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Guidance Released on Accountable Care Organizations Participating in the Medicare Shared Savings Program

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services' Office of Inspector General (OIG), the Internal Revenue Service (IRS), the Antitrust Division of the Department of Justice (DOJ), and the Federal Trade Commission (FTC) released much-awaited guidance addressing accountable care organization (ACO) requirements for participation in the Medicare Shared Savings Program (Shared Savings Program) established under the Patient Protection and Affordable Care Act of 2010 (PPACA).

The Shared Savings Program is part of the government's broad attempt to improve care for individuals, to improve health for populations, and to reduce growth in health care expenses (Three-Part Aim). Under the Shared Savings Program, certain medical providers and suppliers that meet eligibility criteria established by the Secretary of the Department of Health and Human Services (HHS) may establish an ACO. Such providers and suppliers include, among others, hospitals, physicians, physician assistants, nurse practitioners, and other providers and suppliers of medical care approved by CMS.

Under the Shared Savings Program, ACO participants are held accountable for the quality, cost, and overall care of the traditional fee-for-service Medicare beneficiaries assigned to the ACO. If the ACO holds costs below certain benchmarks and satisfies the quality standards established by HHS, it receives a shared savings payment, in addition to the fee-for-service payments the ACO participants and providers and suppliers receive under Medicare Parts A and B for medical services rendered.

To obtain the public's feedback regarding the proposed ACO requirements and related guidance, the following agencies are soliciting comments on their respective proposals by the dates provided below. The agencies will compile all of the public comments, make any necessary revisions to the proposed ACO regulations that they determine are appropriate, and then likely finalize the ACO regulations.

Agency	Proposal	Final Date to Submit Comments
CMS	Requirements of Participating in Shared Savings Program	June 6, 2011
CMS / OIG	Waivers to the application of the federal Anti-Kickback Statute, the Physician Self-Referral Law, and the Civil Monetary Penalties Law Waivers to the application of the federal Anti-Kickback Statute, the Physician Self-Referral Law, and the Civil Monetary Penalties Law	June 10, 2011
DOJ / FTC	Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations	May 31, 2011
IRS	Notice setting forth guidance for tax-exempt organizations participating in the Shared Saving Program	May 21, 2011

Below are highlights of CMS's Notice of Proposed Rulemaking regarding requirements of participating in the Shared Savings Program (ACO Proposed Rules), as well as summaries of the CMS/OIG fraud and abuse law waiver proposal (CMS/OIG Waivers), the DOJ/FTC proposed antitrust enforcement policy statement (DOJ/FTC Proposed Statement), and the IRS's guidance for tax-exempt organizations participating in the Shared Savings Program (IRS Guidance).

ACO PROPOSED RULES

ACO Participants

CMS proposes the following groups of providers and suppliers to be eligible to form an ACO:

- Physicians, physician assistants, nurse practitioners and clinical nurse specialists (ACO Professionals) in group practice arrangements.
- Networks of individual practices of ACO Professionals.
- Partnerships or joint venture arrangements between hospitals and ACO Professionals.
- IPPS-paid hospitals employing ACO Professionals.
- Critical access hospitals that bill under "Method II."
- Such other Medicare-enrolled providers of services and suppliers as determined by the HHS Secretary.

ACO Requirements

ACOs wishing to participate in the Shared Savings Program must comply with numerous requirements relating to the ACO's structure, operation, and performance, as summarized below:

Legal Structure and Governance

An ACO must be recognized as a legal entity in the state in which it was established, authorized to do business in each state in which it operates, and have its own TIN. An ACO must have a governing body that has broad responsibility for the ACO's administrative, fiduciary, and clinical operations. The governing body must include both ACO participants and at least one Medicare fee-for-service beneficiary who is served by the ACO and who does not have a conflict of interest with the ACO (FFS Beneficiaries). The ACO participants must have

at least 75 percent control of the ACO's governing body, and each ACO participant must have proportionate control over the decision making of the governing body.

Individuals who serve on the ACO's governing body may also serve on an ACO participant's governing body. If the ACO consists of multiple independent entities, then the ACO's governing body must be separate and unique to the ACO. If the ACO is a single legal entity that is financially and clinically integrated, that has a governing body that consists of at least 75 percent of its own representatives, and that satisfies all other eligibility and governance requirements, the ACO governing body may be the same as the governing body of that entity.

