McDermott Will & Emery

ACOs Get Broad Waivers from the Fraud & Abuse Laws

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The Centers for Medicare & Medicaid Services and the Office of the Inspector General (HHS) have issued, and seek public comment on, broad waivers of the federal fraud and abuse laws for ACOs seeking to participate in the Medicare Shared Savings Program.

On October 20, 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General, Department of Health and Human Services (OIG) (collectively, the Agencies) issued for public inspection an interim final rule with comment period (the Final ACO Waivers Rule) setting forth the scope, terms and conditions of waivers of four federal laws that would otherwise prohibit or impede the development and operation of accountable care organizations wishing to participate in the Medicare Shared Savings Program (the Shared Savings Program).[1] The release of the Final ACO Waivers Rule was concurrent with the release of the final rule for the Medicare Shared Savings Program (the Final ACO Rule). Both rules were published in the Federal Register on November 2, 2011[2] and, while the Medicare Shared Savings Program (the Final ACO Rule) is effective January 3, 2011,[3] the Final ACO Waivers Rule is effective November 2, 2012.[4] Comments on Final ACO Waivers Rule are due no later than 5 p.m. on January 3, 2012.[5]

The Final ACO Waivers Rule represents a dramatic departure for the Agencies, especially with regard to enforcement of the federal physician self-referral or Stark law and the CMP law's broad restrictions on "gainsharing." By allowing compensation to physicians to incentivize more efficient and effective care, and by focusing on procedural requirements such as (a) determinations by the ACO's governing body that the financial arrangement is reasonably related to the purposes of the Shared Savings Program, (b) contemporaneous documentation (but no signed writing requirement), and (c) public disclosure of the arrangement (but not disclosure of the financial details), the Agencies are relieving ACOs and their participants of substantial regulatory uncertainty and burdens that would otherwise interfere with effective participation in the Shared Savings Program.

This white paper provides a brief introduction to and overview of the waivers. It then explains the five waivers in detail, discusses the scope of the four waivers for arrangements with referral sources, considers the implications of the waivers for commercial ACO arrangements, and considers the implications of the waivers for hospital-physician clinical integration and alignment strategies.

Introduction and Overview

The four federal laws addressed by the Final ACO Waivers Rule are the federal physician self-referral or Stark law (the Stark Law),[6] the federal anti-kickback statute (the Kickback Law),[7] the provisions of the civil monetary penalties law prohibiting hospital payments to a physician to induce the physician to reduce or limit care to a Medicare or Medicaid beneficiary under the physician's direct care (the Gainsharing CMP),[8] and the provisions of the civil monetary penalties law prohibiting inducements to a Medicare or Medicaid beneficiary likely to influence the beneficiary's choice of a provider, practitioner or supplier (the Beneficiary Inducements CMP)[9] (collectively, the F&A Laws).

The Agencies issued five waivers:

- ACO pre-participation waiver
- ACO participation waiver

[1] Finding good cause to waive publication of a notice of proposed rulemaking, the Agencies issued the Final ACO Waivers Rule as an interim final rule with comment period. However, there is a 60-day comment period, and the Agencies are required to consider comments and publish a final rule addressing those comments within 3 years.
[2] *See* Final Waivers in Connection With the Shared Savings Program at 76 FR 67992–6801076; *See* Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations 76 FR 67802–67990.
[3] 76 FR 67802
[4] 76 FR 67992.
[5] *Id.*
[6] 42 U.S.C. § 1395nn.
[7] 42 U.S.C. § 1320a-7b(b).
[8] 42 U.S.C. § 1320a-7a(b)(1) and (2).
[9] 42 U.S.C. § 1320a-7a(a)(5).

- Shared savings distributions waiver
- Compliance with Stark Law waiver
- Patient incentive waiver

The waivers are self-implementing, there being no filing or application procedures, and a *financial arrangement need only meet one of the waivers to be protected*. The Final ACO Waivers Rule will be posted on the Agencies' websites, but will not be codified in the Code of Federal Regulations. Notably, the waivers only apply to accountable care organizations with *bona fide* intent to participate in, or that actually participate in, the Shared Savings Program, including the Advance Payment Initiative of the Center for Medicare & Medicaid Innovation (the Innovation Center). Although the waivers do not apply to the Innovation Center's Pioneer ACOs, the Agencies have the authority to issue, and are expected to issue, similar and, perhaps, broader waivers for Pioneer ACOs, as well as waivers for Innovation Center demonstrations.

