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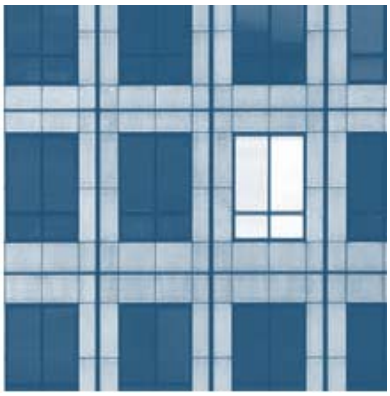
On the Subject



Health Industry Advisory

October 11, 2010

The FTC, CMS and OIG hosted a public workshop on October 5, 2010, featuring panel and listening discussions on regulatory issues surrounding how the development and operation of accountable care organizations would be affected by the use of waivers, safe harbors and other exceptions to various fraud and abuse laws.

Workshop Examines Effects of Waiver Authority on Development of ACOs

The U.S. Federal Trade Commission, the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) hosted a public workshop October 5, 2010. A previous newsletter at http://mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/c2712282-91ec-40ab-9270-a970cb0ba847.cfm summarized the morning sessions of the workshop, which concerned antitrust issues. This newsletter focuses on the afternoon sessions of the workshop, which featured a panel discussion and listening session regarding how the secretary of the U.S. Department of Health and Human Services (HHS) may encourage the creation and development of accountable care organizations (ACOs) by using the position's waiver authority or creating new exceptions and safe harbors related to the Anti-Kickback Law, the Stark Law and the Civil Monetary Penalty Law.

Summary

Workshop participants shared a range of viewpoints concerning how the formation and operation of ACOs would be affected by the use of waivers, safe harbors and other exceptions to various fraud and abuse laws. The OIG and HHS did not provide any details as to precisely what forms such waivers, safe harbors and exceptions might take, instead, they merely received input from participant-stakeholders regarding the range of views and possible approaches that should be considered when structuring the ACO model.

The afternoon workshop session revealed there are many competing concerns among stakeholders. Providers should note the OIG and CMS still appear to be in the early states of determining what factors and considerations may shape how its waiver authority is implemented, therefore it is imperative that stakeholders stay engaged in the process as the OIG and CMS consider alternatives. Based on comments by workshop participants, the decisions by the OIG and CMS are likely to create relative "winners" and "losers."

Background

Section 3022 of the Patient Protection and Affordable Care Act directs the secretary of HHS to establish a shared savings program that promotes accountability for a patient population, coordinates services under Parts A and B of Medicare and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Section 3022 specifically provides for the creation of ACOs to carry out the shared savings program. ACOs that meet quality performance standards established by the HHS are eligible to receive shared savings payments. Each ACO must be accountable for the quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

The Stark Law, the Anti-Kickback Law and the Civil Monetary Penalty Law (collectively, "fraud and abuse laws") each present potentially significant obstacles to the formation and operation of ACOs. However, Section 3022 gives the secretary broad authority to create waivers with respect to fraud and abuse laws in order to carry out the shared savings program. In addition to such waiver authority, the secretary may consider creating new safe harbors or exceptions to the fraud and abuse laws that are applicable to appropriately structured and operated ACOs.

Panel Discussion

The topic of whether and how CMS should use its waiver authority and perhaps promulgate new exceptions and safe harbors was divided into three segments: waivers, safeguards and future actions to encourage innovation.

Waivers

The initial discussion centered on whether any consensus exists regarding fraud and abuse safe harbors or other waivers. CMS asked panelists to recommend the necessary elements of such waivers, but the discussion among panelists revealed there are competing core concerns, depending on the point of the view of the stakeholder.

One point of view expressed was that CMS should primarily be concerned with encouraging experimentation and competition among ACOs. From that perspective, any waivers should be broad, simple and expansive to encourage innovation. One panelist observed that large, integrated systems already have a head start on ACO development, and that the use of broad waivers would open ACO participation opportunities for new and perhaps smaller groups. Another panelist noted that waivers should serve to level the playing field and therefore should be applied uniformly to all similarly situated ACOs.

