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UPDATE
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Federal Agency Guidance on Accountable Care Organizations Released

As a supplement to our recently released article regarding the final rule for accountable care organization (ACO) participation in the Medicare Shared Savings Program (which can be accessed here), we are providing the following summaries of the interim final rule for the fraud and abuse law waivers issued by the Centers for Medicare and Medicaid Services (CMS) and Department of Health and Human Services Office of Inspector General (OIG) (CMS/OIG Waivers), the final antitrust enforcement policy statement issued by the Department of Justice (DOJ) and Federal Trade Commission (FTC) (DOJ/FTC Statement), and the Internal Revenue Service's (IRS) final guidance for tax-exempt organizations participating in the Shared Savings Program (IRS Guidance).

CMS/OIG WAIVER DESIGNS FOR THE SHARED SAVINGS PROGRAM

In an interim final rule, CMS and the OIG have released the CMS/OIG final waivers regarding the application of certain federal fraud and abuse laws to ACO arrangements under the Medicare Shared Savings Program. The fraud and abuse laws to which the waivers apply are the Physician Self-Referral Statute (the Stark law), the Anti-Kickback Statute (AKS), the civil monetary penalty law provision that prohibits hospital payments to physicians to reduce or limit services (Gainsharing CMP) and the civil monetary penalty law provision that prohibits health care providers from providing inducements to beneficiaries of a federal health care program (Beneficiary Inducement CMP) (collectively the Fraud and Abuse Laws). To facilitate the achievement of the goals of the Shared Savings Program, CMS and the OIG have finalized five specific waivers (each a Waiver and collectively the Waivers) of the application of the Fraud and Abuse Laws to ACOs participating in the Shared Savings Program. The Waivers are specific to the Shared Savings Program, and do not apply to other integrated models for health care delivery, including the Pioneer ACO Model and other models developed in conjunction with private payors or commercial health plans.

The Fraud and Abuse Laws

The Stark law is a civil statute that prohibits physicians from making referrals for "designated health services" reimbursable by Medicare or Medicaid, including hospital services, to entities with which they or their immediate family members have a financial relationship unless a specific exception to the referral prohibition applies. The AKS provides for criminal penalties for individuals or entities that knowingly and willingly offer, pay, solicit, or receive remuneration to induce or reward the referral of business that is reimbursable under any federal health care program. Under the Gainsharing CMP, a hospital is prohibited from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under that physician's direct care. The Beneficiary Inducement CMP prohibits a health care provider or institution from providing anything of value (with very narrow exceptions) to a Medicare or Medicaid beneficiary to influence the beneficiary's decision making regarding choice of provider, practitioner or supplier of items or services paid for by Medicare or Medicaid.

The Waivers

The ACO Pre-Participation Waiver

Pursuant to the CMS/OIG Waivers, the Stark law, the AKS and the Gainsharing CMP do not apply to "start-up arrangements" that predate an ACO's participation agreement with CMS, provided that certain conditions, as outlined below, are met (Pre-Participation Waiver). For the purposes of the Pre-Participation Waiver, a start-up arrangement refers to medical or non-medical items, services, facilities or goods provided by such ACO, ACO participants, or ACO providers and suppliers (including providers or suppliers that are outside of the ACO) that are used to create or develop an ACO. Examples of a start-up arrangement include, but are not limited to, providing infrastructure, hiring new staff, furnishing care coordination mechanisms, providing incentives to attract primary care physicians to join the ACO, and providing capital investments in the ACO.

The Pre-Participation Waiver will apply to a start-up arrangement if the following six conditions have been met.

