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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.

[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

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[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.