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Delicate Balance: Waiver of Fraud and Abuse Laws and Implementation of Program Integrity Requirements for the Medicare Shared Savings Program



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Given the attention paid to the Medicare Shared Savings Program (MSSP) since the passage of the Patient Protection and Affordable Care Act (PPACA), virtually everyone in the health care industry is aware that groups of health care providers and suppliers may form an accountable care organization (ACO) to coordinate care furnished to Medicare fee-for-service beneficiaries and then receive additional Medicare payments for shared savings if certain performance standards are met.

The MSSP is a cornerstone of the part of the PPACA that seeks to reform the health care system through the implementation of more cost-effective approaches to providing high-quality health care.

To facilitate the development of ACOs, the Centers for Medicare & Medicaid Services and the Department of Health and Human Services Office of Inspector General recently issued an interim final rule (the "Waiver Rule")¹ detailing the circumstances in which the agencies will waive certain health care fraud and abuse laws in connection with the MSSP.

Although broader and more flexible than the waivers proposed earlier this year, the five waivers detailed in

the Waiver Rule do not come without a price; ACOs, ACO participants, and ACO providers/suppliers still must comply with strict program integrity requirements implemented by CMS as part of the final rule that will govern participation in the MSSP (the "Final Rule").²

I. The Waiver Rule

A. Statutory Authority

Because the shared savings and other aspects of such arrangements technically would implicate many laws meant to address overutilization, underutilization, waste, and health care decision-making skewed by financial incentives, Congress authorized the waiver of various fraud and abuse laws, including:

- the federal Anti-Kickback Statute³ (the "AKS"),
- the Stark law,⁴ and
- the provisions of the Civil Monetary Penalties law⁵ (the "CMP Law") prohibiting payments to physicians to reduce or limit services⁶ (the "Gainsharing CMP") and beneficiary inducement (the "Beneficiary Inducements CMP").⁷

¹ Medicare Program; Final Waivers in Connection With the MSSP, 76 Fed. Reg. 67992 (Nov. 2, 2011).

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² Medicare Program; Medicare MSSP: Accountable Care Organizations, 76 Fed. Reg. 67802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

³ 42 U.S.C. § 1320a-7b(b).

⁴ 42 U.S.C. § 1395nn.

⁵ 42 U.S.C. § 1320a-7a.

⁶ 42 U.S.C. § 1320a-7a(b) prohibits a hospital or a critical access hospital from knowingly making a direct or indirect payment to a physician as an inducement to reduce or limit services.

⁷ 42 U.S.C. § 1320a-7a(a)(5) prohibits the offer or transfer of remuneration to any individual eligible for benefits under a

B. Application

The Waiver Rule applies only in the context of the MSSP, including the Advance Payment Initiative to be administered by the Center for Medicare & Medicaid Innovation.⁸ Further, the waivers cover only the enumerated fraud and abuse provisions and do not extend to any other provisions of state or federal law, such as the Internal Revenue Code.

Although the Waiver Rule defines five waivers, parties need only comply with one of the waivers if more than one could apply. Further, if an arrangement does not fit within any waiver, it is not necessarily illegal. For example, an existing safe harbor under the AKS or an exception under the Stark law may apply, or the arrangement may not otherwise violate the law.

Parties need not seek approval that the arrangement satisfies the conditions of a waiver. In fact, CMS and OIG expressly declined to establish a process for approval of waiver requests and instead have left it to ACOs, ACO participants, and ACO providers and suppliers to conduct a reasonable evaluation of compliance with the conditions of an applicable waiver or with existing legal requirements, such as an AKS safe harbor or a Stark law exception.⁹

C. Overview

The Waiver Rule goes far beyond the original proposal published April 7 (the “Notice”),¹⁰ by creating three new waivers and by modifying the two previously announced waivers.

The following two waivers appeared in the Notice:

- **Shared Savings Distribution Waiver:** waiver of the Stark law, the AKS, and the Gainsharing CMP applicable to distributions and uses of payments earned under the MSSP.
- **Compliance with the Physician Self-Referral Law Waiver:** waiver of the Gainsharing CMP and the AKS for ACO arrangements that implicate the Stark law but meet an existing exception.

