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HEALTH CARE UPDATE

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Andrew's health care practice is focused in the areas of compliance, regulation, transactions and non-profit governance. Andrew regularly advises health care providers on a variety of compliance and regulatory issues, including the Anti-Kickback Statute, the Physician Self-Referral (Stark) law, EMTALA, licensing, physician recruitment, and HIPAA and state privacy laws.

CMS AND OIG ISSUE WAIVERS FROM FRAUD AND ABUSE LAWS FOR THE MEDICARE ACO SHARED SAVINGS PROGRAM

"Subject to (Reasonable) Conditions"

If necessity is the mother of invention, then it only makes sense that the final rules governing accountable care organization (ACO) eligibility for the new Medicare Shared Savings Program (MSSP) be accompanied by waivers of certain fraud and abuse laws. After all, creating an ACO eligible for shared savings will be challenging. Creating an eligible ACO to ensure complete compliance within the existing fraud and abuse framework would have been impossible.

BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) issued its final ACO rules in October. [1] These rules are derived from the section of the Patient Protection and Affordable Care Act (ACA) that seeks to encourage the development of accountable care organizations (ACOs) through their participation in the MSSP. [2] ACOs are designed to foster innovative approaches to enhancing quality and efficiencies, and to lowering the costs of delivery of health care. Under the MSSP, groups of providers and suppliers meeting the criteria in the ACA may work together as ACOs as long as they agree "to become accountable for the quality, cost, and overall care delivered to Medicare fee for service beneficiaries for which they will be held responsible. In return Medicare will share resulting savings with eligible ACOs." [3]

REASONS FOR THE WAIVERS

The problem that Congress confronted when enacting the ACA is that the existing fraud and abuse laws directly impede the establishment of particular arrangements the new ACO rules encourage. These laws - the physician self-referral law (Stark Law), the federal anti-kickback statute (AKS), the gainsharing civil monetary penalty law (Gainsharing CMP), and the beneficiary inducements civil monetary penalty (CMP) - prohibit healthcare providers, absent satisfaction of statutory exceptions, from entering into financial arrangements with each other and discourage the use of certain financial incentives in the delivery of health care. As a result, the ACA authorized the Secretary of the CMS to issue rules waiving the imposition of the fraud and abuse laws for MSSP participants. [4]

Last April, the CMS and the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) jointly issued a proposed rule for waivers, and received

[1] The "Shared Savings Program final rule," 76 Federal Register ("Fed. Reg.") 67992, published November 2, 2011.

[2] Patient Protection and Affordable Care Act, §3022; codified as 42 U.S.C. §1395jjj.

[3] Medicare Shared Savings Program Application, posted November 10, 2011.

[4] Patient Protection and Affordable Care Act, §1899(f); 42 U.S.C. §1395jjj(f).

significant comment. In response, the CMS and the OIG have issued a new "interim final rule with comment period" (IFC). The IFC sets forth substantive waivers from the fraud and abuse laws applicable to ACOs formed in connection with the MSSP.

The derivation and purpose of these waivers is highlighted within the CMS's analysis of the comments received in response to last April's proposed waiver rule. Based upon these comments, a broad array of potential participants strongly confirmed that certain elements of the Stark Law exceptions and AKS safe harbors could not sufficiently support the development of innovative ACO structures. In particular, commentators identified requirements of the exceptions and safe harbors, such as the "fair market value" or "set in advance" elements, as specific burdens to creating innovative ACO arrangements. In the distribution of savings, for instance, commentators stated that, in order to achieve the goals of the MSSP, they would employ financial incentives and reward participants and providers in the ACO with compensation arrangements that could not always satisfy the statutory exceptions and safe harbors. Many commentators thus supported a broad approach to waivers of the fraud and abuse laws. The CMS and the OIG have responded to this call. The waivers are broad and afford participants a greater degree of flexibility than in the proposed rule published in April. In the IFC, the CMS has recognized that waivers for arrangements necessary to allow for start-up, operating, and maintenance costs in the context of innovative arrangements are necessary in order to carry out the Shared Savings Program. [5] The establishment of the waivers is designed to provide participants with a "coordinated approach to the waivers of the fraud and abuse laws" and to ensure that these laws "do not unduly impede development" of ACOs. [6]

The waivers all apply uniformly to each ACO, ACO participant, and ACO provider or supplier participating in the Shared Savings Program. [7] The waivers are intended to be self-implementing, meaning that apart from the applicable waiver conditions (as discussed below) no special action is required by the parties to be covered by a waiver, and parties need not apply for an individualized waiver. [8] This guidance is good news for providers interested in participating in the Shared Savings Program, who can now focus on the ACO application issued late in November. Of course, the waivers come with conditions.