The ACO pre-participation waiver, ACO participation waiver, and the patient incentive waiver were not part of the April 7, 2011, proposed waivers notice (the Proposed Waivers), and were developed in response to public comments arguing that the Proposed Waivers were not broad enough to achieve the objectives of the Medicare Shared Savings Program. The ACO pre-participation waiver allows an ACO participant or ACO provider/supplier, *e.g.*, a hospital, to furnish or fund ACO development services for the economic benefit of *all* of the ACO's participants, including referring physicians, without risk of liability under the F&A Laws. The ACO participation waiver allows an ACO participant or ACO provider/supplier to fund or otherwise support an ACO's operations during the term of the ACO's participation agreement, including arrangements benefiting other ACO participants or ACO providers/suppliers, without risk of liability under the F&A Laws. The key limitations on the scope of these two waivers is that the ACO's governing body must make a *bona fide* determination that the arrangement is reasonably related to the purposes of the Shared Savings Program; the arrangements must be documented, contemporaneously, and, except for their financial or economic terms, publicly disclosed.

The shared savings distributions waiver protects distributions to ACO participants and ACO providers/suppliers, *and* protects distributions to outside parties if conveyed as compensation for activities reasonably related to the purposes of the Shared Savings Program. The Agencies note that shared savings distributions can also be structured to fit within one of the other waivers.

The compliance with the Stark Law waiver protects arrangements that implicate the Stark Law, and that qualify for one of the Stark Law exceptions, from liability under the Kickback Law and the Gainsharing CMP. Finally, the patient incentive waiver allows ACOs to offer Medicare beneficiaries preventative care items or services, or other in-kind services or items designed to advance certain clinical goals.

The Agencies indicate that they plan to closely monitor ACOs entering the Shared Saving Program in 2012 through June 2013, and will narrow the waivers for applicants entering the program after June 2013 unless information gathered by that time suggests that the waivers are adequately protecting the Medicare program and beneficiaries. The Agencies solicit comments on narrowing the waivers, including the following:

- Imposing fair market value or commercial reasonable standards
- Limiting the waivers to compensation for services by referral sources
- Placing caps on the amount of start-up costs, information technology, medical training, care coordination, or goods or services furnished to a referral sources' patients
- Precluding waiver protection for arrangements with outside parties

The Agencies also request recommendations for additional waivers.

The specific scope and requirements of each waiver is discussed below, after first introducing the meaning of key terms used in the waivers.

Key Terms

For purposes of the Final ACO Waivers Rule, ACO, ACO participant, and ACO provider/supplier have the same meanings they have for purposes of the Shared Savings Program (42 CFR § 425.20), summarized here. An *accountable care organization (ACO)* is a legal entity formed by one or more of the following Medicare-enrolled providers, suppliers, and combinations of providers and suppliers:

- ACO professionals[10] in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Critical access hospitals that bill under Method II[11]
- Rural health clinics
- Federally Qualified Health Centers

An *ACO participant* is any Medicare-enrolled ACO provider/supplier (defined below) that, alone or with other ACO participants, comprises an ACO, and is included on the ACO's required list of ACO participants submitted with its application. An ACO participant does not have to be one of the above-listed providers or suppliers that is eligible to form an ACO (an *eligible ACO participant*). An *ACO provider/supplier* is a Medicare-enrolled provider or supplier that has reassigned its right to Medicare payment to an ACO participant, and is included on the ACO's required list of ACO providers/suppliers submitted with its application.[12] The Agencies refer to any other entity that furnishes health care services or items on behalf of an ACO as an "*outside party*," the term that we will use in this white paper.