In response to the many comments noting that the proposed waivers were too narrow and lacked the flexibility needed to encourage the development of ACOs, CMS and OIG included the following three additional waivers in the Waiver Rule:

- **ACO Pre-Participation Waiver:** waiver of the Stark law, the AKS, and the Gainsharing CMP applicable to ACO-related start-up arrangements (with some limitations) in anticipation of participating in the MSSP.
- **ACO Participation Waiver:** waiver of the Stark law, the AKS, and the Gainsharing CMP that applies broadly to ACO-related arrangements during the term of the ACO’s participation agreement.

state or federal health care program if such person knows or should know it is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made by a state or federal health care program.

⁸ 76 Fed. Reg. at 67993.

⁹ See 76 Fed. Reg. at 68002.

¹⁰ Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19655 (Apr. 7, 2011).

- **Patient Incentive Waiver:** waiver of the Beneficiary Inducement CMP and the AKS for certain incentives offered to beneficiaries by ACOs to encourage preventive care and compliance with treatment regimes.

D. The Three New Waivers

Taken together, the waivers cover all phases of the ACO’s development and operations. Although the three newly proposed waivers are broad enough to cover most, if not all, necessary activities, CMS and OIG nevertheless retained the two previously proposed waivers, likely to avoid the appearance of limiting the breadth of the waivers. This Insights article focuses on the newly defined waivers because they likely will come into play more often than those proposed in the Notice.

1. The ACO Pre-Participation Waiver

This waiver of the AKS, the Stark law, and the Gainsharing CMP protects start-up arrangements that precede the ACO’s participation agreement, provided that certain conditions are met.¹¹ The Waiver Rule includes a long list of the types of activities that would reasonably qualify as start-up arrangements, which indicates that CMS and OIG apparently understand the breadth of activities that the parties will need to undertake to get an ACO up and running.

To qualify for protection under the pre-participation waiver, the parties must include the ACO and at least one ACO participant of the type eligible to form an ACO,¹² which means that, by its terms, the waiver apparently would not protect pre-participation activities and expenses incurred before the ACO itself is formed.

The parties must have a “good faith” intent to develop an ACO; they must be taking “diligent steps” toward developing an ACO that would be eligible for participation in the MSSP; and they must make a bona fide determination that the arrangement is “reasonably related to the purposes of the [MSSP].”¹³ CMS and OIG provided an expansive list of activities that are “reasonably related to the purposes of the [MSSP],” including:

- promoting evidence-based medicine and patient engagement;
- meeting requirements for reporting on quality and cost measures;
- coordinating care through the use of telehealth, remote patient monitoring, and other enabling technologies;
- establishing clinical and administrative systems for the ACO;
- meeting the clinical integration requirements of the MSSP;
- meeting the quality performance standards for the MSSP;
- evaluating health needs of the ACO’s assigned population;
- communicating clinical knowledge and evidence based medicine to beneficiaries; and

¹¹ 76 Fed. Reg. at 68002-68003.

¹² 76 Fed. Reg. at 68000.

¹³ 76 Fed. Reg. at 68000.

- developing standards for beneficiary access and communication, including beneficiary access to medical records.

This approach differs significantly from the Notice, where CMS and OIG proposed to protect only those arrangements that would be “*necessary* for and *directly* related to ACO” purposes.¹⁴ In response to widespread criticism of this restrictive term, CMS and OIG decided to adopt a broader, more flexible standard as part of the Waiver Rule.

The parties also must comply with specific procedural requirements to qualify for protection under the pre-participation waiver.

If the ACO ultimately does not submit an application, it must instead provide a statement of the reasons why it could not do so. The parties must contemporaneously document compliance with the criteria discussed above, but they are *not* required to enter into a written agreement (which is a condition of compliance with many Stark law exceptions and AKS safe harbors).

The ACO must maintain this documentation for 10 years after submitting the application or after notifying CMS of the reasons why it could not put forward an application.