Leadership and Management

The ACO's operations must be managed by an officer, general partner, or other executive or manager who is subject to the governing body's control and whose leadership team has demonstrated the ability to improve efficiency processes and outcomes. Clinical operations must be managed by a full-time, senior-level medical director who is board-certified, licensed in the state where the ACO is located, and physically present at one of the ACO's established locations on a regular basis.

ACO Participants, providers, and suppliers must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include financial investment and/or investments of time and effort in the ACO's operations. In addition, the ACO must have a quality assurance program that is subject to oversight by a physician-directed quality assurance and process improvement committee.

ACOs must implement evidence-based guidelines to ensure that the care provided by the ACO is consistent with the Three-Part Aim. ACO Participants, providers, and suppliers must agree to comply with such guidelines and be subject to performance evaluations and remedial actions or expulsion in the event they fail to comply. The ACO must have a technological infrastructure that enables it to collect and evaluate data to improve the quality of care rendered to patients. In addition, in furtherance of CMS's goal to have all primary care providers participating in the Electronic Health Records (EHR) Incentive Program, at least 50 percent of an ACO's primary care physicians must be meaningful EHR users by the start of the second performance year.

Responsibility for Beneficiaries

ACOs must certify that ACO participants have agreed to become accountable for and report to CMS on the cost, quality, and care of all FFS Beneficiaries assigned to the ACO. ACOs that attempt to exclude high-risk FFS Beneficiaries are subject to sanctions, including termination from the Shared Savings Program. CMS monitors the ACO's activities to ensure it is not taking steps to avoid high-risk beneficiaries.

Minimum Number of Beneficiaries

An ACO must have at least 5,000 assigned FFS Beneficiaries and have sufficient primary care professionals within the ACO to care for such individuals. An ACO is deemed to meet the 5,000 beneficiary requirement if it has historically been assigned 5,000 or more FFS Beneficiaries. If the number of assigned beneficiaries is less than 5,000 at the end of a performance year, CMS issues a warning to the ACO and the ACO is subject to a Corrective Action Plan (CAP). ACOs remain eligible for Shared Savings Program payments (and losses)

during a performance year in which they are subject to the CAP. If, by the end of the next performance year, the ACO does not have at least 5,000 FFS Beneficiaries assigned to it, then CMS terminates the ACO's agreement, and the ACO is not be eligible for Shared Savings Program payments for that year.

FFS Beneficiaries are retroactively assigned to an ACO based on their utilization of primary care services. The assignment of FFS Beneficiaries to particular ACOs does not prohibit them from choosing to seek care from unaffiliated providers; an ACO may not develop policies that restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

Three-Year Commitment

An ACO must agree to enter into a three-year written agreement with CMS to participate in the Shared Savings Program (Three-Year Agreement). Moreover, all contractors, providers, suppliers, and ACO participants must agree to comply with the terms of the Three-Year Agreement and all other applicable participation requirements.

Because CMS assigns FFS Beneficiaries to ACOs based on their use of primary care services, primary care physicians can only participate in one ACO per three-year period. All other ACO participants, providers, and suppliers can participate in more than one ACO during a three-year period.

CMS will establish a deadline by which ACO applications must be submitted and will make a determination of each ACO's eligibility to participate in the Shared Savings Program no later than the end of the calendar year in which such applications are submitted. All applications will take effect on January 1 following the application's approval.

