Friday, November 6, 2015

On October 29th, 2015, the Centers for Medicare and Medicaid Services (“CMS”) issued its final rule (“Final Rule”) for waivers of fraud and abuse laws in the context of the Medicare Shared Savings Program (“Shared Savings Program”). The Shared Savings Program utilizes accountable care organizations (“ACOs”) to encourage better care for individuals, better health for populations, and lower growth in health care expenditures. As discussed in the Final Rule, CMS continues to recognize that participation in the Shared Savings Program may require providers to integrate in ways that potentially implicate fraud and abuse laws. To alleviate these potential concerns, on November 2, 2011, CMS issued an interim final rule (“Interim Final Rule”) providing waivers for certain fraud and abuse laws. The differences between the Final Rule and the Interim Final Rule, are discussed below, along with a summary of the waivers as finalized by the Final Rule.

Final Rule Versus the Interim Final Rule

The Final Rule finalizes all five of the original waivers promulgated in the Interim Final, except for the changes discussed below.

(A comparison of the two iterations can be found here.)

1. Gainsharing CMP No Longer Waived due to MACRA

When the Interim Final Rule was originally published in 2011, hospitals were prohibited from knowingly making a payment, directly or indirectly, to induce a physician to reduce or limit any services. There was concern that the objectives of the Shared Savings Program — including the reduction of waste — could run afoul of the prohibition. As a result, the Interim Final Rule provided waivers for the reduction or limitation of medically unnecessary services in all five waivers. Subsequently, Section 512(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) revised the Gainsharing CMP so that it prohibits reductions or limitations of medically necessary services. This narrowing of the prohibition to only medically necessary services eliminated the reason for including the Gainsharing CMP within the waivers. Consequently, references to the Gainsharing CMP have been removed from the finalized waivers.

2. Clarification Regarding Documentation Requirements

CMS has made relatively minor revisions to the wording of the waivers protecting ACO-start up and an ACO’s ongoing activities once it enters into a participation agreement. These waivers, known as the ACO Pre-Participation Waiver and the ACO Participation Waiver, both require that the arrangement, and its authorization by the governing body, be documented. In describing the documentation requirements, the Final Rule now clarifies that this documentation must (as opposed to “should”) include the governing body’s basis for determining that the ACO arrangement is reasonably related to the purposes of the Shared Savings Program. While swapping “must” for “should” may appear to be a substantive revision, the commentary to the Interim Final Rule left little doubt that the documentation must include the governing body’s basis for their determination.
3. Clarification of “Home Health Supplier”

Under both the Interim Final Rule and the Final Rule, the Pre-Participation Waiver does not cover arrangements involving drug and device manufacturers, distributors, durable equipment (DME) suppliers, or home health suppliers. (CMS carved out DME suppliers and home health suppliers due to CMS’ belief that these types of entities have historically posed a heightened risk of program abuse.) In response to a commenter pointing out that the term “home health supplier” does not have a specific meaning in the Medicare program, the Final Rule clarifies that, for purposes of the Final Rule, the term “home health supplier” means a provider, supplier or other entity that is primarily engaged in furnishing “home health services” as that term is defined in Section 1861(m) of the Social Security Act.

What Is (and Isn’t) “Reasonably Related” to the Purposes of the Shared Savings Program

In addition to the changes described above, CMS uses the commentary of the Final Rule to discuss a phrase contained in a number of exceptions: “reasonably related to the purposes of the Shared Savings Program.” CMS uses this phrase to require a nexus between the activity protected under a waiver and the purposes of the Shared Savings Program. In the Final Rule, CMS continues to define “purposes of the Shared Savings Program” in accordance with the Program’s statutory purposes, which include (1) promoting accountability for the quality, cost, and overall care for a Medicare population; (2) managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and (3) encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients. As in the Interim Final Rule, CMS lists a number of examples of activities that are reasonably related to the purposes of the Shared Savings Program, including:

- promoting evidence-based medicine and patient engagement;
- meeting requirements for reporting on quality and cost measures;
- coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies;
- establishing clinical and administrative systems for the ACOs;
- meeting the clinical integration requirements of the Shared Savings Program;
- meeting the quality performance standards of the Shared Savings Program;
- evaluating health needs of the ACO’s assigned population;
- communicating clinical knowledge and evidence-based medicine to beneficiaries; and
- developing standards for beneficiary access and communication, including beneficiary access to medical records.

In the Interim Final Rule, CMS gave an example of an activity that would not be considered reasonably related to the purposes of the Shared Savings Program, namely, a per-referral payment (e.g., expressly paying a specialist $500 for every referral generated by the specialist or paying a nursing facility staff member $100 for every patient transported to the ACO’s hospital) as not being reasonably related to the purposes of the Shared Savings Program. In the Final Rule, CMS provides additional examples, including:

- An arrangement whereby a physician, a physician practice, or other provider is required to pay a sum to receive ACO-related referrals (e.g., “pay-to-play” arrangements);
- medical directorships or personal service arrangements where referring physicians or other providers receive payments for no actual services performed;
- payments to induce a physician or other provider to stint on medically necessary care for beneficiaries; or
- free gifts, such as sporting event tickets, to referring ACO providers/suppliers or ACO participants.

