focus on "shared savings." Fisher and McClellan *et al* note that this feature of the ACO model is imperative so that participation in the model is attractive to providers. Fisher and McClellan *et al* at 222. Under the statute, these "shared savings" are equal to a percentage (determined by the Secretary) of the difference between estimated per-capita Medicare expenditures for Medicare beneficiaries assigned to the ACO and a "benchmark." Social Security Act § 1899(d)(1)(B)(i). The "benchmark" amount is equal to an average of the three most recent years of per-beneficiary expenditures for beneficiaries assigned to the ACO. Id. at clause (ii). Both estimated expenditures and the benchmark are to be risk-adjusted. Id. In the event that there are no shared savings because the estimated expenditures exceed the benchmark, there is no requirement that ACOs return the excess Medicare spending to the program; thus, ACOs and the providers that are members of it do not bear insurance risk.

As a legal matter, the requirement of Social Security Act § 1899(b)(2)(C) that an ACO "have a formal legal structure that would allow the organization to receive and distribute payments of shared savings ... to participating providers of services and suppliers" raises significant issues. Emphasis added. These issues arise under the Medicare program, title XI of the Social Security Act, the federal tax laws, and federal antitrust law.[4] In part, the statute attempts to address some of these issues by permitting the Secretary of HHS to "waive such requirements of sections 1128A and 1128B and title XVIII of" the Social Security Act, "as may be necessary to carry out the provisions of" the ACO statute. Social Security Act § 1899(f).

We turn now to an analysis of each of these federal laws and the implication of the waivers.

III. Applicable Federal Laws

A. Medicare

The ability of the Secretary of HHS to waive "such requirements of ... title XVIII ... as may be necessary to carry out the provisions of" the ACO statute is broad. Title XVIII of the Social Security Act encompasses the entire Medicare program and includes the Medicare benefit design, the operation of the Medicare prescription drug benefit, Medicare's coverage and payment rules, the program's relationship with its contractors, the conditions of

[4] Similar issues arise under various State laws. For example, many States have laws that parallel the Medicare fraud and abuse laws and federal antitrust law. An analysis of these State laws is beyond the scope of this memorandum, other than to note that section 1899 in no way expressly pre-empts State law. Thus, absent a finding of implied conflict pre-emption, State law would continue to regulate the conduct of participants in an ACO.

participation and other requirements applicable to Medicare participating providers and suppliers, and the administration of the program.[5] Using the waiver authority in section § 1899(f), the Secretary could waive any of these provisions.[6]

Although HHS has not yet officially identified those provisions of title XVIII that it is considering waiving in developing the ACO model, CMS has suggested that one likely provision is the prohibition on physician self-referrals contained at section 1877 of the Social Security Act, 42 U.S.C. § 1395.[7] Section 1877(a) flatly prohibits any physician that "has a financial relationship with an entity" from making a referral to the entity "for the furnishing of designated health services," unless an exception applies. Id. The statute makes clear that "financial relationship" includes "a compensation arrangement." Id. at subsection (a)(2)(B). "Compensation arrangement," in turn, is defined as "any arrangement involving any remuneration." Id. at subsection (h)(1)(A).

It would seem clear that any payment directly from a hospital to a physician would implicate the physician self-referral statute if a physician referred a patient to the hospital for services, as both inpatient and outpatient hospital services are "designated health services." Social Security Act at § 1877(h)(6)(K). Whether a payment from an ACO to a physician, rather than from the hospital that is a member of the ACO to the physician, violates the statute might be an open question. Through its waiver authority in section 1899(f), however, HHS can merely waive the application of the prohibition in the case where the payment of a portion of shared savings is made to a physician by the ACO and avoid addressing the question entirely.

B. Health Care Civil and Criminal Penalties

The statute also permits the Secretary to waive sections 1128A and 1128B of the Social Security Act. These sections contain the authority for the Inspector General of HHS to impose civil monetary penalties, and bring criminal charges, against health care providers engaging in specified proscribed conduct. At the outset, it bears mention that, unlike provisions of title XVIII, HHS has no independent authority to waive sections 1128A and

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[5] Although broad, it should be noted that this grant of authority is no broader than authority the Secretary has possessed since 1967 to "waive compliance with the requirements of" the Medicare program in conducting certain demonstration projects. Social Security Act Amendments of 1967, Pub. L. No. 90-248, 81 Stat. 821 (Jan. 2, 1968) § 402(b).

