Accountable Care Organization Waivers: Addressing Fraud and Abuse Compliance Issues in the Shared Savings Program

Patrick D. Souter
Gray Reed & McGraw PC
Dallas, TX

The federal government has, for quite some time, attempted to address improvement of the delivery of health care through a number of initiatives focused not only on quality but also on value. With the passage of the Patient Protection and Affordable Care Act (ACA) (as amended by the Health Care Education Reconciliation Act of 2010),[1] the federal government took its most significant step to date by providing for the establishment of accountable care organizations (ACOs).[2] An ACO's purpose is to improve value through a more-coordinated effort among ACO participants.[3] This effort is accomplished by developing financial incentives tied to the quality and value of care provided, which leads to increased coordination of care among ACO participants. While the idea of increased value through coordinated care is not new to health care, the latest efforts to develop integrated delivery systems bearing financial responsibility have been redesigned to incorporate other projects sponsored by Medicare. This initiative is based on a directive for the Secretary of the U.S. Department of Health & Human Services (HHS) to establish a shared savings program for Medicare beneficiaries (Shared Savings Program), whereby the federal government and the ACO will share in any savings generated by the initiative if it meets certain benchmarks and indicators.[4]

An ACO participating in the Shared Savings Program has mandates for participation like other health care professionals and entities participating in a federal program. It must comply with requirements related to governance and management, as well as program integrity and transparency.[5] However, in light of federal fraud and abuse laws, the integrated efforts among the ACO and its participants may raise questions regarding the legality of certain underlying arrangements. To address these possible fraud and abuse issues, the Centers for Medicare & Medicaid Services (CMS) formally published an interim final rule on November 2, 2011 (Final Rule) that established five waivers (Waivers) related to those issues that may arise through participation in the Shared Savings Program.[6] This article sets forth a summary of the Waivers, and how to demonstrate compliance with them.

ACO Waivers

In developing the Waivers, CMS segments each with a different circumstance or legal requirement that Shared Savings Program participants may encounter. The Final Rule sets forth these waivers:[7]

- An "ACO pre-participation" waiver of the Physician Self-Referral Law (Stark Law),[8] Federal Anti-Kickback Statute (Anti-Kickback Statute),[9] and the Gainsharing Civil Monetary Penalty (Gainsharing CMP)[10] (collectively, Fraud and Abuse Laws) that applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program;
- An "ACO participation" waiver of the fraud and abuse laws that applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the Shared Savings Program and for a specified time thereafter;
- A "Shared Savings Distributions" waiver of the fraud and abuse laws that applies to distributions and uses of shared savings payments earned under the Shared Savings Program;
- A "Compliance with the Physician Self-Referral Law" waiver of the Gainsharing CMP and the Anti-Kickback Statute for ACO arrangements that implicate the Stark Law and meet an existing exception; and

- A "Patient Incentive" waiver of the Beneficiary Inducements Civil Monetary Penalty[11] and the Anti-Kickback Statute for medically related incentives offered by ACOs under the Shared Savings Program to Medicare beneficiaries to encourage preventive care and compliance with treatment regimes.

In reviewing the Waivers, one will note that instances arise where the Waivers extend into the purview of the safe harbors and exceptions of the Anti-Kickback Statute or Stark Laws. However, these Waivers do not extend to any other laws or regulations. This includes the Internal Revenue Code and state laws and regulations.[12] If an arrangement does not specifically fit within a particular Waiver, it does not necessarily violate the law. Rather, it should be evaluated on a case-by-case basis to determine compliance with the applicable law of concern.

Waiver Compliance

ACOs must have a compliance plan.[13] In fact, as part of the application process the ACO applicant must certify that it currently has a compliance plan that meets the mandated requirements that will be in place if the ACO is granted certification. However, CMS has provided little guidance up to this point on a compliance structure other than from a global standpoint.[14] As for more-structured ACO guidance, CMS has stated it will come forth with guidance in the future.[15] In addition, HHS Office of Inspector General (OIG) guidance could serve as a framework for how to develop such a compliance plan.[16] A number of the Waivers have similar requirements that allow for similar compliance standards. Other Waivers have specific requirements just for that specific individual Waiver. The general requirements for each Waiver are as follows:

Pre-Participation Waiver and Participation Waiver[17]

These two Waivers have the most onerous requirements for compliance purposes. The ACO's governing body must review the proposed arrangements related to the waiver to ensure that the arrangement meets the "triple-aim" purposes of the Shared Savings Program.[18] If an arrangement seeks protection under either of these Waivers, the ACO must post the arrangements on its public website. In addition, after the completion of the arrangement, the ACO must maintain the records related to the arrangement and waiver for a period of at least ten years.

For compliance purposes, the ACO should have policies and procedures related to the specific requirements of the two Waivers to ensure it meets these mandates. Those policies and procedures should include how the proposed arrangement is presented to the ACO's governing body, the recordation of the governing body's action, specifically as it relates to the basis on which the proposed arrangement falls within the triple-aim goals of the Shared Savings Program, and that a recorded vote of the governing body approved such an arrangement. As to public notification, the governing body approval should include a directive that the arrangement shall be posted on the ACO's website. Finally, the ACO's general records retention policy, approved by the governing body, should clearly note the record retention mandates. As listed below, these specific requirements as set forth for the Pre-Participation Waiver and the Participation Waiver are not required for the other three Waivers.