1. The start-up arrangement must be entered into by parties with a good faith intention to (1) develop an ACO that will participate in the Shared Savings Program in a "target year" and (2) submit a completed application to participate in the Shared Savings Program in such target year. Participants in the start-up arrangement must include the ACO or an ACO participant that is eligible to form an ACO. The parties to a start-up arrangement may not include drug and device manufacturers, distributors, durable medical equipment suppliers, or home health suppliers.
2. The parties to a start-up arrangement must take diligent steps to develop an ACO that would participate in the Shared Savings Program in the target year, including diligent steps to satisfy Shared Savings Program requirements regarding governance, leadership and management of the ACO.
3. The ACO's governing body must make and duly authorize a bona fide determination that the start-up arrangement is reasonably related to the "purposes of the Shared Savings Program." (As used in the Waivers, "purposes of the Shared Savings Program" means one or more of the following: promoting accountability for the quality, cost and overall care for a Medicare patient population as described in the Shared Savings Program, managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO, or encouraging investment in infrastructure and redesigned care processes for high-quality and efficient service delivery for patients,

including Medicare beneficiaries.)

4. The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO must be contemporaneously documented. All documents must be maintained for 10 years and include certain specified elements.
5. There must be public disclosure of the start-up arrangement (not to include the financial or economic terms of the arrangement) at a time and in a manner established in guidance issued by the Secretary of Health and Human Services. CMS and the OIG are soliciting comments on minimally burdensome methods for public disclosure of start-up arrangements.
6. An ACO that fails to submit an application for participation in the Shared Savings Program by the last available application due date for the target year must submit a statement outlining the reasons for such failure on or before the last applicable application due date for the target year in a form and manner to be determined by the Secretary.

If a start-up arrangement qualifies for the Pre-Participation Waiver, the application of such Waiver will begin on either (1) November 2, 2011 for 2012, or (2) one year preceding the Shared Savings Program application due date for 2013 or later. The application of the Pre-Participation Waiver and will end on (1) the start date of the ACO's participation agreement; (2) the denial date if an ACO's application is denied, except with respect to any arrangement that qualified for the waiver before the date of the denial notice, in which case the waiver period would end on the date that is six months after the date of the denial notice; (3) the earlier of the Shared Savings Program application due date or the date that the ACO submits a statement regarding its failure to submit such an application. If an ACO failed to submit an application but plans to do so, it may apply for an extension of the Pre-Participation Waiver. An ACO may use the Pre-Participation Waiver only one time.

The ACO Participation Waiver

The Stark Law, the AKS and the Gainsharing CMP are waived with respect to arrangements of an ACO, one or more of its participants or its ACO providers or suppliers if each of the following five conditions are met (ACO Participation Waiver).

1. The ACO has entered into a participation agreement with CMS and remains in good standing.
2. The ACO satisfies Shared Savings Program requirements regarding governance, leadership and management of the ACO.
3. The ACO's governing body must make and duly authorize a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.
4. The arrangement and its authorization by the governing body must be contemporaneously documented. All documentation must be maintained for 10 years following completion of the arrangement and include certain specified elements.
5. There must be public disclosure of the arrangement (not to include the financial or economic terms of the arrangement) at a time and in a manner established in guidance issued by the Secretary.

If the arrangement meets the above conditions, the application of the ACO Participation Waiver period will begin on the start date of the ACO's participation in the Shared Savings Program and end six months after the earlier of (1) the expiration of the ACO's participation agreement with CMS or any renewal period, or (2) the date on which the ACO voluntarily

terminates the participation agreement. If an ACO's participation in the Shared Savings Program is terminated by CMS, the waiver period will end on the date of the termination notice.

CMS and the OIG are soliciting comments as to whether the ACO Pre-Participation Waiver and the ACO Participation Waiver should exclude outside party arrangements or contain additional conditions for arrangements with parties outside of the ACO. Potential additional conditions for these waivers could include commercial reasonableness, a fair market value requirement, and/or a prohibition against requiring exclusivity as part of a start-up or operating arrangement.