[6] The statute shields from judicial review many determinations by the Secretary in implementing the ACO model. See Social Security Act § 1899(g). This preclusion of judicial review, however, does not divest a court of jurisdiction to hear a challenge to a decision of the Secretary to waive or not waive a particular provision of title XVIII. See id. at paragraphs (1) through (6) (not including waivers as shielded from judicial review). Thus, an entity aggrieved by a decision of the Secretary to waive or not waive a particular provision of title XVIII in implementing the ACO model could, assuming that other jurisdictional prerequisites are met, challenge that decision in federal court.

[7] See CMS-OIG-FTC Notice at 57040.

1128B of the Social Security Act. See Robert Wood Johnson University Hospital v. Thompson, 2004 U.S. Dist. LEXIS 8498 at *18 - *21.

Much like the application of the waiver authority to all of the provisions of title XVIII, the federal anti-kickback and civil monetary penalty statutes are also quite broad. It would be unprecedented for the Secretary of HHS to waive the majority of the provisions of these statutes. The HHS Office of Inspector General (OIG) has focused on only three provisions of these statutes that might be waived: section 1128B(b) (the federal anti-kickback statute), and sections 1128A(b)(1) and (2) (the civil monetary penalty law). See CMS-OIG-FTC Notice at 57040.

The first statute mentioned in the CMS-OIG-FTC notice – Social Security Act § 1128B(b) – is commonly referred to as the federal anti-kickback statute. This statute prohibits the knowing and willful solicitation, and the knowing and willful payment, of remuneration in return for a referral to a provider of a health care item or service for which payment is made under a federal health care program. A solicitation or payment by any person may be sufficient to violate the law if the requisite intent is present[8]; unlike the physician self-referral statute (which only proscribes financial relationships with the provider of a designated health service), the anti-kickback statute prohibits payment by any person or entity. Absent the waiver, then, it seems that the payment of shared savings from an ACO to a hospital or to a physician could be construed as a payment to induce a referral in violation of the statute.

The second and third statutes referenced in the notice – Social Security Act § 1128A(b)(1) and (2) – authorize the imposition of civil monetary penalties on hospitals that pay, or physicians that receive, payment that is an inducement to "reduce or limit services provided to" Medicare and Medicaid beneficiaries. As is the case with the physician self-referral statute, the proscribed conduct in section 1128A(b) is the payment by a hospital, or the receipt of such a payment by a physician, not an entity such as an ACO. Nevertheless, perhaps out of concern that a case could be made that the payment by an ACO is nothing more than a disguised payment by a hospital, the OIG is considering waiving these statutes as well.

Of all of the waived statutes identified, AdvaMed members may be most concerned about the waiver of this civil monetary penalty statute. AdvaMed's position is clear that shared savings programs, if not structured properly, create an incentive for providers to limit patient access to and under-utilize appropriate devices, diagnostics and other advanced medical technologies. AdvaMed has noted that shared savings programs have the potential to reduce physician choice, limit patient access to the most appropriate care, and reduce the quality of care, as well as hindering medical innovation. *See generally* Letter from AdvaMed to CMS, Comments regarding Physician Fee Schedule Final Rule with Comment Period (The Exception for Incentive Payments and Shared Savings Programs (§ 411.357(x)) in section

[8] Note that the anti-kickback and the physician self-referral statute differ in that the physician self-referral statute does not require a showing of intent to violate the statute.

II.N.1) (Feb. 17, 2009). Creating an incentive to reward physicians who "reduce or limit services provided to" Medicare beneficiaries would seem to conflict with one of AdvaMed's key concerns.

C. Federal Income Tax Law

The ACO program raises at least two significant federal income tax issues. First, can an ACO be structured in a manner that permits the receipt of shared savings free of tax? Second, can a hospital that is exempt from federal income tax participate in an ACO, and share savings with physicians, without violating the premises of its tax exemption? As described below, it may be difficult to accommodate these concerns without violating the fundamental premises under which participants may wish to operate an ACO. The following paragraphs describe each of these issues in turn.

1. Structuring for Tax-Free Receipt of Shared Savings

As described above, the ACO statute contemplates that an ACO will be formed as a legal entity. Two forms of entity may provide the ACO with the ability to receive shared-savings amounts free of federal income tax: (1) a partnership; and (2) a tax-exempt organization.

First, if the ACO entity is a partnership (or another form of entity, such as a limited liability company, that may be treated as a partnership for federal income tax purposes), then the entity itself will not be subject to federal income tax. Rather, each partner (that is, each participant in the ACO) will be subject to tax on that partner's share of the ACO's net taxable income each year. Partners are subject to tax on their share of the partnership's income each year, regardless of whether that income is actually distributed to them; actual distributions of pre-taxed income attract no further tax.