Patient Centeredness

ACOs must demonstrate that they are focused on patient centeredness by carrying out the following:

- Implementing a beneficiary care survey and describing how it will use the results of the survey to improve quality of care
- Ensuring that patients are involved in ACO governance
- Implementing a procedure for evaluating the health needs of FFS Beneficiaries assigned to it and implementing a plan that addresses those needs and takes into account the diversity of the ACO's patient population.
- Identifying high-risk individuals and developing individualized care plans for such individuals who utilize community resources based on their needs
- Coordinating care through the use of care coordinators, technology, or both
- Communicating clinical knowledge and evidenced-based medicine to FFS Beneficiaries in a way that is understandable to them
- Engaging beneficiaries in shared decision making in a way that takes into account their needs, values, priorities, and preferences
- Having a process for communicating to beneficiaries and a separate process that allows beneficiaries to access their medical records
- Having internal systems to measure physician performance that the ACO can use to improve the care and services it provides to beneficiaries

Information to HHS

ACOs must provide HHS with sufficient information about their professionals so that HHS can assign FFS Beneficiaries to ACOs, implement reporting requirements (including quality reporting requirements), and determine eligibility for Shared Savings Program payments. ACOs must report the TIN of the ACO participants, along with a list of associated National Provider Identifiers (NPIs).

Demonstrate Compliance with Quality Criteria

For ACOs to become and remain eligible to participate in the Shared Savings Program, CMS calculates a score for each ACO, based on its satisfaction of certain quality performance standards and measures it establishes. For the first year of participation, ACOs are only required to report on quality. The 65 measures are grouped into five "domains": patient/care giver experience, care coordination, patient safety, preventative health, and at-risk population/frail elderly health. CMS assigns performance benchmarks and a point scale for each category. ACO performance is determined by data submitted to CMS by the ACO. The first time an ACO fails to meet the standards, it is given a warning. CMS then reevaluates the ACO in the following year and may terminate the ACO's participation agreement if it fails to meet the standards. Alternatively, CMS may subject the ACO to a CAP or a special monitoring plan.

ACO performance and continued eligibility is monitored through a variety of methods, including data analysis; site visits; reviewing complaints from both providers and beneficiaries; conducting claims, medical record and coding audits; and beneficiary survey reviews.

Shared Savings Payment Methodology

Shared Savings Program payments are based on an ACO's ability to keep costs below applicable benchmarks while meeting the quality and other requirements of the Shared Savings Program. CMS establishes the benchmark for each ACO by determining the per capita Medicare Part A & B expenditures for beneficiaries who would have been assigned to the ACO under the beneficiary assignment rules in any of the prior three most recent years and by then adjusting for health status and demographics, as well as overall growth trends. CMS notes in the preamble to the ACO Proposed Rules that it is proposing to exclude EHR incentives for eligible professionals under the HITECH Act from the computations of both benchmark and actual expenditures during the agreement period, so as to reduce the chances that incentives intended to encourage and reward participation in one Medicare program may discourage participation in another.

CMS has proposed two models for ACO participation, referred to as the "one-sided" model and the "two-sided" model. Under the one-sided model, an ACO is eligible to receive Shared Savings Program payments but is not at risk for any losses. Under the two-sided model, an ACO is eligible to receive a greater share of Shared Savings Program payments but is also responsible for sharing losses if its expenditures are above its benchmark.

An ACO may elect to participate under the one-sided model at the outset but must convert to the two-sided model in its third year of participation. This method of participation is referred to as "Track 1." In the alternative, an ACO may elect to participate under the two-sided model from the start. This method of participation is referred to as "Track 2." ACOs may elect to participate under Track 1 or Track 2, depending on their risk tolerance level. Track 2 is an option for more experienced ACOs that wish to participate under the two-sided model from the start and, thus, are eligible for a greater share of savings while also responsible for sharing potential losses.

Under Track 1, as noted, the ACO has no downside risk at the commencement of participation but does take on downside risk in the two-sided model during its third year of participation. Under the one-sided model, the percent of shared savings an ACO may earn is up to 50 percent, depending on quality performance, with up to 2.5 percent additionally available for an ACO that includes FQHCs and/or RHCs as ACO participants. To receive a shared savings payment, the ACO's expenditures must be below the minimum savings rate (MSR), which is applied to account for normal variations in expenditures. Under the one-sided model, the MSR varies from 2 percent to 3.9 percent, based upon the total number of assigned FFS Beneficiaries, decreasing as the number of FFS Beneficiaries increases. Once an ACO has surpassed its MSR under the one-sided model, the ACO shares in a savings net of 2 percent of the ACO's benchmark. Under the one-sided model, shared savings payments are capped at 7.5 percent of the ACO's benchmark. For ACOs participating in Track 1, losses (applicable in year three only) are capped at 5 percent of the benchmark.