As an added safeguard, the waiver requires public disclosure of the arrangement, but exempts the economic terms from disclosure.¹⁵

This expansive waiver is meant to respond to the many commenters who expressed concern that the originally proposed waivers would not protect ACO start-up costs. Although well intentioned, this waiver still could present future compliance challenges because key terms such as “good faith intent,” “diligent steps,” and “bona fide determination” are left undefined.

Further, CMS and OIG have yet to spell out the details of certain elements, such as the terms of public disclosure.

2. The ACO Participation Waiver

The ACO participation waiver, which also applies to the Stark law, the AKS, and the Gainsharing CMP, protects most, if not all, aspects of the ACO’s ongoing operations, as long as the waiver criteria are met.

The waiver period runs from the start date of the ACO’s participation agreement until the earlier of six months after expiration or the ACO’s voluntary termination of its participation agreement. If CMS terminates the participation agreement, the waiver period ends on the date of the termination notice.

To comply with the participation waiver, the ACO must have a participation agreement in place; must meet CMS’s governance, leadership, and management requirements; and must be in good standing. In addition, similar to the pre-participation waiver, this waiver requires:

- a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP;
- documentation of the arrangement and its authorization by the ACO’s governing body; and

¹⁴ 76 Fed. Reg. at 19658 (emphasis added).

¹⁵ 76 Fed. Reg. at 68000.

- public disclosure of the arrangement (with the exception of its financial terms).¹⁶

3. The Patient Incentive Waiver

To facilitate the engagement of patients in management of their own care, CMS and OIG established a waiver of the AKS and the Beneficiary Inducement CMP to allow an ACO, ACO participants, and ACO providers/suppliers to provide items or services to beneficiaries for free or below fair market value in certain circumstances.

As with the participation waiver, the ACO must have a participation agreement and must be in good standing. In addition, the items or services provided must meet specific standards.

First, they must have a “reasonable connection” to the medical care provided to the beneficiary.

Second, the items or services must be in-kind, which means that they cannot be cash or a cash equivalent, such as a gift certificate or waiver of coinsurance or a deductible.

Finally, the items or services must advance adherence to a treatment or drug regime or a follow-up care plan or management of a chronic condition.¹⁷

As noted by the Waiver Rule, some items and services that do not fall within the patient incentive waiver may nevertheless meet the preventive care exception to the Beneficiary Inducement CMP.

CMS codified this particular waiver as part of the regulations outlining beneficiary protections. The regulation prohibits providing anything of value to a beneficiary as an inducement for: (1) receiving items or services from or remaining in an ACO or with ACO providers/suppliers in a particular ACO, or (2) receiving items or services from ACO participants or ACO providers/suppliers¹⁸ but does allow in-kind items or services to be given to beneficiaries under the conditions set forth in the Final Rule, which are identical to those of the patient incentive waiver.¹⁹

E. Medically Necessary Services

As part of the Waiver Rule, CMS and OIG made clear that ACOs may qualify for protection under the waivers even if providing incentives for “the provision of *alternate and appropriate* medically necessary care consistent with the purposes of the [MSSP] (such as the provision of coordinated outpatient care rather than inpatient services or the use of evidence-based protocols for medically necessary care).”²⁰

CMS provided this clarification in response to several commenters who noted that the Gainsharing CMP, which prohibits limitations on medically necessary services, could present an obstacle because ACOs may need to make reasonable choices among alternative treatment options.

F. Lack of Codification

Without providing any meaningful explanation, CMS and OIG declined to codify the waivers in the Code of Federal Regulations, but they are seeking comments on this approach.

¹⁶ 76 Fed. Reg. at 68000-68001.

¹⁷ 76 Fed. Reg. at 68007.

¹⁸ 76 Fed. Reg. at 68007.

¹⁹ 76 Fed. Reg. at 67958; *see also* 76 Fed. Reg. at 67981.

²⁰ 76 Fed. Reg. at 68006 (emphasis in original).

Given that a validly promulgated regulation would have the force and effect of law (which is not the case with agency guidance), this decision is troubling because it fails to provide full legal protection to ACOs who are structuring a vast array of novel relationships to coordinate care and investing substantial sums of money in reliance upon the waivers.