Many participants in ACOs presumably will be hospitals, which are commonly structured as non-profit corporations that are exempt from federal income tax because they are "organized and operated exclusively for ... charitable ... purposes." Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "Tax Code"). A tax-exempt hospital is nonetheless taxed on any income (commonly called "UBTI") earned in the regular conduct of any "unrelated trade or business," that is, "any trade or business the conduct of which is not substantially related (aside from the need for funds) to the exercise or performance" by the hospital of the purpose of function on which its tax exempt is based. Sections 511, 512 and 513 of the Tax Code. Further analysis is needed to determine whether shared-savings payments are considered UBTI.

If a partnership-style ACO entity included tax-exempt hospitals as well as other partners that were not tax-exempt entities, the partnership would also raise issues concerning "private inurement" and "private benefit." Section 501(c)(3) of the Tax Code requires that "no part of the net earnings of [a tax-exempt hospital] inures to the benefit of any private shareholder or individual . . . ." A violation of this principle can cause a tax-exempt hospital to lose its tax-exempt status altogether, or can trigger draconian financial penalties to the hospital, the "benefitted" person, and officers or directors of the hospital who approved the

transaction. (These penalties are provided under section 4958 of the Tax Code, which governs "excess benefit transactions." Because the penalties are less severe than revocation of tax-exempt status, they are often called "intermediate sanctions.")

The Internal Revenue Service has for decades devoted much attention and critical scrutiny to partnerships between tax-exempt and taxable partners. Much of this scrutiny has involved partnerships and other financial-sharing arrangements between hospitals and others, such as physicians. While such arrangements can be structured in a manner that survives scrutiny, careful attention must be given to this issue. In some cases, advisors may recommend seeking a private letter ruling from the Internal Revenue Service.

A second form of ACO entity that may be able to receive shared-savings payments free of federal income tax is a tax-exempt organization. Many types of organizations, in additional to traditional charitable and educational organizations, are exempt from federal income tax: among others, section 501(c) of the Tax Code sets forth a list of 29 types of organizations that qualify for exemption. Of these, the only type likely to lend itself to possible use as an ACO entity is an organization described in section 501(c)(3). Section 501(c)(3) entities take many forms, but two forms appear to be possibilities for an ACO entity. First, the entity could be formed as a non-profit corporation and structured as a "supporting organization" of one or more hospitals under sections 501(c)(3) and 509(a)(3) of the Tax Code. As a supporting organization, the ACO entity would be required to be "organized, and . . . operated, exclusively for the benefit of, to perform the functions of, or to carry out the purposes of one or more [tax-exempt hospitals]." The entity would need to apply to the Internal Revenue Service for recognition of its status as a tax-exempt supporting organization.

Alternatively, it may be possible to structure an ACO in manner that qualifies for section 501(c)(3) status as a "cooperative hospital service organization" described in section 501(e) of the Tax Code. A cooperative hospital service organization must be organized and operated solely "to perform, on a centralized basis, one or more of the following services," for tax-exempt hospitals: . . . billing and collection." Section 501(e)(1)(A), (B) of the Tax Code. As with a supporting organization, cooperative hospital service organization must apply to the Internal Revenue Service for recognition of its status as a tax-exempt organization.

2. Sharing Savings with Physicians

A hospital's agreement to share savings with physicians, directly or indirectly, unless properly structured, may constitute prohibited "private inurement" or "private benefit." As described above, a finding of prohibited "private inurement" or "private benefit" would risk the imposition of draconian financial penalties on the physicians, the hospital, and its officers and directors, or, in an extreme case, could cause the Internal Revenue Service to threaten revocation of the hospital's tax exemption.

The issue of private inurement or private benefit in hospital-physicians relationships has generated a vast body of court cases, administrative rulings, and scholarly commentary. Unfortunately, much of this material is contradictory, and no clear standards have emerged.

In general, however, two points may be made. First, as a substantive matter, any amount paid to a physician must be commercially reasonable, and no more than an arms-length payment that would be made to anyone else for similar services; amounts paid under "revenue-sharing" arrangements have been subjected to special scrutiny. Second, as a procedural matter, the hospital can follow certain "safe-harbor" procedures provided by tax regulations. If these procedures are followed, the hospital can benefit from a "rebuttable presumption" that the arrangement does not result in prohibited private inurement or private benefit. Treas. Reg. § 53.4958-6(a) - (f). Among other things, these safe-harbor procedures require approval by disinterested directors based on sufficient independent data regarding the commercial reasonableness of the amounts to be paid.