Another core concern was that the "process" itself be emphasized, apart from the outcome, so that the development by CMS of new waivers, exceptions and safe harbors be perceived as methodical, transparent and fair. One panelist, who expressed the minority view that the fraud and abuse laws as they exist are not an insurmountable impediment to ACO development, stressed that the notice and comment period was of particular importance so that all stakeholders would have a chance to have their concerns vetted.

The panelists also discussed whether waiver protection should be extended to the initial formation of and investment in an ACO. One panelist emphasized that a waiver only for ACO operations, after the ACO is up and running, would be inadequate to address any fraud and abuse law issues that may arise in connection with the formation and investment stages of ACOs. For example, a waiver only with regard to ACO gainsharing arrangements would be insufficient to protect the development of the ACO.

Safeguards

Under the Patient Protection and Affordable Care Act, the assignment of a patient to an ACO is to be based on whether the patient's primary care physician was part of an ACO. The panelists offered that the patients would want to know the benefits of being within a particular ACO from a quality perspective. If patients were provided this information, they could respond by staying in or leaving the ACO, making it more truly accountable. However, another panelist noted, as a practical matter, this is not possible because the ACO itself may not even know which patients are assigned to it until 12 months after a performance year.

(Note: Section 3022 contemplates that Medicare beneficiaries will never know whether they have been assigned to an ACO or not. This requirement would appear to entail significant legal liability and political risks. Moreover, Medicare beneficiaries who are assigned to an ACO may seek care outside the ACO with no financial or other disincentives. These appear to be fundamental flaws in Section 3022 that will almost certainly need to be addressed by amendment if ACOs are to be successfully implemented.)

Several panelists emphasized that measurements of ACO success centered on quality and not cost savings will constitute important safeguards if the fraud and abuse laws are waived in whole or in part. They expressed concern that outcome-based quality measurements were not universally appropriate as safeguards because, in a shared-savings context such as an ACO, use of these measures may deter participation by safety net providers or reduce access to care by underserved patients.

Additionally, panelists recommended CMS establish parameters for any mandated compliance plan for ACOs. It was noted that private accreditation organizations may well play a key role. In this regard, one panelist advocated that CMS should build in a feedback loop to provide information on whether any compliance plan is promoting quality care or possibly having unintended negative consequences, such as stimulating undesirable levels of over- or under-utilization of health care services by ACO providers.

Future action to encourage innovation

Generally, panel members recognized that a paradigm shift in health care services delivery is reshaping the "old model." The current network of fraud and abuse laws may need to be reinvented from the ground up if it proves too stifling to innovation that can successfully bring about both cost savings and increased quality with improved outcomes. One panelist suggested that fraud and abuse compliance enforcement is simply not working well and needs to be overhauled in light in of the Patient Protection and Affordable Care Act. Another panelist opined that the current system only works for large, highly integrated systems with employed physicians and no physician ownership. As a result, the OIG and CMS need to bring exceptions and safe harbors in line with the current thinking on state-of-the-art integrated delivery.

Listening Session

A wide-variety of comments were made during the listening session by various provider, industry and patient advocacy stakeholders. Although the OIG and CMS provided no significant responses to the issues raised, the range of speakers' comments demonstrated the challenges ahead in crafting an ACO model that

will meet the needs of all interested parties. In addition to topics covered during the panel discussion, listening-session speakers brought to light several other salient issues including incentive payments or services offered to patients and providers to help foster ACO goals (which currently do not appear to be permitted under Section 3022); tracking of metrics to detect under-utilization; restriction by ACOs of provider opportunities to participate in ACOs; interaction between Medicare ACOs and ACOs receiving payment from other public and private payors; the development of ACOs in rural areas; and the implications of state-managed care laws for ACO development (e.g., though not mentioned specifically, laws such as California's may require ACOs to obtain prohibitively costly and time-consuming HMO-type licensure).

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