Under Track 2, the ACO accepts liability for downside risk under the two-sided model during all three years of its agreement. The percent of shared savings increases under the two-sided model to up to 60 percent (depending on quality performance, with up to 5 percent additionally available for an ACO including FQHCs and/or RHCs as participants in the ACO). The MSR and minimum loss rate under the two-sided model is fixed at 2 percent; the ACO shares in first-dollar savings if its expenditures for the performance year are at least 2 percent below its benchmark for the year or is responsible for sharing losses if its expenditures are at least 2 percent above its benchmark. Shared savings payments under the two-sided model are capped at 10 percent of the ACO's benchmark. In Track 2, ACO losses are capped at 5 percent of the benchmark in year one, 7.5 percent in year two, and 10 percent in year three.

CMS proposes to withhold from an ACO 25 percent of any Shared Savings Program payment as a surety against the ACO's repayment of any future losses. In addition, an ACO must take steps to secure Medicare's repayment of potential losses prior to participating in the two-sided model. These steps may include obtaining surety bonds or reinsurance, placing funds in escrow, or securing a line of credit, which the Medicare program may draw upon to repay any losses. An ACO must submit documentation of its ability to repay any losses with its application and must demonstrate the adequacy of its repayment mechanisms before the start of each performance year.

Termination

An ACO failing to comply with applicable regulations may be subject to termination; however, CMS has discretion to take certain actions prior to termination, including providing the ACO with a warning notice, requesting a CAP or imposing a special monitoring plan. These pre-termination measures, however, do not apply to antitrust violations or the determinations of other governmental agencies.

The ACO Proposed Rules provide 16 grounds upon which an ACO may be terminated. By way of example, these include avoidance of at-risk beneficiaries; failure to meet quality performance standards; failure to submit complete and accurate information; failure to meet eligibility requirements, including failures due to the ACO's material change (such as a material change in the ACO's governing body) or any adverse action (including sanctions) imposed by a federal, state, or local governmental agency; violation of Stark, Anti-Kickback, civil monetary penalties law, antitrust, or other laws, rules and regulations "relevant" to ACO operations; failure to provide beneficiaries with an opt-out option for sharing claims information; use or disclosure of claims information received from CMS in violation of the Privacy Act, the Medicare Part D Data Rule, the HIPAA Privacy Rule, or the data use agreement (discussed

below); or failure to demonstrate an ability to repay losses or failure to maintain such capability during the term of the ACO agreement. Termination can be based on the conduct of the ACO itself or on the conduct of any of its participants, providers, suppliers, or contracted parties.

An ACO may voluntarily terminate its agreement with CMS. The ACO must provide at least 60 days' notice to CMS, the ACO participants, and other organizations and must provide timely notice to beneficiaries.

The ACO foregoes all rights to receive its 25 percent surety withhold in the event of a termination for any reason. A terminated ACO must wait until the original three-year period expires before being eligible to reapply to CMS to participate in the Shared Savings Program.

Additional Highlights of the ACO Proposed Rules

Data Sharing

ACOs can obtain data from CMS about their participant beneficiaries to assist them in better coordinating care and understanding of their patient population. The data available to ACOs may include both aggregate (financial, quality performance, and utilization) and beneficiary-identifiable claims data (including Parts A, B, and D data elements). However, beneficiaries are permitted to opt out of sharing their data with the ACO, with the exception of CMS's initial provision of such beneficiary's name, date of birth, sex, and health insurance claim number at the beginning of a three-year ACO term. ACOs must request data from CMS in accordance with regulatory requirements, which include an obligation to enter into a Data Use Agreement (DUA). The DUA obligates the ACO to comply with applicable privacy and confidentiality requirements (including HIPAA) and to use the requested information only for permitted purposes. Misuse or unauthorized disclosure renders the ACO unable to receive further data and could result in termination from the Shared Savings Program as well as the imposition of sanctions or other penalties.

Marketing Materials

CMS must approve an ACO's marketing materials prior to distribution, along with any changes in those marketing materials. Marketing materials are defined broadly to include:

> [G]eneral audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, data sharing opt out letters, mailings, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Saving Program.[1]

CMS has discretion to impose a CAP or terminate an ACO that does not comply with marketing requirements.

