Medicare Shared Savings Program Fraud and Abuse Waivers: Common Questions and Concerns

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A Health Care Bulletin

On November 2, 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (together, the "Agencies") published an Interim Final Rule with Comment (IFC)1 creating five types of waivers from specified federal fraud and abuse laws2 for Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP). The Agencies' aim is to "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."3

Specifically, the five waivers4 are:

- The Pre-Participation Waiver protecting certain start-up activities in connection with ACOs;
- The Participation Waiver protecting ACO arrangements with participants, providers and suppliers5 during their participation in the MSSP;

- The Shared Savings Distribution Waiver protecting distributions from an ACO to its participants, providers and suppliers;
- The Compliance with the Stark Law Waiver protecting ACO arrangements that comply with the federal Stark Law; and
- The Patient Incentive Waiver protecting certain ACO incentives to Medicare beneficiaries.

Collectively, these five waivers offer substantial protection from fraud and abuse concerns to participants, providers, and suppliers forming ACOs to participate in the MSSP. Yet, questions remain regarding the scope and application of these waivers to particular activities, structures, and arrangements.

For example, because there is both a Pre-Participation Waiver and a Participation Waiver, some ACO stakeholders remain uncertain how these waivers may protect an ACO as its participation status changes. Generally, the Pre-Participation Waiver protects arrangements that predate the ACO's MSSP participation agreement, whereas the Participation Waiver applies once the ACO enters into an MSSP participation agreement. In other words, arrangements covered during the start-up phase by the Pre-Participation Waiver can be covered by the Participation Waiver when the ACO enters into its MSSP participation agreement if the arrangement meets all requirements of the Participation Waiver.6

Arrangements are covered by the Participation Waiver beginning on the start date of the MSSP participation agreement and ending 6 months after the earlier of: (i) the expiration of the participation agreement (including renewals), or (ii) the termination of the participation agreement, whether voluntarily, or involuntarily by CMS. If an ACO's application for the MSSP is denied, start-up arrangements remain protected by the Pre-Participation Waiver for 6 months after the denial notice. Together, these two waivers enable parties involved in forming ACOs to protect bona fide ACO start-up operating and similar arrangements before the ACO enters into an MSSP participation agreement, and thereafter, to seamlessly protect these same arrangements under the Participation Waiver.

For purposes of applying the Pre-Participation Waiver, start-up is defined broadly as "any items, services, facilities, or goods (including non-medical items, services, facilities, or goods) used to create or develop an ACO that are provided by such ACO, ACO participants, or ACO providers or suppliers. . . . [including] a subsidy for these items, services, facilities or goods."7 This broad definition offers parties involved in forming ACOs significant assurance that a wide array of start-up efforts and contributions for ACO formation are protected, including both in-kind and capital contributions.

Another common concern is how ACOs can ensure that their method of distributing shared savings does not run afoul of the Anti-Kickback Statute. Generally, under the Shared Savings Distribution Waiver, ACOs may use any method to distribute shared

savings earned under their MSSP participation agreement, so long as the savings are either (i) distributed to those who currently are ACO participants, providers or suppliers or were during the year the savings were earned, or (ii) used for activities reasonably related to purposes of the MSSP. And, for distributions paid by a hospital to physicians, distributions are not knowingly made to induce physicians to reduce or limit medically necessary care to patients under the care of such physicians.8

Significantly, unlike the Stark Law and the Anti-Kickback Statute requirements for compensation paid to referring physicians, the Shared Savings Distribution Waiver does not require shared savings distributions to be fair market value or commercially reasonable. As a result, application of the Shared Savings Distribution Waiver offers significant relief from these key fraud and abuse compliance risks. Similarly, the waiver decreases a typical concern with the Gainsharing CMP by prohibiting knowing inducements of physicians with respect to medically necessary care only, versus with respect to any services. As the IFC explains, this waiver clearly protects incentives to physicians to use coordinated outpatient care or evidence-based protocols without concern about violating the Gainsharing CMP.

Many ACO stakeholders also have lingering concerns about how ACOs can offer patients incentives to receive services from the ACO's providers and suppliers. Generally, the Patient Incentives Waiver permits ACOs to give Medicare beneficiaries free or below market 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., the ACO cannot give cash or cash equivalents); and, (iii) the items and services are preventative or further a beneficiary's treatment or drug regiment, care plan, or chronic disease management.9

Under this waiver's protection, ACOs have significant flexibility to offer beneficiaries preventative care items in an effort to motivate them to better manage their care. The Agencies recognized the importance of engaging patients to take preventative steps and comply with care management programs and, as a result, chose to allow ACOs greater flexibility to offer appropriate incentives that are "reasonably related" to the beneficiary's medical care.