II. Fraud and Abuse and Program Integrity Provisions in the Final Rule

Although CMS and OIG relaxed various fraud and abuse restrictions to encourage the development of ACOs, the agencies will maintain the ability to protect the integrity of the MSSP through a number of provisions included in the Final Rule.

A. Screening of ACOs

CMS finalized the proposed screening requirements, which distinguish between entities that are and are not eligible to enroll in Medicare, without making any changes. Medicare-eligible ACOs and ACO participants will be subject to Medicare's usual enrollment screening process.²¹

Due to statutory constraints, however, CMS cannot apply these same requirements to ACOs that do not qualify for Medicare eligibility, such as those that consist of a group of providers and suppliers that are not already integrated and join together to form an ACO through a new legal entity.

In addition, CMS will consider the program integrity experience of all ACOs, ACO participants, and ACO providers and suppliers when reviewing applications.²² CMS declined to establish a bright-line test for rejecting applications based on adverse findings, but stated that it would consider factors such as the nature of the issues (including the program integrity history of affiliated individuals and entities), available evidence, and the entity's diligence in identifying and correcting the problem.²³

While CMS intends to protect the MSSP from fraud and abuse, it recognizes that "some program integrity allegations may not have been fully adjudicated,"²⁴ which presumably means that a pending government investigation or court case premised on alleged violations of fraud and abuse laws will not automatically lead to rejection of an ACO's application.

B. Implementation of a Compliance Plan and a Conflict of Interest Policy

CMS made few changes to the proposed compliance plan requirements in the Final Rule. Each ACO must have a compliance plan²⁵ in place that includes at least the following elements:

- a designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body;
- mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;

- a method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer;
- compliance training for the ACO, ACO participants, and ACO providers/suppliers; and
- a requirement for the ACO to report "probable violations of law" to an appropriate law enforcement agency.

CMS expects ACOs to draw upon their current compliance programs and noted that they may want to coordinate compliance activities with those of its providers and suppliers.

ACOs that already have a compliance program in place should have the ability to build upon current compliance activities because the required elements are similar (but not identical) to those previously endorsed by the OIG in its compliance program guidance documents.

As long as the requirements are met, the compliance program's design and structure can vary, depending upon the ACO's size and business structure.²⁶

An existing organization can appoint its current compliance officer to serve as the ACO's compliance officer, but CMS has made clear that the compliance officer cannot also serve as the ACO's legal counsel.²⁷

In response to comments received, CMS clarified that the compliance officer can, however, be an attorney as long as he or she is not serving as the ACO's legal counsel. CMS believes that this segregation of duties will ensure that the compliance officer conducts "independent and objective legal reviews and financial analyses of the organization's compliance efforts and activities."²⁸

Even though CMS bifurcated the roles of compliance officer and legal counsel, it did not address whether the ACO's compliance officer can have a dual reporting relationship with the ACO's governing body and with senior management, such as the general counsel. The OIG has previously questioned a reporting structure where the compliance officer is subordinate to the general counsel, but did not mention the issue in the Final Rule.

ACOs also should note that the compliance plan must compel reporting of "probable violations of law" even though a few commenters recommended that this requirement be removed because it "deviates from accepted compliance practices."²⁹ The OIG's compliance program guidance documents do not mandate self-disclosure and instead typically require that a process be in place for reporting detected offenses to relevant authorities in appropriate circumstances. The reporting obligation imposed by the Final Rule appears to require self-disclosure without specifying a mechanism for doing so or providing any guidance on what constitutes a "probable violation of the law."

While Medicare and Medicaid providers and suppliers have a legal obligation to report and return overpayments, the suggestion that an ACO must report all violations of law is troubling and could even raise constitu-

²¹ 76 Fed. Reg. at 67954.

²² 76 Fed. Reg. at 67955; *see also* 76 Fed. Reg. at 67981.

²³ 76 Fed. Reg. at 67955.

²⁴ 76 Fed. Reg. at 67955.