ACO Pre-participation Waiver

The ACO pre-participation waiver protects pre-participation start-up arrangements involving an ACO, ACO participant, or ACO provider/supplier, and all of the parties to the arrangements, from liability under the Stark Law, the Kickback Law, and the Gainsharing CMP.[13] *Start-up arrangements* mean items, services, facilities and/or goods[14] provided by the ACO, an ACO participant, or ACO provider/supplier, and used to create or develop an ACO, including donations of or subsidies for these items, services, facilities or goods. For purposes of guidance only, the Agencies provide a long, illustrative list of start-up arrangements, recognizing that it is impossible to create an exhaustive list of *bona fide* start-up arrangements. The list includes funding, capital contributions, legal and consulting services, hiring of staff, incentives to attract primary care physicians, performance-based compensation to physicians, and information technology.[15] The Agencies request comments on their definition of start-up arrangements.

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[10] "ACO professionals" means physicians, nurse practitioners, physician assistants, and clinical nurse specialists.
[11] As described at 42 C.F.R. §413.70(b)(3).
[12] Presumably, the Agencies do not expect an ACO provider/supplier that is, itself, an ACO participant, to make the required reassignment. The Agencies' notion here appears to be that ACO participants will be ACO provider/suppliers that are institutions or group practice entities, and ACO providers/suppliers will be individuals who have reassigned their rights to Medicare payments/benefits to such institutions and group practice entities.
[13] For purposes of the *ACO pre-participation waiver*, ACO, ACO participant, and ACO provider/supplier are individuals and entities that *would meet the regulatory definition of ACO, ACO participant or ACO provider/supplier* had the ACO submitted its application and the required lists of ACO participants and ACO provider/suppliers. Note that the Final ACO Rule prohibits ACOs from using data that CMS furnishes it through the Shared Savings Program to reduce or limit services to an individual Medicare beneficiary. 42 CFR 425.704(c).
[14] The items, services, facilities and/or goods can be medical or non-medical.
[15] 76 FR 68003

The pre-participation waiver is broad, but comes with significant procedural, documentation and disclosure burdens designed to safeguard against fraud and abuse.

1. *Requisite Parties and Protected Parties*

The start-up arrangement must be undertaken by parties having a good-faith intent to develop an ACO and submit a completed application to participate in the Shared Savings Program in a particular year (the *target year*). An ACO or an eligible ACO participant must be a party to the arrangement, but the waiver is not limited to arrangements between or among an ACO, an ACO participant, or an ACO provider/supplier, and the protection of the waiver extends to outside parties to the arrangement. (The Agencies, however, request comments on whether the waiver should extend to arrangements with outside parties.) A drug and device manufacturer, distributor, durable medical equipment supplier, or home health agency may *not* be a party to the start-up arrangement.

2. *ACO Determination and Authorization*

Consistent with the fiduciary duty owed by the ACO's governing body members to the ACO, and its conflicts of interest policy, 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. "*Purposes of the Shared Savings Program*" means the following aims:

- Promoting accountability for the quality, cost and overall management for a Medicare patient population
- Managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO
- Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients

The Agencies are silent on whether this determination and authorization must be made prior to the commencement of the start-up arrangement. However, since the waiver is designed for pre-application, as well as pre-participation agreement activity, and the ACO is not required to represent that it has a governing body until the date of its Shared Savings Program application, it appears that the ACO's governing body can make this determination and authorization *after* the start-up arrangement has commenced or, in the case of a one-time transaction, after the transaction is over. Presumably, the Agencies will provide additional guidance on this timing issue. The Agencies solicit comments on whether they should specify particular methods by which the governing body makes determinations and authorizations, to ensure that they are *bona fide* and meaningful.

3. *Diligent Steps Requirement*

The parties must take diligent steps to develop an ACO that would be able to participate in the Shared Savings Program in the target year, including taking diligent steps to meet the Shared Savings Program's ACO governance, leadership and management requirements.[16] Since the ACO's governing body must make a bona fide determination that the start-up arrangement is reasonably related to the purposes of the Shared Savings Program, it appears that the ACO must have a governing body at least before the ACO pre-participation waiver ends to qualify for the protection of the waiver.

4. *Time Limitations; Effect of Application Denial and Failure to Submit Application*

The waiver only protects start-up arrangements occurring one year preceding the application due date for the ACO's target year, unless the target year is 2012, in which case the waiver protects start-up arrangements occurring on and after the waiver's publication date, i.e., November 2, 2011.[17] The Agencies do not explain why the pre-participation waiver is not given a retroactive effective date for a target year of 2012.

