3 Things Accountable Care Organizations Can Do Now

Law360, New York (November 16, 2010) -- A frustrated doctor walks into the patient’s room after reviewing the medical record and the results of numerous tests. The doctor shakes her head and declares to the patient, “I’m stumped. We’ll have to wait for the autopsy.” With similar trepidation, many health care providers (and their counsel) looked at the shared savings and accountable care organization, or ACO, provisions of the Patient Protection and Affordable Care Act.

On the one hand, the ACO provisions called for greater integration among some currently nonintegrated providers in order to improve care and share financial incentives. Yet, the PPACA invests $250 million over the next decade for increased fraud and abuse enforcement, targeting certain integrated behavior that may be necessary for the ACO model to succeed.

As described below, there is hope that new regulatory action will ultimately set up clear guidelines or waivers from existing law for the acceptable creation of ACOs. However, future hope is little comfort to providers who are struggling now to form ACOs in order to participate in ACO provisions of the PPACA. We recommend three things providers can do now to limit fraud and abuse risk associated with ACOs.

First, make it obvious that the purpose of an ACO is consistent with the purpose of fraud and abuse laws. Second, consider how the ACO could be structured to take advantage of existing safe harbors and exceptions. Finally, develop an ACO that can evolve quickly to meet requirements of a changing regulatory landscape.

The Fraud and Abuse Issues with ACOs

The ACO model raises a number of concerns about potential fraud and abuse implications for participating ACO provider members under both the federal anti-kickback statute and federal physician self-referral law, commonly known as the Stark law. The anti-kickback statute is an intent-based statute that makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.

Violating the statute may result in imprisonment and significant civil monetary penalties, as well as exclusion from participating in federal health care programs. Sanctions may result even where only one purpose of the remuneration is to induce referrals. The anti-kickback statute provides a number of “safe harbors” that immunize certain payments and business practices that would otherwise be implicated by the statute. Complying with a safe harbor means that the parties are guaranteed to be free from prosecution under the anti-kickback statute. Failure to comply with a safe harbor does not mean that an arrangement is per se illegal.

By comparison, the Stark law prohibits a physician from referring Medicare patients for certain designated health services, or DHS, to any entity with which the physician has a financial relationship, e.g., an ownership or compensation relationship, unless an exception applies to the financial relationship.
Qualifying for a Stark law exception requires that any financial relationship between a physician and the entity that submits claims to Medicare for DHS, such as a hospital, be consistent with fair market value in an arm's-length transaction and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties. Stark law violations have resulted in significant civil money penalties and served as the basis for liability under the False Claims Act, which can significantly increase the potential penalties for alleged violators.

Fully integrated ACOs — i.e., those vertically integrated systems with employed physicians, providing both inpatient and outpatient services — can easily comply with rather straightforward anti-kickback safe harbors and Stark law exceptions. Contractual ACOs — e.g., networks of or other contractual arrangements between unrelated providers, such PHOs, IPAs or co-management agreements — have greater challenges.

For example, the PPACA contemplates that integrated ACOs providing complete, cohesive patient information across specialties and with processes to promote evidence-based care will ultimately yield better outcomes at a lower cost. A contractual ACO might pay providers some type of risk-based payment based on the savings generated by those specific providers. A contractual ACO might also require providers to refer within the ACO unless it is medically necessary to refer patients outside the ACO, because the ACO is based on the premise that patients staying within the system will receive better care at a lower cost over time, due to the ability to be able to track patients, share information and develop a consistent plan across providers and treatment types.

The PPACA requires that an ACO must have a legal structure able to distribute financial incentives related to meeting quality performance measures. Providers in the contractual ACO are incentivized to utilize the ACO and provide efficient care because they reap financial benefit from doing so. A contractual ACO could be in violation of the anti-kickback statute or the Stark law because there are, by design, financial incentives to keep and refer patients within the ACO. This is the struggle many in the provider community are having and what the Office of the Inspector General of the U.S. Department of Health and Human Services and the Centers for Medicare & Medicaid Services are considering when assessing how to revise or reinterpret the anti-kickback safe harbors and Stark law exceptions.