Notice to Beneficiaries

Each ACO participant must notify its FFS Beneficiaries that it participates in an ACO by posting a sign in each of its facilities and notifying patients in writing about its participation in the Shared Savings Program.

Public Reporting

The ACO Proposed Rules require ACOs to make information relating to quality and cost available to the public. This information must be accessible in a manner established by CMS. Publicly available information includes the ACO's name, primary location, and contact information; the names of participating providers and suppliers; the identification of any joint ventures between ACO Participants and hospitals; shared savings and loss information; quality performance scores; the amount of any shared savings payments received or losses repaid to CMS; and the total proportion of savings distributed among ACO participants, along with the total proportion of the distribution used by the ACO to support quality performance and in furtherance of the Three-Part Aim.

CMS / OIG WAIVER DESIGNS FOR THE SHARED SAVINGS PROGRAM

As discussed at the beginning of this article, CMS and the OIG have released the CMS/OIG Waiver Notice describing the proposed waivers (Proposed Waivers) of the application of the Physician Self-Referral Statute (Stark law), the Anti-Kickback Statute (AKS), and the civil monetary penalty law provision that prohibits hospital payments to physicians to reduce or limit services (Gainsharing CMP). The Proposed Waivers, as authorized under PPACA, are intended to respond to stakeholder concerns that the restrictions these laws place on certain financial arrangements between physicians, hospitals, and other individuals and entities may impede innovative ACO models envisioned by the Shared Savings Program. The Proposed Waivers are specific to the Shared Savings Program and do not apply to other integrated models for health care delivery.

Qualifying for the Proposed Waivers

CMS and the OIG propose that to qualify for the Proposed Waivers, (1) an ACO must enter into an agreement with CMS to participate in the Shared Savings Program and (2) the ACO and all ACO participants, providers, and suppliers must comply with that agreement and the requirements of the Shared Savings Program.

The Stark Law and the Anti-Kickback Statute

The Stark law is a civil statute that prohibits physicians from making referrals for Medicare "designated health services," 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, unless a safe harbor applies. CMS and the OIG propose to waive the application of the Stark law and the AKS to *distributions of shared savings* received by an ACO from CMS under the Shared Savings Program (1) to or among ACO participants, providers or suppliers, and individuals and entities that were ACO participants, providers, or suppliers during the year in which the shared savings were earned by the ACO or (2) for activities "necessary for and directed related to" an ACO's participation in operations under the Shared Savings Program (a standard not yet defined). CMS and the OIG intend that these waivers will protect the financial relationships created by the distribution of shared savings payments within an ACO, as well as distributions to certain entities outside of the ACO; however, to receive the protections afforded by these proposed waivers, distributions outside of an ACO, including those to referral sources, must be necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program.

In addition, CMS and the OIG propose to waive the application of the AKS to *any* financial relationships between or among the ACO and ACO participants, providers, or suppliers that are "necessary for and directly related to" the ACO's participation in and operations under the Shared Savings Program, provided such financial relationship implicates the Stark law and fully complies with an exception. All financial arrangements that implicate the AKS must comply with existing law.

It is important to note that the proposed waiver of the Stark law is limited to the distribution of shared savings payments under the Shared Savings Program. Thus, all other financial relationships with referring physicians or entities participating in the Shared Savings Program that implicate the Stark law need to comply with the law or fit into an existing exception.

Gainsharing CMP Proposed Waivers

Under the civil monetary penalties law, 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. These arrangements are often referred to as gainsharing arrangements. CMS and the OIG propose to waive the application of the civil monetary penalties to gainsharing arrangements under two scenarios: (1) distributions of shared savings payments from a hospital to a physician if such distribution is not made knowingly, to induce the physician to reduce or limit necessary services, and the hospital and physicians are ACO participants or were ACO participants during the year in which the savings were earned and (2) financial relationships between and among an ACO, ACO participants, providers, or suppliers that are necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program that implicate the Stark law and comply with its exceptions.