²⁵ 76 Fed. Reg. at 67980.

²⁶ 76 Fed. Reg. at 67952.

²⁷ *Id.*

²⁸ 76 Fed. Reg. at 67952.

²⁹ 76 Fed. Reg. at 67953.

tional self-incrimination issues in the case of a probable violation of a criminal law, such as the AKS.

Although CMS changed its terminology to require reporting of “probable” rather than “suspected” violations in response to comments, this revision did not address all potential implications of the reporting requirement.

CMS’s separation of the legal and compliance functions and disclosure requirement could foreshadow upcoming guidance on the required core elements for compliance programs implemented by Medicare, Medicaid, and Children’s Health Insurance Program (“CHIP”) providers and suppliers in accordance with the PPACA.

All providers and suppliers thus should take note of these requirements even if not part of an ACO.

The Final Rule also requires the ACO’s governing body to implement a conflict of interest policy requiring governing body members to disclose relevant financial interests and describing the process for doing so.³⁰

CMS declined to provide specific guidance on the contents of such policies, which may differ based on the governing body’s composition, but recommended consistency with state and federal law and with “relevant best practices in the industry and general principles of good corporate governance.”³¹

CMS also directed organizations unfamiliar with such policies to the sample policy made available to tax exempt organizations by the Internal Revenue Service.

C. Prohibition on Certain Required Referrals and Cost-Shifting

CMS finalized its proposal to prohibit the ACO from conditioning participation on referrals of federal health care program business to the ACO, its ACO participants, or its ACO providers/suppliers for services they know or should know are being provided to beneficiaries who are not assigned to the ACO.³² The purpose of this requirement, according to CMS, is to prevent inappropriate cost-shifting that could result if an ACO, ACO participants, and ACO providers/suppliers offer, or are offered, inducements to over utilize services or to otherwise increase federal health care program costs for unassigned beneficiaries.³³

In addition, CMS modified the Final Rule to include a prohibition on limiting or restricting referrals of patients to ACO participants or ACO providers/suppliers within the same ACO. An underlying purpose of this prohibition is to ensure patient choice.

Although this prohibition does not apply to employees or contractors acting within the scope of their employment or contractual arrangement to make referrals to the employer or contracting entity, the referring party must have the freedom to honor the patient’s choice if he or she expresses a preference for a different provider, practitioner, or supplier; if the patient’s insurer determines the provider, practitioner, or supplier; or if the referral is not in the patient’s best medical interests, in the judgment of the referring party.³⁴

To illustrate how this provision would apply in practice, CMS observed that, for example, a hospital may re-

quire its employees and contractors to refer to the hospital’s laboratory or imaging center, as long as the employee or contractor is free to honor patient choice, insurer requirements, and the patient’s best medical interests.³⁵

Though CMS expects the ACO, ACO participants, and ACO providers/suppliers to discuss the need for services with the beneficiary using shared decision-making, the ACO should not establish roadblocks to prevent beneficiaries from using the providers or suppliers of their choice.³⁶

Left unsaid is how ACOs that opt to share risk under Track 2³⁷ will address their legitimate need to keep referrals within a defined network of providers and suppliers in order to control costs. Although such restrictions are common in the risk-contracting world, CMS apparently chose not to allow such practices in connection with the MSSP.

D. Monitoring/Terminating ACOs

To ensure compliance with the MSSP requirements and to guard against fraud, waste, and abuse, CMS will rely upon many of the monitoring techniques already used to monitor Medicare Advantage and Medicare prescription drug programs, such as analysis of financial and quality data and aggregated annual and quarterly reports; site visits; investigation of beneficiary and provider complaints; and audits.³⁸

Monitoring activities will focus on, among other things, determining whether ACOs are avoiding acceptance of at-risk beneficiaries, adhering to quality performance standards, ensuring beneficiary freedom of choice, or inappropriately shifting costs.³⁹

CMS has broad authority to impose appropriate sanctions on non-compliant ACOs, up to and including termination from the MSSP.