In a recently hosted public workshop, the Federal Trade Commission, the CMS and the OIG attempted to comfort providers with the knowledge that the FTC will consider expediting review of ACO arrangements (for antitrust compliance), that the OIG and CMS will consider new anti-kickback safe harbors and Stark law exceptions, and that the PPACA gives the HHS secretary the ability to waive aspects of the fraud and abuse laws to implement the shared savings program. The problem is that the ACO shared savings program begins in 2012 and providers have to prepare now to be eligible to participate by that time.

Of course, this ignores that the commercial market is already engaging providers to structure similar risk-based, integrated models. What can providers do now other than to simply wait for the autopsy of ACOs who fail the test of the existing fraud and abuse regulatory structure?

**Three Things ACOs Can Do Now**

First, recognize that one of the policies behind the anti-kickback and Stark laws is to prevent financial arrangements that interfere with a provider's professional judgment and that encourage unnecessary referrals and treatment, resulting in higher costs to the Medicare program. Although a contractual ACO may have financial incentives coupled with a referral requirement, the ACO purpose is consistent with the policies of the anti-kickback and Stark laws: to promote efficient care with better outcomes at a lower cost.

Additionally, over the past few years, the OIG has approved gain-sharing relationships involving the payment of incentive payments to providers for savings generated by providing more efficient care. Counsel for ACOs should review those advisory opinions and incorporate features from them where appropriate. Structuring an ACO consistent with regulatory policy and advisory opinions does not alone help an ACO comply with the strict liability of Stark law. However, it does help to justify an ACO structure under the intent-based anti-kickback statute.
Second, recognize that certain existing Stark exceptions might be available depending upon the structure of the ACO. For example, under the PPACA, an ACO must be able to distribute shared savings across participating physicians and physician groups for the system’s achievement of improved quality and resulting shared savings. The ACO may be able to identify specific groups and their specific activity contributing to the shared savings. However, it might not. The question would be whether the ACO could pay physicians for achieving shared savings on top of any other payments made by the ACO for other services provided.

Under Stark, the CMS has made it clear that organizations can pay physicians, in part, for achieving “patient satisfaction or other quality measures unrelated to the volume or value of business generated by the referring physician” under the personal services arrangement exception. The personal services arrangement exception is straightforward. The key to the exception is that the total compensation is fair market value. The difficulty is assessing what is fair market value for achieving satisfaction and quality objectives, although providers have done it before outside of the ACO context.

Other Stark exceptions, such as the physician incentive plan exception in the context of Medicare advantage arrangements, are also available in the ACO context. In the early phase of ACO development, counsel must work as a partner with clients to understand the desired structure and objective of the ACO and think how the existing Stark exceptions might apply.

Finally, structure ACOs in a manner that is at the same time consistent with existing law and regulatory guidance and yet nimble enough to change when (not if) federal regulators provide new ACO-specific guidance. By necessity, developing an ACO will require extensive communication and resolution of structural issues among providers. How will electronic health records be integrated across providers? How will practice improvement efforts be shared? In the midst of such discussions, an ACO will have to address the appropriate means of contracting with physicians and distributing financial incentives in a manner which achieves the ACO’s goals.

During that process, counsel should implement methods of complying with the anti-kickback statute and Stark law that they have used in arrangements such as gainsharing or co-management agreements, which may have similar quality based, reduced-cost objectives as ACOs. They should also avoid locking in a long-term compensation structure in order to revise the ACO structure, as appropriate, when regulators provide new guidance.

Conclusion

Federal regulators have left much to do to define the ACO shared savings program. The PPACA’s limited outline of the ACO shared savings program and re-emphasis on fraud and abuse enforcement has caused frustration and confusion among providers who believe regulators are on one hand telling providers to integrate to provide better care and on the other reminding them to beware of integration. Regulators are working to identify new ways for ACOs to comply with fraud and abuse laws.

Meanwhile, providers should break down contemplated ACO structures to manageable pieces and apply their experience with fraud and abuse compliance from similar integrated care efforts. While this patient may continue with a fever until Washington recommends a clear course of treatment, providers can still move forward crafting ACOs to comply with fraud and abuse laws and without the need to wait for a post-mortem.

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