If the ACO enters into a Shared Savings Program participation agreement with CMS for the target year, the ACO pre-participation waiver ends on the ACO's participation agreement start date. Thereafter, the ACO must rely on the ACO participation waiver to protect start-up arrangements commencing, or continuing on, after the ACO's participation agreement start

[16] These requirements are at 42 C.F.R. § 425.106 and 425.108.
[17] 76 FR 68005.

date. If the ACO submits an application prior to the application due date for the target year, but the application is denied, the waiver ends six months after the date of the denial notice for continuing, previously protected start-up arrangements. No new start-up arrangements after the denial notice are protected. (The Agencies request comments on the six-month "tail" period.)

If, notwithstanding its good-faith intent to file an application, the ACO fails to submit an application by the last available application due date for the target year, the ACO must submit an explanatory statement to CMS on or before the last available application due date for the target year. In such case, the ACO pre-participation waiver ends on the earlier of the application due date or the date the ACO submits the explanatory statement. However, the ACO can apply for and be granted an extension of the pre-participation waiver period if it can demonstrate a likelihood of successfully developing an ACO that would be eligible to participate in the Shared Savings Program by the next available application due date.[18]

Note that the ACO pre-participation waiver may only be used once by an ACO.[19] Therefore, the parties to a start-up arrangement should be careful in selecting the ACO's target year, and diligent in preparing and filing the application.

5. *Documentation*

The start-up arrangement (and any later material modifications to the arrangement), the required determination and authorization by the governing body, and the diligent steps to develop the ACO, must be documented (in electronic or paper form), and the documentation must be contemporaneous. The documentation must identify at least the following:

a. A description of the arrangement; the parties to the arrangement; the date of the arrangement; the purpose(s) of the arrangement; the items, services, facilities, and/or goods covered by the arrangement; and the financial or economic terms of the arrangement[20]
b. The date and manner of the governing body's authorization of the arrangement, including the basis for the governing body's determination that the arrangement is reasonably related to the purposes of the Shared Savings Program
c. A description of the diligent steps taken to develop an ACO, including relevant dates and how the steps relate to the development of an ACO that would be eligible for a participation agreement

The documentation must be retained for at least 10 years following completion of the arrangement, or, in the case of the diligent steps, for at least 10 years following the date the ACO submits its application, or, if the ACO fails to submit an application for its target year, the date the ACO submits its explanatory statement. The documentation must be made available to the CMS upon request. Any party to the start-up arrangement that needs or may need the protection of the waiver should take steps to assure that these documentation requirements are met, and should retain a copy of the documentation.

6. *Public Disclosure*

A description of the arrangement, except the financial or economic terms, must be disclosed at a time and in a place and manner established by CMS. The Agencies request comments on the form and timing of the public disclosure, and state in commentary that, for now, parties desiring the protection of the waiver should post the disclosure on a public website belonging to the ACO or an individual or entity forming the ACO, clearly labeled as an arrangement for which waiver protection is sought. The disclosure should be made within 60 days of the date of the arrangement, and include the name of the ACO (or, if the name of the ACO is not known, the parties forming the ACO) and other identifying information sufficient to allow individuals conducting an electronic internet search using a widely available search engine to readily locate the website.

[18] CMS will establish procedures for requesting this extension in future guidance.
[19] 76 FR 68005.
[20] The start-up arrangement does not need to be set forth in a binding agreement or signed by the parties.

ACO Participation Waiver

The ACO participation waiver is very similar to the ACO pre-participation waiver, but covers arrangements occurring or commencing *after* the ACO has entered into a Shared Saving Program participation agreement. Specifically, the ACO participation waiver protects arrangements involving an ACO, one or more of its ACO participants or ACO provider/suppliers, or a combination of thereof, and the parties to the arrangements, from liability under the Stark Law, the Kickback Law, and the Gainsharing CMP. "*Arrangements*" is not defined, but the Agencies note in commentary that even start-up arrangements can qualify for the ACO participation waiver. Thus, "arrangements" presumably includes items, services, facilities and/or goods, including donations of or subsidies for items, services, facilities or goods, used *either* to develop the ACO *or* to support its ongoing operations and activities after the ACO enters into a participation agreement.