Shared Savings Distribution Waiver

The application of the Stark law, the AKS and the Gainsharing CMP are waived with respect to (1) distributions of shared savings earned by an ACO during its participation in the Shared Savings Program to or among ACO participants, ACO providers or suppliers, and individuals and entities that were ACO participants or ACO providers or suppliers during the year in which the shared savings were earned by the ACO, and (2) use of shared savings for activities that are reasonably related to the purposes of the Shared Savings Program. In both cases the ACO must enter into, and remain in good standing under, a Shared Savings Program participation agreement, and the shared savings must be earned by the ACO pursuant to the Shared Savings Program during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of the agreement. The waiver of the application of the Gainsharing CMP to distributions of shared savings is limited to payments made directly or indirectly by a hospital to a physician that are not made knowingly to induce the physician to reduce or limit medically necessary items or services to Medicare or Medicaid patients. CMS and the OIG will interpret what is medically necessary in accordance with existing Medicare rules and standards of practice.

Compliance with the Stark Law

Pursuant to the CMS/OIG Waivers, CMS and the OIG have waived the application of the AKS and the Gainsharing CMP to any financial relationship between or among the ACO, ACO participants and ACO providers or suppliers that implicates the Stark law, provided that (1) the ACO has entered into, and remains in good standing under, a Shared Savings Program participation agreement, (2) the financial relationship is reasonably related to the purposes of the Shared Savings Program, and (3) the financial relationship fully complies with an exception to the Stark law. This Waiver is structured so as to begin on the start date of the ACO's participation agreement and continue until the ACO's participation agreement with CMS, including any renewals, expires or terminates. CMS and the OIG are soliciting comments on whether this Waiver should continue to apply for a period of time after the ACO's participation agreement expires or terminates.

Waiver for Patient Incentives

Application of the Beneficiary Inducement CMP and the AKS are waived with respect to items or services provided for free or below fair market value to Medicare or Medicaid beneficiaries by an ACO participating in the Shared Savings Program, the ACO's participants or providers or suppliers if: (1) the ACO has a participation agreement with CMS and is in good standing under such participation agreement; (2) there is a reasonable connection between the items or services provided and the beneficiary's medical care; (3) the items or services are in-kind (for

example, not patient copayments or deductibles); and (4) the items and services are preventive in nature or advance a clinical goal of adherence to a treatment regime, drug regime or follow-up care plan, or management of a chronic disease or condition. If an arrangement meets these conditions, the Waiver will apply beginning on the start date of the participation agreement and will end on the earlier of the expiration of the participation agreement or the termination of the participation agreement.

Conclusion

The Waivers are effective as of November 2, 2011. The Waivers are necessary only for those arrangements that implicate one or more of the Fraud and Abuse Laws and do not fit within an existing exception or safe harbor. However, an arrangement that fails to comply with the conditions of a Waiver is not necessarily a violation of the Fraud and Abuse Laws. CMS and the OIG will monitor application of the Waivers in 2012 and 2013, and may narrow the Waivers in the future. As CMS and the OIG have stated in the interim final rule, CMS and the OIG are "aiming for an approach that will provide ACOs with flexibility, certainty, and latitude for beneficial innovation and variation in connection with the new Shared Savings Program, while also protecting Medicare beneficiaries and the Medicare program from fraud and abuse."

DOJ/FTC ANTITRUST ENFORCEMENT POLICY FOR ACOs PARTICIPATING IN THE SHARED SAVINGS PROGRAM

The DOJ/FTC Statement makes two significant departures from the DOJ/FTC proposed statement that was released in connection with the Proposed Rule. First, the entire DOJ/FTC Statement, other than the option for an expedited review (described below), applies to all ACOs, regardless of when they were formed. The proposed statement only applied to ACOs formed after the enactment of the Patient Protection and Affordable Care Act (PPACA). Second, the DOJ/FTC Statement does not contain a procedure for mandatory antitrust review, because such review is not a requirement of the Final Rule.