D. Federal Antitrust Law

Section 1 of the Sherman Antitrust Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States ... is declared to be illegal." 15 U.S.C. § 1.

We begin with a series of assumptions regarding how ACOs would be treated for antitrust purposes. First, we believe that, for purposes of the antitrust law, an ACO would be considered a form of "multiprovider network," which is defined in the "Statement of the Department of Justice and Federal Trade Commission Enforcement Policy on Multiprovider Networks" (the "Multiprovider Statement") as "ventures among providers that jointly market their health care services to health plans and other purchasers." If this is the case, the Multiprovider Statement as a whole should apply to ACOs.

Second, we believe that it is likely that some of the participants in the ACO would be Physician Network Joint Ventures, defined in the "Statement of the Department of Justice and Federal Trade Commission Enforcement Policy on Physician Network Joint Ventures" (the "JV Statement") as "a physician-controlled venture in which the network's physician participants collectively agree on prices or price-related terms and jointly market their services."[9] If this is the case, the JV Statement as a whole should also apply to ACOs. Finally, assuming that the ACO engages in joint purchasing of goods or services, the "Statement of the Department of Justice and Federal Trade Commission Enforcement Policy on Joint Purchasing Arrangements among Health Care Providers" (the "Joint Purchasing Statement") would apply.

Underlying each of the DOJ/FTC statements is what, in antitrust parlance, is called "Rule of Reason analysis." Put simply, each of the joint activities will be evaluated under the Rule of Reason, which means that the proponent of an arrangement must be prepared to show that the pro-competitive benefits of the arrangement outweigh its anti-competitive effects. In addition, in the case of the JV Statement and the Joint Purchasing Statement, the DOJ/FTC

[9] It bears mention that this analysis is more likely to apply where payers in addition to Medicare are reimbursing the ACO. Given that Medicare payments to physicians and hospitals are statutorily determined, Social Security Act §§ 1848 and 1886, these participants in an ACO would not be able to negotiate or "collectively agree" on prices they would charge to the Medicare program.

has delineated certain "antitrust safety zones" in which the agencies will assume that an arrangement is legal. (The DOJ/FTC hastens to add that, just because an arrangement is outside one of these safety zones, does NOT mean that it is illegal.)

A joint purchasing arrangement will be in the DOJ/FTC safety zone where (1) the purchases account for less than 35% of the total sales of the purchased product or service in the relevant market; and (2) the cost of the products and services purchased jointly accounts for less than 20% of the total revenues from all products and services sold by each competing participant in the joint purchasing arrangement. If the joint purchasing arrangement is outside the safety zone, then a conventional Rule of Reason analysis should be conducted. Antitrust concerns are lessened if (1) the purchasing arrangement is non-exclusive; (2) negotiations are conducted by an independent employee of the joint purchasing facility who is not an employee of any of the competing members; and/or (3) communications between the joint purchasing agent and each individual participant are confidential (that is, the communications are not shared among competitors).

A Physician Network Joint Venture will be in the DOJ/FTC safety zone where (1) the members of the JV share substantial financial risk and (2) the physician participants constitute 20% or less for exclusive arrangements or 30% or less for non-exclusive arrangements in each physician specialty with active hospital staff privileges that practice in the relevant geographic market. The JV Statement lists "indicia of non-exclusivity" by which the agencies will evaluate whether the physicians' participation is truly non-exclusive or merely non-exclusive on paper. If the JV is outside the safety zone, then a conventional Rule of Reason analysis should be conducted.

Conventional Rule of Reason analysis in the health care field (as in other fields) focuses on two factors (a) does the JV incur financial risk such that the participants might not engage in the activity in the absence of the JV; and (b) does the JV create economic efficiencies?

In the health care field, examples of shared financial risk include (i) JVs that provide health plans at a "capitated" rate; (ii) JVs that provide health care for a predetermined percentage of an insurer's premiums; (iii) JVs that incorporate financial incentives for physician participants (e.g., rewards based on cost control or performance); and (iv) JVs that provide complex or extended courses of treatment for a fixed payment, where actual costs of patient treatment may vary significantly. As drafted by Congress, the ACO law does not stress shared financial risk although it gives the Secretary the option of proposing risk-based payment alternatives.