By way of example, the IFC clarifies that "blood pressure cuffs for hypertensive patients" are protected under the waiver for hypertensive patients, whereas, "beauty products or theater tickets" are not protected.10 The IFC also cautions that this waiver will not protect financial incentives, such as waiving or reducing co-payments or deductibles, due to the increased risk of abuse from financial incentives. Significantly, the Patient Incentives Waiver is not limited to incentives given to the ACO's assigned beneficiaries (due to the method of assigning beneficiaries under the MSSP11), which means that ACOs can use this waiver to offer incentives to all beneficiaries under the care of their participants, providers and suppliers.

Health systems and others involved in forming ACOs are also considering how their

ACO involvement will affect compensation approaches for employed physicians. Generally, involvement in ACOs will require modifying physician employment agreements. For example, employment agreements may be amended to add duties requiring physicians to better manage care and costs, and to achieve quality measures in line with the MSSP's triple aim: better care, better quality, reduced growth in health care expenditures. Similarly, employers may be tying an increasing portion of physician compensation to the achievement of global ACO goals versus rewarding physicians for their individual productivity, such as under prevalent wRVU-based compensation models. There may also be more compensation tied to physicians using systems and protocols appropriately, such as EHR systems, quality reporting systems, and evidence-based protocols designed to coordinate and manage care within appropriate guidelines and costs.

While these and other similar questions and concerns about the scope and application of the fraud and abuse waivers remain, ACO stakeholders should take comfort in the broad protection offered by the five waivers, as well as the Agencies' clear purpose to ensure that fraud and abuse concerns do not impede the development of ACOs under the MSSP.

Footnotes

- Section 3022(f) of the Affordable Care Act of 2010 authorizes the Secretary of Health and Human Services to waive the following laws in connection with the MSSP: (1) Civil Money Penalty Law Prohibition on Payments to Reduce or Limit Care (Gainsharing CMP), 42 USC §1320a–7a(b); (2) Civil Monetary Penalty Prohibition on Inducements to Beneficiaries (Inducement CMP), 42 USC §1320a–7a(a)(5); (3) The Stark Law, 42 USC §1395nn; (4) The Anti-Kickback Statute, 42 USC §1320a–7b(b)(1) and (2); and (5) Prohibition Against Charges or Collections Above Medicare Allowable, 42 USC §1320a–7a(a)(2).

- 76 Fed. Reg. at 67993.

- ACO formation and participation activities and arrangements need only

satisfy one of the five waivers to be protected from the fraud and abuse laws, although more than one waiver may apply. In addition, the waivers are self-implementing, meaning there is no application or approval by the Agencies and the waivers may be relied on if all requirements are met.

- Note: Participants, providers, and suppliers are defined terms under the MSSP Final Rule. 42 CFR Part 425.

- The Pre-Participation waiver waives application of the Stark Law, the Anti-Kickback Statute, and the Gainsharing CMP for arrangements pre-dating an ACO's participation agreement if (i) the parties have a good faith intent to develop an ACO to apply and participate in the MSSP in a specified target year, (ii) the parties take diligent steps to form an ACO to participate in the target year; (iii) the ACO's governing body has duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP, and (iv) the arrangement and its authorization and the diligent steps are contemporaneously documented and documentation is maintained for 10 years Note that arrangements involving drug and device manufacturers, DME suppliers, and home health suppliers are expressly not protected. The Participation Waiver waives application of the Stark Law, the Anti-Kickback Statute, and the Gainsharing CMP if (i) the ACO has entered into an MSSP participation agreement, (ii) the ACO meets the MSSP 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 MSSP; and (iv) the arrangement and its authorization by the governing body are contemporaneously documented; (v) a description of the arrangement (except financial or economic terms) is publicly disclosed as required by HHS).

- 76 Fed. Reg. at 68003.

- The Shared Savings Distribution Waiver waives application of the Stark Law,

the Gainsharing CMP, and the Anti-Kickback Statute. and in addition to the above requirements, also requires that i) the ACO must have entered into an MSSP participation agreement and be in good standing. Note that distributions remain protected by this waiver if they are made after the end of the ACO's MSSP participation agreement so long as the savings were earned during the participation agreement.

- The Patient Incentives Waiver waives application of the Anti-Kickback Statute and the Inducement CMP and, in addition to the above requirements, also requires that the ACO must have entered into an MSSP participation agreement and be in good standing.

- 76 Fed. Reg. at 68007.

- Under the MSSP, beneficiary assignment occurs in stages with quarterly updates. Final beneficiary assignment is not known until after the end of each performance year based on data for that year. As a result, ACOs cannot know who their assigned beneficiaries will be at the time incentives are offered. 42 CFR 425.400.