Background

Federal antitrust laws are designed to promote free and open competition among competitors and to ensure that consumers have a variety of suppliers from which to choose on the basis of price, quality and service. The DOJ and FTC believe that ACOs have the potential for anti-competitive conduct because they are comprised of individuals and entities who may otherwise be competitors. While the DOJ and FTC acknowledge that the benefits of ACOs include improved health for populations and reduced cost of health care services, they are concerned that an ACO will leverage the collective market power of its participants to obtain higher prices from payors, while delivering lower-quality care. The DOJ/FTC Statement is intended to protect Medicare, commercial payors and ACO beneficiaries from the damages of anti-competitive practices, while ensuring that ACOs are able to maximize their effectiveness and provide better health for ACO beneficiaries.

Applicability to ACOs

The DOJ/FTC Statement applies to any ACO or any organization applying to become an ACO that is comprised of individuals and entities who are otherwise competitors. The DOJ/FTC

Statement does not apply to mergers or to an ACO that is a single, integrated entity.

Rule of Reason

Under federal antitrust laws, most price-fixing and market allocation agreements among competitors are illegal. However, the DOJ and FTC permit certain price agreements among competing health care providers if (1) the health care providers involved in the arrangement are either financially or clinically integrated and (2) the joint price agreement is reasonably necessary to accomplish the pro-competitive benefits of integration (Two-Part Test). Satisfying the Two-Part Test does not mean that the arrangement complies with antitrust law. The DOJ and FTC will apply a "rule of reason" analysis to determine whether the collaboration is likely to result in substantial anti-competitive effects, and whether the collaboration's potential pro-competitive efficiencies outweigh those effects.

The DOJ and FTC have determined that CMS' eligibility criteria for ACOs in the Shared Savings Program (CMS Criteria) are consistent with part 1 of the Two-Part Test, which requires that competing health care providers involved in a joint arrangement are either clinically or financially integrated. As such, the DOJ and FTC have confirmed that they will apply the rule of reason analysis to an ACO participating in the Shared Savings Program that meets the CMS Criteria. In addition, an ACO that participates in the Shared Savings Program and also operates in the commercial market is eligible for rule of reason analysis if (1) it provides the same or essentially the same services in the commercial market, and (2) uses the same governance, leadership, clinical and administrative structures and processes in the commercial market as it uses in the Shared Savings Program.

Antitrust Safety Zone

The DOJ and FTC have established a "safety zone" for ACOs. If an ACO falls within the safety zone, it is considered unlikely to raise anti-competitive concerns and the DOJ and FTC will not challenge the ACO, except in cases of improper conduct. An ACO outside of the safety zone may still be legal, provided it does not interfere with competition in relevant markets. Qualification for the safety zone does not protect an ACO from private causes of action, but it may be harder to maintain a private cause of action against an ACO in a safety zone.

To be classified within the safety zone, an ACO whose participants provide the same service (a common service) must have a combined market share of 30 percent or less for each such common service in each participant's primary service area (PSA). A PSA is the least number of zip codes from which the ACO participant obtains at least 75 percent of its patients.

For purposes of evaluation of the safety zone only, a "service" is defined as: (1) physician specialties; (2) major diagnostic categories for inpatient facilities; and (3) outpatient categories (as defined by CMS) for outpatient facilities. The DOJ and FTC consider each physician, practice group, and inpatient facility to have its own PSA. Inpatient facilities are analyzed separately, even if they are part of the same hospital system.

To calculate PSA shares for a common service, the ACO must (1) identify each common service, (2) identify the PSA for each participant who provides the common service, and (3) calculate the ACO's share in the PSA of each such participant. A newly formed ACO may need to estimate expected participation. This process is described in detail in an appendix to the DOJ/FTC Statement. The appendix also includes an example of how a PSA is identified.

ACOs with questions about PSA share calculation may email their questions to aco_psa_questions@ftc.gov.

The safety zone's availability depends in part on whether an ACO participant is an exclusive or non-exclusive participant in the ACO. To be eligible for the safety zone, the ACO must allow non-exclusive participants to contract with commercial payors independent of the ACO. In determining whether an ACO participant is an exclusive or non-exclusive provider, the DOJ and FTC will look beyond the ACO's internal documents to the actual conduct of the ACO and its participants. It is important to note that hospitals and ambulatory surgery centers must participate in ACOs on a non-exclusive basis, regardless of the hospital's or ambulatory surgery center's market share.