Shared Savings Distributions Waiver[19]

The Shared Savings Distributions Waiver does not require governing body approval, particular documentation, or publication but does contain specific requirements that a compliance program should address. The Waiver requires that, in the event of distributions to ACO participants and provider/suppliers, the distributions will occur during the year the ACO received the shared savings. If the distributions were made to non-ACO participants and provider/suppliers, they must use the distributions in such a way that relates to the purpose of the Shared Savings Program. To demonstrate compliance with this requirement, the circumstances behind such distributions should be examined and documented. In the event a hospital makes the distributions to a physician, the distributions cannot be for the purpose of knowingly inducing the physician to reduce or limit medically necessary items or services. For compliance purposes, the policies and procedures regarding distributions should follow those commonly followed for Anti-Kickback and Stark Law consideration. However, those policies and procedures also should include information on the Shared Savings distribu-

tions. Specifically, the policies and procedures should address the triple-aim goals of the Shared Savings Program, the methodology approved by the governing body and used by the ACO to determine distributions, and how such distributions advance those goals.

Stark Law Waiver[20]

The Stark Law Waiver is consistent with the typical compliance concerns that one would examine to ensure no Stark Law violation exists. Again, any financial relationship must be reasonably related to the purposes of the Shared Savings Program. An ACO's policies and procedures, as they relate to the Stark Law, should take into account and specifically incorporate the purpose of the Shared Savings Program and its operations.

Patient Incentives Waiver[21]

The Patient Incentives Waiver allows beneficiaries enrolled in the ACO to receive items or services free or below fair market value, provided that they are reasonably related to the beneficiaries' medical care, are in kind, and are used for preventative care or advance certain clinical goals. However, this Waiver does not allow gifts to beneficiaries to induce them to remain in the ACO or to utilize providers or suppliers in the ACO. For compliance purposes, it is imperative the ACO incorporate these limitations into its compliance policies regarding gifts and related remuneration for the ACO-specific categories.

As for the ACO participant, the lack of guidance for compliance purposes at the ACO level may cause one to consider incorporating or referencing these Waiver mandates into its own compliance plan. While not mandatory under the current compliance requirements, in some instances this may demonstrate good practices if concerns arise at the ACO compliance level.

An ACO also should recognize that these Waivers may be limited at some point in the future. CMS stated that it intends to monitor the ACOs entering the program in 2012 through June 2013.[22] Based on the information gathered during that time period, it may narrow the Waivers unless the information demonstrates that the Waivers "have not had the unintended effect of shielding abuse of arrangements."[23] An example of such abusive arrangements would be apparent patterns of utilization occurring because of the Waivers.[24] If CMS determines that this is occurring, it will modify the Waivers to address the specific problems noted from the oversight.[25] These modifications could take the form of adding or substituting conditions tailored to address specific abusive conduct; limiting ACO arrangements involving referral sources to those that are fair market value, commercially reasonable, or involve services performed by the referral source;[26] or CMS could preclude Waiver protection in arrangements that involve third parties not part of the ACO.[27]

While ACOs must have compliance plans, the requirements for the plans and how to address the Waivers have not evolved to the same level as the application and operational requirements. In structuring a compliance plan, the ACO and its participants should focus on the specific Waivers and the differing requirements, rather than just addressing them globally. Based on what has been established up to this point, it is incumbent upon the ACO's governing body to ensure the specific Waiver requirements are met. By incorporating the Waiver specifics into the general compliance plan, the governing body may rest assured that this will occur. However, because CMS indicated it will monitor the Waivers and their use, the governing board must be prepared to amend its compliance program if this occurs.

---

1 Pub. L. 111-148.
2 According to 42 C.F.R. § 5.10, an ACO means a legal entity is recognized and authorized under applicable state, federal, or Tribal law, is identified by a Taxpayer Identification Number (TIN), and is formed by one or more ACO participants.
3 According to 42 C.F.R. § 425.10, an ACO participant is individual or group of ACO providers/suppliers identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprises an ACO, and is included on the list of ACO participants submitted to in its application to participate in the program.
4 42 U.S.C. § 1395jjj.
5 76 Fed. Reg. at 67994.
6 76 Fed. Reg. 67992.
7 76 Fed. Reg. at 67993.
8 42 U.S.C. § 1395nn.
9 42 USC § 1320a-7b(b).
10 42 U.S.C. § 1320a-7a(b).
11 42 U.S.C. § 1320a-7a(a).
12 76 Fed. Reg. at 67994.
13 *Id.*
14 *See* 42 C.F.R. § 425.300. The compliance plan must include at least the following elements: a designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body; mechanisms to identify and address compliance problems; methods to anonymously report suspected problems to the ACO compliance officer; compliance training; and a requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.
15 76 Fed. Reg. at 67993.
16 OIG Compliance Guidance, *available at* http://oig.hhs.gov/compliance/compliance-guidance/index.asp.
17 76 Fed. Reg. at 68000.
18 76 Fed. Reg. at 67803. The "triple aim" of the Shared Saving Program is to provide better health for the population, provide better care for individuals, and reduction in growth of resources spent for such care.
19 76 Fed. Reg. at 68001.
20 *Id.*
21 *Id.*
22 76 Fed. Reg. at 68008.
23 *Id.*
24 *Id.*
25 *Id.*
26 *Id.*
27 *Id.*