The following specific conditions apply:

1. *Requisite Parties and Protected Parties*

The arrangement must involve an ACO, one or more ACO participants, and ACO provider/suppliers, but the waiver is not limited to arrangements between or among an ACO, an ACO participant, or an ACO provider/supplier. In addition, the protection of the waiver extends to outside parties to the arrangement. The Agencies, however, request comments on whether the participation waiver should extend to arrangements with outside parties such as laboratories, equipment and supply companies, drug and device manufacturers, distributors, and purchasing organizations, and, if so, whether additional conditions should apply, such as a requirement that the arrangement be on commercially reasonable and fair market value terms, or a prohibition on exclusive arrangements.

2. *Participation Agreement; Duration of Waiver*

The ACO must have entered into a Shared Savings Program participation agreement, and be in good standing under its agreement. The waiver expires six months following the expiration of the participation agreement (including any renewals thereof), or the date on which the ACO voluntarily terminates the participation agreement, whichever comes first. However, if CMS terminates the participation agreement, the waiver period ends on the date of the termination notice. (The Agencies request comments on the six-month "tail" period.)

3. *Governance, Leadership and Management*

The ACO must meet the Shared Savings Program's ACO governance, leadership and management requirements.[21]

4. *ACO Determination and Authorization*

This requirement is identical to the ACO determination and authorization requirement described above for the ACO pre-participation waiver. Consistent with the fiduciary duty owed by the ACO's governing body members to the ACO, and its conflicts of interest policy, the ACO's governing body must make and duly authorize a bona fide determination that the arrangement is reasonably related to the purposes (triple aims) of the Shared Savings Program (set forth above). The Agencies recognize that the waiver is broad, protecting arrangements, among others, in which an ACO might receive funding or in-kind contributions from ACO participants or ACO providers/suppliers, and redistribute them to other ACO participants or ACO providers/suppliers. However, the Agencies caution that arrangements should be scrutinized with care to ensure that the reasonable relationship between an arrangement and the purposes of the Shared Savings Program can be clearly identified.22

5. *Documentation*

This requirement tracks the documentation requirement described above for the ACO pre-participation waiver. Both the arrangement (and any later material modifications to the arrangement), and the required determination and authorization by the governing body must be documented (in electronic or paper form).

[21] These requirements are at 42 C.F.R. § 425.106 and 425.108.
[22] 76 FR 68004.

The documentation must be retained for at least 10 years following completion of the arrangement, and made available to CMS upon request. As with the document required for the ACO pre-participation waiver, any party to the arrangement that needs or may need the protection of the waiver should take steps to assure that these documentation requirements are met, and should retain a copy of the documentation.

6. *Public Disclosure*

This requirement is identical to the public disclosure requirement of the ACO pre-participation waiver. A description of the arrangement, except the financial or economic terms, must be disclosed at a time and in a place and manner established by CMS, which, for now, requires a disclosure on a public website belonging to the ACO or an individual or entity forming the ACO.

Shared Savings Distribution Waiver

The shared savings distribution waiver protects "distributions or use of" shared savings earned by an ACO during the term of, and pursuant to, the ACO's Shared Savings Program participation agreement. The waiver applies to the Stark Law, the Kickback Law and the Gainsharing CMP, and extends to distributions earned during the term of the ACO's participation agreement, even if distributed after the agreement expires. To qualify for the waiver, the shared savings distribution must either be used for activities reasonably related to the purposes of the Shared Savings Program (defined above). or distributed to or among the ACO's ACO participants, its ACO providers/suppliers, or individuals or entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO.

However, if the shared savings distributions are made directly or indirectly by a hospital to a physician, the payments may not be made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the physician's direct care. The Agencies indicate that the waiver protects incentives to provide alternative and appropriate care (e.g., evidenced-based protocols), so long as the care is medically necessary.23

Distributions to physicians outside the ACO are protected by the waiver if the distribution is compensation for activities reasonably related to the purposes of the Shared Savings Program.

Compliance With the Stark Law Waiver

The Kickback Law and the Gainsharing CMP are waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Stark Law,24 provided that all of the following requirements are met:

- The ACO has entered into a participation agreement and remains in good standing under the agreement
- The financial relationship is reasonably related to the purposes of the Shared Savings Program (defined above)
- The financial relationship fully complies with one of the Stark Law's DHS, ownership/investment, or compensation exceptions (42 C.F.R. § 411.355 - § 411.357)

The waiver period commences on the start date of the ACO's participation agreement, and ends on the earlier of the expiration of the participation agreement's term (including renewals thereof), or the date on which the participation agreement is terminated. The Agencies are considering extending the time period for the waiver for another 3 to 12 months, and request comments on this approach.