Under the safety zone's "dominant provider limitation," if the ACO includes a participant that has a greater than 50 percent share of any service in its PSA that no other ACO participant provides to patients in that PSA, then (1) such participant must be non-exclusive to the ACO and (2) the ACO cannot require commercial payors to contract with it on an exclusive basis, or otherwise restrict any commercial payor's ability to contract with other ACOs or provider networks. In addition, under the safety zone's "rural exception," an ACO may include one physician per specialty from each rural county, as well as rural hospitals (as defined in the DOJ/FTC Statement), both on a non-exclusive basis and still qualify for the safety zone, even if the inclusion of these physicians causes the ACO's share of any common service to exceed 30 percent in any ACO's PSA for that service.

The safety zone is available for the duration of an ACO's participation agreement with CMS, provided the ACO continues to meet the safety zone's requirements.

Additional Guidance for ACOs Outside the Safety Zone

Failure to fall within the safety zone does not necessarily mean that an ACO is unlawful. An ACO will not raise competitive concerns if it does not interfere with competition. In this regard, the DOJ/FTC Statement advises ACOs with high PSA shares or other indicia of market power to avoid the following types of conduct that may raise anti-competitive concerns:

- Discouraging or restricting commercial payors from incentivizing or otherwise directing patients to certain providers within or outside of the ACO;
- Tying sales of ACO services to services outside of the ACO, whether implicitly or explicitly;
- Entering into exclusive contracts with ACO physicians, hospitals or other providers, which prevent or discourage them from contracting outside of the ACO; and
- Restricting the ability of commercial payors to provide data on cost, quality, efficiency and performance to health plan enrollees, if such data is similar to information used in the Shared Savings Program.

CMS will provide the FTC and DOJ with data and information that will allow the agencies to analyze and monitor the competitive effects of ACOs.

Expedited Antitrust Review

Newly formed ACOs seeking additional antitrust guidance may request a voluntary, expedited 90-day review of their formation and planned operation. A "newly formed ACO" is an ACO that,

as of March 23, 2010 (the date that PPACA was enacted), has not signed contracts with, or negotiated with, commercial payors and has not participated in the Shared Savings Program. An ACO comprised of providers who previously negotiated contracts with commercial payors is not considered "newly formed."

To obtain an expedited review, an ACO should submit a completed cover sheet (available on the DOJ's and FTC's websites) along with a request for review, to both the DOJ and FTC prior to entering into the Shared Savings Program. The DOJ and FTC will determine which agency will conduct the review. The reviewing agency will examine the potential anti-competitive effects of the proposed ACO and, to the extent possible, will utilize the rule of reason analysis in its review.

Upon receiving notice of which agency will conduct the review, the ACO must submit comprehensive documentation to the reviewing agency, including its ACO application, documents discussing its business strategies and the type and level of competition among the ACO's participants and information regarding the common services provided by the ACO's participants to patients from the same PSA. Within 90 days of receiving all information requested, the reviewing agency will inform the ACO whether it likely, potentially, or does not likely raise competitive concerns. If it appears that the ACO may raise competitive concerns, then the agency may further investigate the ACO and take any enforcement action that it deems appropriate, whether before or during such ACO's participation in the Shared Savings Program. Both the ACO's request for review, and the reviewing Agency's response, will be made public.

IRS ENFORCEMENT POLICY FOR ACOs PARTICIPATING IN THE SHARED SAVINGS PROGRAM

The IRS Guidance confirms that participation in an ACO through the Shared Savings Program in accordance with the rules and regulations relating to the proper creation and maintenance of such Shared Savings Program or ACO will not, in and of itself, affect the tax consequences for a tax-exempt participant.