"REASONABLY RELATED TO THE PURPOSES OF THE SHARED SAVINGS PROGRAM"

A striking theme throughout the IFC is perhaps an obvious one - that ACOs be developed in a manner "reasonably related to the purposes of" the Shared Savings Program. The IFC, in fact, establishes this as a specific condition in order for the waivers to apply. This condition mandates that an ACO demonstrate through both its governance documentation and its actions, that it will "promote accountability for the quality, costs, and overall care for the Medicare population" as described in the ACO rules. This means that in order to avail themselves of the waivers, ACOs must demonstrate how they will (i) manage and coordinate care for Medicare fee-for-service beneficiaries through the ACO, (ii) encourage investment in infrastructure, and (iii) redesign care processes for high-quality and efficient service delivery for patients. [9] Additional purposes to satisfy the "reasonably related" threshold include promoting evidence-based medicine and meeting requirements for reporting on quality and cost measures, among others.

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[5] 76 Fed. Reg. 67993

[6] Ibid.

[7] 76 Fed. Reg. 67999

[8] Ibid.

[9] 76 Fed. Reg. 68002

THE IFC'S WAIVERS

The IFC establishes five waivers. The CMS has announced that the "multiplicity of waivers is intended to provide flexibility to ACOs in varying circumstances and to be responsive to public comments outlining a wide variety of arrangements ACOs of various types might need to undertake in order to be successful in carrying out the Shared Savings Program."

The five waivers include:

ACO Pre-participation Waiver

The applications of the Stark Law, AKS, and Gainsharing CMP are waived with respect to start-up arrangements that pre-date an ACO's participation agreement with the CMS subject to the following conditions.

1. Arrangements must be undertaken with the good faith and intent to develop an ACO and to submit an ACO application for that year. The arrangement at a minimum must include at least one ACO participant of a type eligible to form an ACO. It may not include drug and device manufacturers, distributors, durable medical equipment suppliers, or home health suppliers.
2. "Diligent steps" must be taken to develop an ACO that would be eligible for a participation agreement to be effective during the target year. The parties must take diligent steps concerning the ACO's governance, leadership, and management.
3. The governing body of the ACO must make and authorize a bona fide determination that the arrangement is reasonably related to the purposes of the shared savings program.
4. Documentation of the diligent steps to develop the ACO must be created contemporaneously with the establishment of the arrangement. The documentation must identify the following: (a) a description of the arrangement and parties; (b) the date and manner of the governing body's authorization of the arrangements; and (c) the steps taken to develop the ACO, and the timing of actions undertaken.
5. Public disclosure must be provided pursuant to guidance issued by the CMS.
6. A statement by the ACO if the ACO does not submit an application for participation as to why it has been unable to submit the application

By way of example, the CMS and the OIG consider the provision of the following particular items, services, and goods to be start-up arrangements:

1. Infrastructure creation and provision;
2. Network development and management;
3. Care coordination mechanisms;

"The CMS has announced that the 'multiplicity of waivers is intended to provide flexibility to ACOs in varying circumstances and to be responsive to public comments outlining a wide variety of arrangements ACOs of various types might need to undertake in order to be successful in carrying out the Shared Savings Program.'"

4. Clinical management systems;
5. Quality improvement mechanisms (including a mechanism to improve patient experience of care);
6. Creation of governance and management structure;
7. Care utilization management (chronic disease management, care protocols, and patient education);
8. Creation of incentives for performance-based payment systems and the transition from fee-for-service payment system to one of shared risk of losses;
9. Hiring of staff;
10. Information technology;
11. Consultant and other professional support;
12. Organization and staff training costs;
13. Incentives to track primary care physicians; and
14. Capital investments, including loans, capital contributions, and grants. [10]

ACO Participation Waiver

This waiver provides protection from the Stark Law, Gainsharing CMP, and AKS with respect to any arrangement of an ACO, or its participants or providers, subject to certain conditions:

1. The ACO has entered into a participation agreement with the CMS and remains in good standing.
2. The ACO has complied with the Shared Savings Program's requirements concerning governance, leadership, and management. [11]
3. The ACO's governing body has made a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.
4. The ACO has documented the arrangement and its authorization. Documentation must identify: (a) a description of the arrangement, and (b) the date and manner of the arrangement and the basis for the determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.
5. Public disclosure of the arrangement is done in a manner established through guidance by the CMS. The public disclosure does not require financial or economic terms of the arrangement.
6. This waiver commences on the start date of the participation agreement and ends six (6) months following the earlier of the expiration of the participation agreement or the date on which the ACO has voluntarily terminated the participation agreement. [12]