To determine whether a health care JV results in economic efficiencies, the regulators consider a wide range of factors, including (by way of example) whether (i) the JV provides services that would not otherwise be available; (ii) the JV provides enhanced quality of care; and/or (iii) the JV is able to lower the cost of health care. Perhaps the most important "cost savings" mechanism discussed in the health care antitrust field is "clinical integration." Put simplistically, the more clinical integration, the greater the likelihood that a JV or multiprovider will survive antitrust scrutiny. Put another way, it is assumed that clinical integration leads to more efficient delivery of health care services. The ACO statute partially

addresses this by requiring that the ACO "define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies." Section 1899(b)(2)(G). It is possible that some ACOs may be clinically integrated and achieve the cost-savings objectives of the ACO model; still other ACOs may not be clinically integrated and yet may achieve cost savings by simply using less expensive supplies. The latter arrangements may meet the limited performance measures available, but may actually reduce quality of care.

Note that the ACO model requires a formal legal structure that would allow for the ACO to receive and distribute payments for shared services to participating service providers and suppliers. The ACO model also assumes that an ACO will not be viable unless it (a) lowers costs; and (b) meets quality performance standards. Clearly it is anticipated that the ACO will devise a method of distributing shared savings to providers.

In summary, the ACO model is designed to lower health care costs by incentivizing cost savings without (in theory) lowering the standard of care.

To understand more fully how the DOJ/FTC intends to apply antitrust law to the ACO model, AdvaMed may feel that it would be useful to have answers to the following questions:

1. What mechanisms will be in place to make certain that ACOs compete among themselves for Medicare patients based on quality of care? To maintain a viable health care market, shouldn't the Secretary publicize the medical outcomes of the ACOs? The availability of various treatments from each ACO? The availability of state-of-the-art medical care from each ACO? Will the DOJ/FTC play any role in making sure that such a market is maintained?

2. What controls should be put in place to prevent ACOs from overstressing cost savings to the detriment of quality care? Will the DOJ/FTC recommend that the Secretary insist on a shared savings mechanism that rewards better medical outcomes or should the shared savings mechanism be based solely on putative cost savings? In the DOJ/FTC's view, should participants be permitted to participate in the creation of the shared savings distribution mechanism? If so, what steps, if any, should be taken to prevent them from basing distributions solely on lowering costs (to the detriment of quality care)?

3. Will conventional antitrust standards apply to the ACOs? For example, in evaluating whether an ACO is compliant with the antitrust laws, will the DOJ/FTC be applying the factors set forth in the Joint Purchasing Statement, the JV Statement and the Multiprovider Statement?

4. Will the DOJ/FTC be analyzing the extent to which the participants in an ACO are sharing substantial financial risk? Will this analysis be any different from the analysis undertaken in the general multiprovider context? If so, how?

5. Will the DOJ/FTC be analyzing the degree of clinical integration of an ACO? Will this analysis be any different from the analysis undertaken in the general multiprovider context? If so, how?

6. Does the DOJ/FTC anticipate any antitrust concerns that are special to ACOs? If so, what are they?

7. Should proposed ACOs be disqualified based on excessive market share? Has the DOJ/FTC considered the appropriate number/market share of ACOs and alternatives that will be needed to maintain a viable and healthy Medicare market? Should there be a "too big to fail" rule that prevents excessive expansion of ACOs?

IV. Conclusion

The accountable care organization model is viewed by health policy scholars as an important tool to re-design the health care delivery system. Congress clearly shares that view, having included an ACO model in the Affordable Care Act. However, various federal statutes make the ACO model unworkable.[10] Accordingly, Congress has authorized the Secretary to waive some, but not all, of these statutes. A joint CMS, OIG and FTC meeting in early October will explore the scope of these waiver authorities, and solicit public input on the desirability of the use of those waivers.

AdvaMed has long believed that shared savings programs, such as the ACO model, have the potential to transform the health care system to make it more efficient. However, if the model is not properly structured, there is a real danger that participants in ACO models will merely achieve savings by restricting patient access to appropriate devices, and diagnostics and other cutting-edge and innovative medical technology. The result of such unintended consequences will likely be greater expenses down the road. Accordingly, AdvaMed may want to focus its public comments and statements on those provisions of law eligible for waiver that, if not properly implemented, will lead to this unfortunate result. This memorandum has attempted to identify some such provisions, as well as those provisions of federal law that have not been waived.

[10] As noted, supra n. 4, section 1899 does not expressly pre-empt State laws that may also regulate the conduct of participants in an ACO. These State laws may also make the ACO model unworkable, but unless a court were to find those State laws pre-empted under an implied conflict pre-emption theory, they would continue to apply.