Background

The charitable exemption under Section 501(c)(3) of the Internal Revenue Code (the Code) exempts qualified entities from federal taxation on their income. Qualified companies include those which are organized and operated exclusively for charitable, scientific, or educational purposes, provided no part of the organization's net earnings inures to the benefit of any private shareholder or individual. The IRS has long recognized the promotion of health as a charitable purpose; however, a health institution will not qualify as having a charitable purpose if it is privately owned and is run for the profit of the owners. Notwithstanding an entity's status as tax-exempt, unrelated business taxable income (that is, the gross income derived from any unrelated trade or business regularly carried on by the company) is not exempt from taxation. It is anticipated that tax-exempt entities will participate in ACOs as partners, shareholders, or otherwise, along with other private non-tax-exempt entities. Tax-exempt organizations wishing to take part in ACOs and the Shared Savings Program have expressed concern that payments received under the Shared Savings Program may be viewed as inuring to the benefit of an insider or provide an impermissible private benefit that would jeopardize their tax-exempt status. The IRS recognizes that participation in ACOs and Shared Savings Programs is

expected to reduce health costs and lessen the government's burden. As the lessening of such burden is a charitable purpose, the IRS does not want to discourage participation in these programs. As such, the IRS has determined it will not automatically treat tax-exempt entities that receive shared savings as having received prohibited benefits provided they comply with the Code and the IRS Guidance.

IRS Guidance

A tax-exempt organization can participate in the Shared Savings Program through an ACO provided the participation does not result in (1) any net earnings inuring to the benefit of its board members, officers, key management employees or other insiders or (2) the ACO being operated for the benefit of private parties participating in the ACO. The IRS will determine whether either of these conditions exists by reviewing the facts and circumstances of the arrangement in accordance with the charitable exemption provisions of the Code.

There are no specific federal income tax rules related to a tax-exempt entity's participation in the Shared Savings Program through an ACO. All tax-exempt entities are required to comply with the Code to ensure their tax-exempt status is not negatively affected. To provide guidance to the tax-exempt entities participating in an ACO and the Shared Savings Program, the IRS established a five-factor test to determine whether participation results in inurement or impermissible benefit:

1. The terms of the tax-exempt organization's participation in the Shared Savings Program through the ACO (including its share of shared savings or losses and expenses) are set forth in advance in an arm's length written agreement.
2. CMS has accepted the ACO into, and has not terminated the ACO from, the Shared Savings Program. Termination of an ACO from the Shared Savings Program does not automatically jeopardize the tax-exempt status of a participant. The IRS will review all relevant facts and circumstances, including whether the ACO acts to further charitable purposes even after its termination from the Shared Savings Program.
3. The tax-exempt organization's share of economic benefits derived from the ACO (including its share of Shared Savings Program payments) is proportional to the benefits or contributions it provides to the ACO. The IRS takes into account all contributions that the tax-exempt organization makes to the ACO, in whatever form, including property, cash and services, in determining whether the economic benefits received are proportional to the tax-exempt organizations contributions. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests. If the economic benefits are not proportional, the IRS may view such disparity as impermissible excess benefit to an ACO participant.
4. The tax-exempt organization's share of the ACO's losses (including its share of shared losses) does not exceed the share of ACO economic benefits to which it is entitled.
5. All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

The satisfaction of any one of the foregoing factors will not necessarily be determinative of whether participation in the ACO will result in inurement to insiders or impermissible benefit. The IRS will have discretion in making such a determination based on all of the relevant facts

and circumstances of the ACO.

It is also important to note that even if certain aspects of an organization's conduct do not further a charitable purpose or results in unrelated business income, such conduct will not automatically impact the organization's tax-exempt status. The IRS will analyze all of the facts and circumstances of such situations under the general tax rules and regulations applicable to tax-exempt organizations.

If you have any questions about the Final Rule, CMS/OIG Waivers, DOJ/FTC Statement or IRS Guidance or any other issues regarding ACOs, please contact a member of Robinson & Cole's Health Law Group.

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