Duration of Waivers

CMS and the OIG anticipate that the Proposed Waivers related to the distribution of shared savings payments will apply to all distributions of shared savings payments earned by the ACO during the term of its agreement with CMS, even if the distribution of such payments occurs after expiration of the ACO's agreement. With respect to the AKS and Gainsharing CMP Proposed Waivers for financial arrangements that comply with an existing Stark law exception, those waivers apply only during the term of an ACO's agreement with CMS.

CMS and the OIG are soliciting comments on the Proposed Waivers and on a range of topics that address whether a broader scope of waivers is necessary to enable the formation and operations of ACOs, so as to meet the goals of the Shared Savings Program.

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

In the DOJ/FTC Proposed Statement, the DOJ and FTC propose an enforcement policy regarding the application of the antitrust laws to health care collaborations among independent providers and provider groups, formed after March 23, 2010 (the date of PPACA enactment), that seek to participate, or have been approved to participate, as ACOs in the Shared Savings Program. The DOJ/FTC Proposed Statement provides guidance to allow ACOs to determine whether they are likely to present competitive concerns.

The DOJ and FTC propose a three-part antitrust analysis approach for ACOs in the Shared Savings Program:

1. *The Safety Zone.* First, an antitrust "safety zone" is proposed for ACOs that meet the CMS eligibility criteria to participate in the Shared Savings Program and whose participants provide a "common service" and have a combined market share of 30 percent or less for each common service in each participant's primary service area (PSA). In addition, any hospital or ambulatory surgery center participating in the ACO must participate on a nonexclusive basis, regardless of the hospital's or ambulatory surgery center's market share. The PSA for each service is defined as "the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75 percent of its patients" for that service. The DOJ and FTC have proposed a "rural exception" that allows an ACO to include one physician per specialty from each rural county, as well as rural hospitals (as defined in the Proposed Statement), both on a nonexclusive basis, and still qualify for the safety zone, even if the inclusion of these physicians, or the inclusion of the rural hospital, causes the ACO's share of any common service to exceed 30 percent in any ACO's PSA for that service. Finally, a "dominant provider limitation" is proposed that would apply to any ACO that includes a participant with a greater than 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA. When the ACO includes such a "dominant provider," for the ACO to fall within the safety zone, (1) the ACO participant "dominant provider" must be nonexclusive to the ACO and (2) the ACO cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer's ability to contract or deal with other ACOs or provider networks. The DOJ and FTC will not challenge ACOs that fall within the safety zone, absent extraordinary circumstances.

2. *Mandatory Antitrust Agency Review of ACOs Exceeding 50 percent PSA Share.* An ACO (other than an ACO that qualifies for the rural exception) may not participate in the Shared Savings Program if its share exceeds 50 percent for any common service that two or more independent ACO participants provide to patients in the same PSA, unless, as part of the CMS application process, the ACO provides CMS with a letter from the DOJ or FTC stating that the reviewing agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws. The Proposed Statement specifies the numerous documents and information that an ACO seeking to participate in the Shared Savings Program must submit to the reviewing agency for the mandatory review. The agency conducts an expedited review of the ACO within 90 days of receipt of all required information. While the DOJ and FTC state that exceeding the 50 percent market share threshold "provides a valuable indication of the potential for competitive harm," the DOJ and FTC consider, in determining whether to challenge or recommend challenging the ACO, "any substantial precompetitive justification for why the ACO needs the proposed share to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market."

3. *ACOs Below the 50 percent Mandatory Review Threshold and Outside the Safety Zone.* Finally, the Proposed Statement offers guidance on conduct that, if avoided, significantly reduces the likelihood of an antitrust investigation into ACOs whose participants have combined market shares between 30 percent and 50 percent. Avoiding the identified types of conduct "is important to facilitate payers' ability to offer insurance products that differentiate among providers based on cost and quality" and "ensures that the ACO does not facilitate collusion involving ACO participants that contract with payers outside the ACO." ACOs whose participants have combined market shares between 30 percent and 50 percent will also have the option for expedited FTC or DOJ antitrust review, similar to the mandatory review described above, to provide further certainty regarding the application of the antitrust laws to the ACO's formation and planned operations.