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[23] The Agencies interpret "medical necessity" consistent with Medicare program rules and accepted standards of practice. 76 FR 68006.
[24] To implicate the Stark Law, CMS appears mean that the financial relationship must trigger the Stark Law's referral and billing prohibitions, and, therefore, must meet one of the Stark Law's exceptions.

The Patient Incentives Waiver

The Beneficiary Inducements CMP and the Kickback Law are waived with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to Medicare beneficiaries for free or below fair-market-value, if all of the following requirements are met:

- The ACO has entered into a participation agreement and remains in good standing under its participation agreement
- There is a reasonable connection between the items or services and the medical care of the beneficiary
- The items or services are in-kind
- the items or services meet either of the following conditions:
  - Are preventive care items or services[25]
  - Advance one or more of the following clinical goals:
    - adherence to a treatment regime
    - adherence to a drug regime
    - adherence to a follow-up care plan
    - management of a chronic disease or condition

For now, the waiver is not limited to incentives given to Medicare beneficiaries assigned to the ACO, but the Agencies solicit comments on whether the waiver could and should be so limited. Notably, in commentary, the Agencies rule out beauty products, theatre tickets, baseball tickets, jewelry, and household items that can be used for purposes other than direct health and care-related purposes, even though these are items that could incentivize beneficiaries to adhere to a treatment regime, drug regime, or follow-up care plan. Instead, the Agencies give the example of blood pressure monitors for hypertensive patients as the type of item that would have a "reasonable connection" to the beneficiary's medical condition.[26]

Importantly, the patient incentives waiver does *not* protect gifts or other incentives to Medicare beneficiaries to induce them to remain in an ACO or with a particular ACO provider/supplier, and such incentives are prohibited by the Final ACO Rule.[27] The Final ACO Rule also prohibits ACOs, ACO participants, ACO providers/suppliers, and outside parties performing services related to ACO activities from providing beneficiaries with incentives *to receive items or services from ACO participants or ACO providers/suppliers*.[28] This prohibition is very similar to the Beneficiary Inducements CMP and the Kickback Law; however, CMS indicates that it intends to interpret this prohibition *consistent with* the Final ACO Waivers Rule,[29] and, therefore, incentives for a beneficiary to adhere to a treatment regime, drug regime or follow-up care plan will presumably not violate the Final ACO Rule even if they have the incidental effect of inducing patients to receive clinical care from an ACO participant or an ACO provider/supplier.

[25] "Preventative care items or services" is not defined.
[26] Preventative care items or services presumably have such a reasonable connection regardless of the beneficiary's medical condition, but this is not completely clear.
[27] 42 C.F.R. 425.304(a)(1).
[28] *Id.*
[29] 76 FR 67958.

The patient incentives waiver period commences on the start date of the ACO's participation agreement, and ends on the earlier of the expiration of the participation agreement's term (including renewals thereof), or the date on which the participation agreement is terminated. However, the beneficiary may keep items received before the participation agreement expired or

terminated, and receive the remainder of any service initiated before the participation

agreement expired or terminated.

While giving ACOs the flexibility to incentivize patient compliance with treatment plans and regimes, the patient incentives waiver is not broad enough to support an ACO's efforts to coordinate care by incentivizing beneficiaries to remain "in-network."

The Scope of the Four Referral Source Waivers

In contrast to the Proposed Waivers, the ACO pre-participation and ACO participation waivers (the New Par Waivers) are extraordinarily broad and flexible. Although the shared savings distributions waiver and the compliance with Stark Law waiver do not expand the scope of protection provided by the New Par Waivers, they do not have the explicit ACO governing body authorization and public disclosure requirements of the New Par Waivers. Thus, there is an advantage to structuring the ACO's shared savings distributions to fit within the shared savings distributions waiver, and, to the extent possible, structuring financial arrangements between participating hospitals and referring physicians that implicate the Stark Law to fit within a Stark Law exception.