These arrangements, CMS states, are suspect and subject to ordinary case-by-case review under all applicable fraud and abuse laws.

Summary of the Waivers Finalized in the Final Rule

The Final Rule finalizes the following five waivers, each of which is summarized below.

1. ACO Pre-Participation Waiver
The ACO Pre-Participation Waiver waives the physician self-referral law ("Stark Law") and the Federal anti-kickback statute ("AKS"). It applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program. CMS has provided a list of activities that it believes are representative of the types of start-up arrangements that ACOs enter into, and that may qualify under the ACO Pre-Participation Waiver. These activities include, for example, infrastructure creation, network development, care coordination mechanisms, clinical management systems, hiring of new staff, information technology systems (including EHR systems), and a number of other activities. However, just because one engages in these activities does not mean they qualify for the waiver: like the Interim Final Rule, the Final Rule sets forth certain criteria that must be satisfied in order to take advantage of this waiver’s protection. Specifically, this waiver requires that:

(i) the arrangement must be undertaken with the good faith intent to develop an ACO that will participate in the Shared Savings Program;

(ii) the parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would be become effective during the target year;

(iii) the ACO’s governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the shared savings program;

(iv) the arrangement, its authorization, and the steps taken to develop the ACO are documented;

(v) the description of the arrangement is publicly disclosed, pursuant to the following guidance (such disclosure shall not include the financial or economic terms of the arrangement); and

(vi) if an ACO does not submit an application for a participation agreement by the last available application due date for the target year, the ACO must submit a statement describing the reasons it was unable to submit an application.

The duration of this waiver varies depending on the specific facts of the ACO. Generally, the waivers begin one year preceding their application due date and end either when the ACO enters into a participation agreement, when the ACO has their application denied, or for those ACOs failing to submit an application, on the earlier of the due date or when the ACO submits a statement of reasons for failing to submit an application.

2. ACO Participation Waiver

The ACO Participation Waiver waives the Stark Law and the AKS with respect to any arrangement of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof. To take advantage of this waiver, the following criteria must be satisfied:

(i) the ACO has entered into a participation agreement and remains in good standing;

(ii) the ACO satisfies certain governance, leadership and management requirements;

(iii) the ACO’s governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program;

(iv) the arrangement and its authorization are documented; and

(v) the description of the arrangement is publicly disclosed, pursuant to the following guidance (such disclosure shall not include the financial or economic terms of the arrangement).

Arrangements satisfying the above criteria are eligible for the waiver starting on the date of their participation agreement and ending 6 months after the earlier of the expiration of the participation agreement (including any renewals) or the date on which the ACO has voluntarily terminated the participation agreement. If CMS terminates the participation agreement, the waiver period will end on the date of the termination notice.

3. Shared Savings Distribution Waiver

The Shared Savings Distribution Waiver waives the Stark Law and the AKS with respect to distributions or use of shared savings earned by an ACO, provided that all of the following conditions are satisfied:

(i) the ACO has entered into a participation agreement and remains in good standing;

(ii) the shared savings are earned by the ACO pursuant to the Shared Savings Program;

(iii) the shared savings are earned by the ACO during the term of its participation agreement, even if the actual distributions or use of the shared savings occurs after the expiration of the agreement; and
(iv) the shared savings are distributed during the year in which the shared savings were earned by the ACO, or were used for activities that are reasonably related to the purposes of the Shared Savings Program.

4. **Compliance with the Stark Law Waiver**

The Compliance with the Physician Self-Referral Law Waiver waives the AKS with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the physician self-referral law, provided all of the following conditions are met:

(i) the ACO has entered into a participation agreement and remains in good standing;

(ii) the financial relationship is reasonably related to the purposes of the Shared Savings Program; and

(iii) the financial relationship satisfies one of the exceptions to Stark Law set forth in 42 CFR 411.355 through 357.

The waiver period for this waiver begins on the start date of the participation agreement and ends on the earlier of the expiration of the term of the participation agreement (including any renewals) or the date on which the participation agreement has been terminated.

5. **Patient Incentive Waiver**

The Patient Incentive Waiver waives the AKS as well as the Beneficiary Inducements CMP provisions with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair market value, provided that four criteria are satisfied:

(i) the ACO has entered into a participation agreement and remains in good standing;

(ii) there is a reasonable connection between the items or services and the medical care of the beneficiary;

(iii) the items or services are in-kind; and

(iv) the items or services relate to preventive care, the advancement of clinical goals or the management of a chronic disease or condition.

The waiver period for this waiver begins on the date of the participation agreement and ends on the earlier of the expiration of the term of the participation agreement (including any renewals) or the date on which the participation agreement has been terminated. Beneficiaries may keep items received before the participation agreement expired or was terminated, and can receive the remainder of any service initiated before the termination or expiration.