Applying the Rule of Reason Analysis to ACOs

Generally, price fixing and market allocation agreements among competitors are treated as per se illegal under federal antitrust laws; however, price agreements among competing health care providers are not considered per se illegal and are analyzed under the rule of reason if (1) the health care providers are financially or clinically integrated and (2) the joint price agreement is reasonably necessary to accomplish the procompetitive benefits of integration. A rule of reason analysis evaluates whether a collaboration is likely to result in substantial anticompetitive effects and whether the collaboration's potential procompetitive efficiencies outweigh those effects. In previously released policy statements, the DOJ and FTC have articulated the standards for both financial and clinical integration. The DOJ and FTC have determined that CMS's proposed eligibility criteria for ACOs in the Shared Savings Program (CMS Criteria) are broadly consistent with the indicia of clinical integration that the DOJ and FTC have previously set forth.

In light of the foregoing, the DOJ and FTC have confirmed that they will apply the rule of reason analysis to ACOs that meet the CMS Criteria. In addition, the DOJ and FTC will apply a rule of reason analysis to an ACO that participates in the Shared Savings Program (for the duration of its participation in the Program) and also provides the same or essentially the same services in the commercial market, using the same governance and leadership structure and maintaining the clinical and administrative processes it used to qualify for participation in the Shared Savings Program.

IRS GUIDANCE FOR TAX-EXEMPT ORGANIZATIONS PARTICIPATING IN SHARED SAVINGS PROGRAM THROUGH ACOS

The IRS anticipates that certain ACO participants are tax-exempt organizations and that such organizations may participate in an ACO as members of a nonprofit membership corporation, owners of shares in a corporation, owners of a partnership interest in a partnership, and/or parties to contractual arrangements with the ACO or other ACO participants. The tax implications that such tax-exempt entities need to consider are provided below.

Private Inurement and Private Benefit

Tax-exempt organizations participating in an ACO must ensure that their net earnings do not inure to the benefit of insiders and that the organization continues to be operated for a public benefit.

The IRS Guidance provides that the IRS will not consider a tax-exempt organization's participation in the Shared Savings Program to result in prohibited inurement to insiders or impermissible private benefit if (1) the terms of the tax-exempt organization's participation in the ACO, including distribution of shared savings payments, losses, and expenses, are set forth in an arm's length written agreement; (2) CMS has accepted the ACO and has not terminated such ACO's participation in the Shared Savings Program, (3) the tax-exempt organization's share of economic benefits from the ACO is proportional to the benefits or contributions it provides to the ACO; (4) the tax-exempt organization's share of losses does not exceed the share of ACO economic benefits to which is it entitled; and (5) all contracts and transactions entered into by the tax-exempt organization with the ACO and ACO participants, and by the ACO with the ACO's participants, are at fair market value.

Unrelated Business Income

The IRS anticipates that the participation of tax-exempt organizations in an ACO may raise concerns that a tax-exempt organization's share of savings generated by the ACO may be

subject to the unrelated business income tax. Unrelated business taxable income is gross income derived from a trade or business that is not substantially related to the tax-exempt organization's charitable purpose. That said, the IRS proposes that shared savings payments received by a tax-exempt organization from an ACO be derived from activities substantially related to its charitable purpose of lessening the government's burden. This proposed analysis assumes that (1) no part of the shared saving payment inures to an insider or serves a private benefit and (2) the ACO satisfies all of the eligibility requirements set forth by CMS.

ACO Activities Unrelated to the Shared Savings Program

The IRS anticipates the potential for tax-exempt organizations that are ACO participants to be involved in activities unrelated to the Shared Savings Program, including the negotiation of, and operation under, arrangements with other governmental and commercial payors. At this time, the IRS believes that some of these activities may be related to a charitable purpose; however, other activities unrelated to the Shared Savings Program may not contribute to the furtherance of a charitable purpose and, as a result, may generate unrelated business taxable income. The IRS Guidance does not address the circumstances under which a tax-exempt organization's participation in activities unrelated to the Shared Savings Program may be considered in furtherance of such organization's charitable purpose.

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[1] 76 Fed. Reg. 19528, 19641 (April 7, 2011).

If you have any questions about these issues or the content in these articles, please contact a member of Robinson & Cole's Health Law Group.

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