An Update on the Medicare Shared Savings Program

Current Legal Issues for Accountable Care Organizations

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Accountable care organizations ("ACOs") have been marketed as perhaps the biggest development in Medicare reimbursement since the transition from cost reimbursement to prospective payment. The Centers for Medicare & Medicaid Services ("CMS") is hoping that ACOs and the Medicare Shared Savings Program ("MSSP") will successfully reel in health care spending while improving the quality of care to Medicare beneficiaries.

As of January 2013, approximately 250 ACOs provided care to over 4 million Medicare beneficiaries.[i] Of these, the 106 that were selected to participate in the MSSP roughly doubled the number of Medicare beneficiaries receiving care from an ACO.[ii] Although the number of ACOs has dramatically increased since the first performance period began on April 1, 2012 (when there were only 27 ACOs), the geographic distribution of ACOs remains largely uneven.

Fraud & Abuse Waivers

CMS published the final ACO regulations on November 2, 2011 ("ACO Final Rule"). At the same time, CMS and the United States Department of Health and Human Services Office of Inspector General ("HHS-OIG") published an Interim Final Rule with Comment Period ("Interim Final Rule" or "IFR")[iii] establishing five discrete waivers of the Stark Law, the anti-kickback statute, and certain provisions of the civil monetary penalty law ("CMP"), including the law prohibiting hospital payments to physicians to reduce or limit services ("Gainsharing CMP") and the law prohibiting inducements to beneficiaries ("Beneficiary Inducements CMP").

The IFR reflects a policy concession from enforcement that it will likely be necessary to waive certain otherwise enforceable program integrity rules in order to remove regulatory road blocks to the program objectives of the MSSP. As the IFR states: "These five waivers provide flexibility for ACOs and their constituent parts to pursue a wide array of activities, including start up and operating activities, that further the purposes of the Shared Savings Program."[iv]

The Five Waivers

The IFR provides five waivers addressing the formation and operations of an ACO.

- The Pre-Participation Waiver - The Pre-Participation Waiver protects pre-participation 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 anti-kickback statute, and the Gainsharing CMP.
- The Participation Waiver - The Participation Waiver is similar to the Pre-Participation Waiver, but covers arrangements occurring after the ACO has entered into a MSSP participation agreement ("Participation Agreement").
- The Shared Savings Distribution Waiver - The Shared Savings Distribution Waiver protects "distributions or use of" shared savings earned by an ACO during the term of its Participation Agreement.
- The Compliance with the Stark Law Waiver – The Gainsharing CMP and the anti-kickback statute are waived with respect to any financial relationship among the ACO, ACO participants, and its ACO providers/suppliers that would otherwise implicate the Stark Law, provided:
  - The ACO has entered into a Participation Agreement and remains in good standing under the MSSP;
  - The financial relationship is reasonably related to the purposes of the MSSP; and
  - The financial relationship fully complies within an exception to the Stark Law.

i. CMS Press Release for 2013 ACOs.
ii. Id.
iii. Although the IFR waivers were effective on November 2, 2011, CMS and HHS-OIG may revise the IFR in light of comments received.
iv. 76 Fed. Reg. at 67993.

- The Waiver for Patient Incentives - The Beneficiary Inducement CMP and the anti-kickback statute are waived with respect to items or services provided by an ACO, ACO participants, or ACO providers/suppliers to beneficiaries for free or below fair market value provided:
  - The ACO has entered into a Participation Agreement and remains in good standing under the MSSP;
  - There is a reasonable connection between the items or services and the medical care of the beneficiary;
  - The items or services are in kind (no cash or cash equivalents); and
  - The items and services (1) are preventive care items or services, or (2) advance one or more of the following goals: (i) adherence to a treatment regime; (ii) adherence to a drug regime; (iii) adherence to a follow-up plan of care; or (iv) management of a chronic disease or condition.

Questions and Answers Regarding Scope of the Waivers

Although the five waivers offer ACO stakeholders considerable protection from fraud and abuse liabilities, we have received a number of questions regarding the scope and application of the waivers to specific ACO activities and arrangements. The following examples are representative:

Q. How do the Pre-Participation Waiver and Participation Waiver protect an ACO as its participation status changes?

A. Arrangements covered by the Pre-Participation Waiver may also be covered by the Participation Waiver if the arrangements meet all of the Participation Waiver requirements when the ACO enters into a Participation Agreement.

Arrangements are covered by the Participation Waiver on the effective date of the Participation Agreement and ending 6 months after: (i) the expiration of the Participation Agreement, or (ii) the earlier termination of the Participation Agreement. If an ACO's MSSP application is denied, Pre-Participation Waiver protection continues for 6 months after the date of the denial notice. Collectively, the two waivers protect bona fide ACO start-up arrangements, without interruption, beginning before the ACO enters into a Participation Agreement, and continuing through the term of that agreement.