Although there may be some objections to the public disclosure requirement of the New Par Waivers, it does not require disclosure of the financial or economic terms of the arrangements, and, since the disclosure can be made on a webpage, compliance should not be costly. However, the time limitations on the waivers means that parties contributing significant resources to an ACO, ACO participant, or ACO provider/supplier in reliance on the waivers should consider the cost and burden of unwinding arrangements in the event that the ACO's participation agreement is terminated or not renewed, or an ACO participating provider/supplier withdraws from the ACO.

The breadth of protection afforded by the New Par Waivers is striking. For example, the New Par Waivers allow electronic health record (EHR) and connectivity donations by participating hospitals not currently excepted by the Stark Law, and such donations would not be subject to the December 31, 2013, sunset of the Stark Law's EHR donation exception. Further, if the New Par Waivers' procedural requirements are met, they will allow a hospital to make compensation to ACO participating physicians contingent on reductions in patient length of stay, readmissions, standardization and substitution of lower-cost surgical devices and supplies, and improvements in operating room efficiency, compensation that is not currently permitted by the Gainsharing CMP, at least not without a favorable OIG Advisory Opinion.

However, the outside parameters of what is allowed under the Shared Savings Program remain unclear. The ACO Final Rule prohibits an ACO from *requiring* that beneficiaries be referred *only* within the ACO's provider network. (An ACO, ACO participant, or ACO provider/supplier can require its employees and contractors to refer Medicare beneficiaries *to it*, subject to certain exceptions; however, this is not a license to require such employees or contractors to make referrals to *others* within the ACO's provider network.) Does this mean that an ACO is prohibited from making incentive compensation or shared savings distributions to a physician contingent on the physician making all or a certain percentage of her Medicare referrals within the ACO's provider network? The only guidance that the Agencies provide is to say that, by way of example, while a per-referral payment to a specialist for every in-network referral would be unacceptable, "arrangements with specialists or nursing facility staff members to engage in care coordination for ACO beneficiaries or implement evidence-based protocols could be reasonably related to the purposes of the Shared Savings Program even if the arrangement were to reflect a likelihood that the patient might be referred to or within an ACO."[30] With this vague guidance, ACOs will need to determine at what point financial incentives to engage in care coordination likely to result in in-network referrals crosses the line into unacceptable payments for referrals. The good news, however, is that the risk of an ACO, ACO participant or ACO provider/supplier getting it wrong is not a risk of liability under the Stark Law, the Kickback Law, or the Gainsharing CMP, provided the procedural requirements of the New Par Waivers are met; the risk would be one of sanctions under, or termination from, the Shared Savings Program.

[30] 76 FR 68004.

Implications of the Waivers for Commercial ACO Arrangements

The Final ACO Rule and the Final ACO Waivers Rule do not prevent an ACO from actively seeking and participating in commercial ACO arrangements. Although the Agencies declined to specifically extend the shared savings distributions waiver to distributions of savings earned pursuant to commercial ACO arrangements, the Agencies state that nothing precludes such distributions from qualifying for the ACO participation waiver, and point out that many commercial shared savings arrangements are, or can be, structured to fit within the Stark risk-sharing exception.

The Agencies' statement that nothing precludes commercial ACO distributions from qualifying for the ACO participation waiver is very significant. If an ACO's distributions of savings earned pursuant to an arrangement with a commercial payor can qualify for the protection of the ACO participation waiver, this means that the Agencies believe that such distributions can be reasonably related to *the purposes of the Shared Savings Program*.[31] This strongly suggests that the Agencies are interpreting "purposes of the Shared Savings Program" broadly, recognizing that care coordination arrangements that improve quality and efficiency, and lower costs, benefit the Medicare program and its beneficiaries even if the care coordination and related financial arrangements are "payor-blind." The Agencies' broad and liberal interpretation of "purposes of the Shared Savings Program" underscores the breadth of the waivers themselves.

If you have questions regarding these broad waivers of the fraud and abuse laws for ACOs, or would like to submit comments on the rule with our assistance, please contact your regular McDermott lawyer or:

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[31] "Purposes of the Shared Savings Program" means the aims of:

- promoting accountability for the quality, cost and overall management for a Medicare patient population
- managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO
- encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients

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