Shared Savings Distribution Waiver

This waiver provides protection from the Stark Law, Gainsharing CMP, and AKS with respect to distributions or use of shared savings earned by an ACO, subject to certain conditions:

1. The ACO has entered into a participation agreement and remains in good standing with the CMS.
2. The shared savings are earned by the ACO pursuant to the Shared Savings Program.
3. The shared savings are earned by the ACO during the term of the participation agreement, even if the actual distribution of the shared savings occurs after the expiration of that agreement.
4. The shared savings are: (a) distributed to or among the ACO participants, its ACO providers or suppliers, or individuals and entities that were participants or providers or suppliers

[10] 76 Fed. Reg. 68003

[11] See 42 CFR 425.106 and 425.108

[12] 76 Fed. Reg. 68001

during the year in which the shared savings were earned; or (b) used for activities that are reasonably related to the purpose of the Shared Savings Program.

5. Any waiver of the Gainsharing CMP relating to payments of shared savings distributions made from a hospital to a physician must not have been made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.

The CMS and OIG's intent behind this waiver is to protect arrangements created by the distribution of shared savings within an ACO that qualifies for the waiver, as well as arrangements created through the use of shared savings to pay outside parties, as long as payments are reasonably related to the MSSP.

Physician Self-Referral Law Waiver

This waiver provides protection from the Gainsharing CMP and AKS with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers or suppliers that implicates the Stark Law, provided all of the following conditions are met.

1. The ACO is entered into a participation agreement and remains in good standing with the CMS.
2. The financial relationship is reasonably related to the purposes of the Shared Savings Program.
3. The financial relationship fully complies with a Stark Law exception.

The CMS and OIG have noted that ordinarily, Stark Law compliance does not operate to immunize conduct under the AKS, and mere Stark Law adherence does not prevent scrutiny under the AKS as well. With this waiver, however, the CMS and OIG expressly "are deviating from" these general rules, in part to "minimize burdens on entities establishing or operating ACOs under the Shared Savings Program." [13]

Waiver for Patient Incentives

This waiver provides protection from the beneficiary inducement CMP and the AKS with respect to items or services provided by an ACO, its ACO participants, or its ACO providers or suppliers to beneficiaries for free or below fair market value, subject to four conditions:

"The CMS and OIG's intent behind this waiver is to protect arrangements created by the distribution of shared savings within an ACO that qualifies for the waiver, as well as arrangements created through the use of shared savings to pay outside parties, as long as payments are reasonably related to the MSSP."

[13] 76 Fed. Reg. 68006

1. The ACO is entered into a participation agreement and remains in good standing under its participation agreement.
2. A reasonable connection exists between the items or services and the medical care of the beneficiary.
3. The items or services are "in kind."
4. The items or services are preventive care items or services or advance one of the clinical goals including adherence to a treatment regime, drug regime, and a follow-up care plan, or management of a chronic disease or condition.

Thus, ACO participants and ACO providers/suppliers may provide beneficiaries with "free or below fair market value items and services that advance the goals of preventive care, follow up care regimes, or management of chronic conditions." [14]

RELIANCE ON THE "INTERIM FINAL RULE WITH COMMENT PERIOD"

The CMS and OIG found it contrary to the public interest to delay the issuance of the waivers any further. As a result, the "interim final rule with comment period" can be relied upon for guidance in obtaining the waivers from the fraud and abuse laws for participants in the Shared Savings Program. The CMS is desirous of having ACOs formed as soon as possible under the new rules governing them, and has stated that delaying the issuance of final waivers would effectively delay the MSSP's establishment beyond its statutory deadline and, moreover, "delay the savings that the program is expected to achieve at a time when reducing the Federal budget is a crucial priority." [15] The CMS and OIG have adopted the IFC although further public comment will be accepted until the end of December. Thus, potential participants in the MSSP can rely on these definitive waivers.

WILL THE IFC RESULT IN INCREASED PARTICIPATION IN THE MSSP?

The waivers set forth in the IFC may not be the proverbial "magic bullet" that encourages entities eligible for the Shared Savings Program to commit to ACO development. Yet, having a framework in place that removes, or at least ameliorates, the uncertainty concerning the application of the fraud and abuse laws will be helpful in structuring arrangements between participants in ACOs that wish to test the waters of the Shared Savings Program. At a minimum, these waivers free potential players to focus on the actual business terms and degree of clinical integration between them in considering whether to apply to the MSSP.

[14] 76 Fed. Reg. 68007

[15] 76 Fed. Reg. 68008

If you have any additional questions regarding this Update or have any other Health Care Law needs, please contact any member of the Health Care Law Group.

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