It is worth noting that, in some cases, an arrangement may satisfy the criteria of more than one waiver. In such cases, that arrangement need only fit within one of such applicable waivers to be protected.

Stated differently, an ACO seeking to ensure that an arrangement is covered by a waiver for a specific law may look to any of the waivers that apply to that law. Furthermore, the IFR treats the waivers as self-implementing (*i.e.*, they apply automatically if the applicable waiver conditions, if available, are satisfied).[v] Accordingly, some ACOs may not feel the need to request an Advisory Opinion on their proposed actions.

Q. How can an ACO ensure that its distribution of shared savings under the MSSP does not violate the anti-kickback statute or the Stark Law?

A. The Shared Savings Distribution Waiver permits ACOs to use any method to distribute shared savings, provided that the savings are either (i) distributed to those who are ACO participants, providers or suppliers (or at least were during the year the savings were earned), or (ii) used for activities reasonably related to purposes of the MSSP.

Lastly, a hospital distributing savings to a physician may not knowingly induce physicians to reduce or limit medically necessary care to patients. Notably, the Shared Savings Distribution Waiver does not require shared savings distributions to be made at fair market value or otherwise to be commercially reasonable; this reflects the IFR's intent to foster flexibility in ACO arrangements and to provide relief from the burden of Stark Law and fair market value considerations.

Q. May ACOs offer patients incentives to receive services from ACO providers and suppliers?

A. The Patient Incentives Waiver permits ACOs to give Medicare beneficiaries free or discounted items or services if (i) there is a reasonable connection between the items or services and the Medicare beneficiary's care; (ii) the items or services are given "in kind" (*i.e.*, no cash or other cash equivalents); and (iii) the items and services are either preventative or further a beneficiary's treatment or drug regiment, care plan, or chronic disease management.

Showing a flair for the obvious, the IFR provides the example that "blood pressure cuffs for hypertensive patients" are protected under the waiver, whereas, "beauty products or theater tickets" are not protected.[vi] The Patient Incentives Waiver, however, does not protect the waiver or reduction of co-payments or deductibles. Acknowledging CMS's decision to assign beneficiaries retrospectively, for purposes of the MSSP, HHS-OIG has chosen at this time not to limit the Patient Incentives Waiver to incentives given to an ACO's assigned beneficiaries.

v. *76 Fed. Reg. at 67999.*
vi. *76 Fed. Reg. at 68007.*

An ACO may use this waiver to advance the goals of preventive care, adherence to treatment, and management of a chronic condition for all beneficiaries under the care of its participants, providers, and suppliers, whether or not they are "assigned."

Q. Will ACO participation affect pre-existing physician employment agreements?

A. Yes, ACO participation by physicians will generally require amending physician employment agreements, *e.g.*, to add duties requiring physicians to achieve predetermined cost and quality measures. In addition, some physician employers may wish to tie a larger percentage of physician compensation to ACO related benchmarks.

Thoughts on Health IT Innovations and ACOs

The Health Information Technology ("HIT") objectives found in the ACO Final Rule are reasonably aligned with the CMS Incentive Program for Electronic Health Records ("EHR")[vii] – commonly known as "Meaningful Use" for EHR systems. However, ACO participants may also benefit from other HIT innovations, including: (1) the increasing availability of data for analytical purposes, and (2) available tools for interoperability across EHR systems.

More specifically, the ACO Final Rule provides for data sharing that allows an ACO, with some restrictions, to receive Medicare claims data regarding its assigned beneficiaries. While this data can be used for such analytics as cost base-lining and utilization review, ACO participants should also consider the other data sources that may provide a broader "look."

For example, just recently, CMS announced that it will release hospital charge data and two county-level data sets, including information on overall Medicare spending and utilization on those with chronic conditions.

This publicly available data may be used to enhance an ACO's own data set for benchmarking and competitive analysis. Further, a small but growing number of states also support all payer claims databases ("APCDs") that may serve as an additional, complementary data resource, especially for utilization and charge comparisons.

Regarding tools for interoperability, some ACOs may wish to consider the value that can be gained from participating in one or more health information exchanges ("HIEs"). For example, an ACO may have physician participants with multiple staff appointments (and, thus, disparate EHR systems).

In such situations, HIE participation may provide a "fast track" to interoperability by offering connectivity across those systems at a lower cost point than if standardizing on a single EHR platform. Such an approach also allows ACOs to include specialists and other providers who may have significant EHR investments that they wish to preserve.

The IFR fraud & abuse waivers and recent HIT innovations discussed above are just two of the many topical issues for current and potential ACOs. Other issues, such as beneficiary attribution, valuation of ACO equity interests, priority of distributions of shared savings and the need to monitor initial and ongoing compliance with developing interpretations of applicable antitrust restrictions, will be addressed in subsequent articles.

vii. 42 CFR part 495.