For example, CMS can terminate an ACO if it determines that the ACO took steps to avoid at-risk beneficiaries to reduce the likelihood of increasing costs to the ACO.⁴⁰

CMS may terminate an ACO for other reasons as well, including: (1) non-compliance with eligibility and other program requirements; (2) the imposition of sanctions or other actions taken against the ACO by an accrediting organization or a government agency that results in the ACO’s inability to comply with program requirements; or (3) violations of the Stark law, the CMP Law, the AKS, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.⁴¹

CMS has the authority to impose immediate termination if it identifies a “serious” violation. Short of termi-

³⁵ *Id.*

³⁶ *Id.*

³⁷ ACOs participating in the Shared Savings Program have the option between two tracks: Track 1, and Track 2. Under Track 2, ACOs immediately take on performance-based risk in exchange for higher reward. While under Track 1, ACOs have more time before taking on risk because the ACO is not responsible for any portion of the losses above the expenditure target for the first two years of its agreement. 76 Fed. Reg. at 67904.

³⁸ 76 Fed. Reg. at 67949; *see also* 76 Fed. Reg. at 67982.

³⁹ 76 Fed. Reg. at 67949.

⁴⁰ Section 1899(d)(3) of the Act (codified at 42 U.S.C. 1395jj(d)(3)); 76 Fed. Reg. at 67958.

⁴¹ 76 Fed. Reg. at 67980.

³⁰ 76 Fed. Reg. at 67976.

³¹ 76 Fed. Reg. at 67954.

³² 76 Fed. Reg. at 67981.

³³ 76 Fed. Reg. at 67956.

³⁴ 76 Fed. Reg. at 67957.

nation, CMS may provide a warning notice to the ACO regarding noncompliance; request a corrective action plan; or place the ACO on a special monitoring plan.⁴²

E. Individual Certifications

CMS will require duly authorized executives to provide a variety of certifications that could have implications under various fraud and abuse laws and, in extreme circumstances, could even lead to personal liability. In addition to the annual certification of compliance required at the end of each performance year, examples of other certifications include the following:

- when the ACO submits its application, a duly authorized executive of the ACO must certify that the ACO, its ACO participants, and its ACO providers and suppliers will take responsibility for the quality, cost, and overall care of beneficiaries assigned to the ACO;
- when an ACO requests shared savings payments, a certification of compliance with program requirements and of the accuracy, completeness, and truthfulness of any information submitted to CMS will be required; and
- when data is submitted, including data required for quality reporting purposes, a duly authorized representative of the relevant individual or entity must certify that all data is accurate, complete, and truthful to the best of his or her knowledge, information, and belief.⁴³

⁴² 76 Fed. Reg. at 67982-83.

⁴³ 76 Fed. Reg. at 67980.

CMS intends to publish the certification forms at a later time.⁴⁴ Although the certification language may include one or more of the qualifiers that appears in other Medicare-related certifications, CMS appears to be taking a hard line on the effect of the certifications.

For example, to highlight the potential fraud and abuse implications, CMS noted that the individual who gives the certification as well as other relevant individuals or entities could be subject to liability for making false statements, termination, or other sanctions if CMS learns that the authorized executive knew or should have known that the information submitted was inaccurate.⁴⁵ CMS also made clear that false certifications may trigger liability under the False Claims Act.⁴⁶

III. Conclusion

The MSSP is a cornerstone of health care reform, but the goals of the MSSP clash in many ways with the fraud and abuse laws as written.

Congress thus authorized waiver of the laws presenting an impediment to the MSSP's implementation, and CMS and OIG made a good-faith effort to address the issues raised by providers, suppliers, and other interested parties regarding the narrow scope of and lack of flexibility provided by the two waivers proposed earlier this year.

Only time will tell whether CMS and OIG have gone far enough to ensure the success of ACOs. Stakeholders who continue to have concerns about the Waiver Rule, which took effect Nov. 2, still have time to be heard since CMS and OIG will accept comments until Jan. 3, 2012.

⁴⁴ 76 Fed. Reg. at 67954.

⁴⁵ *Id.*

⁴⁶ 76 Fed. Reg. at 67959.