Importance of a Commercial Reasonableness Opinion for ACO Waivers
(Part Two of a Three-Part Series)

The application of the federal healthcare fraud and abuse laws to Accountable Care Organizations (ACOs) is fraught with uncertainty and confusion. The Centers for Medicare and Medicaid Services (CMS), along with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS), released waivers of certain fraud and abuse laws for ACO participants in the federal Medicare Shared Savings Program (MSSP) in November 2011, and extended these waivers in its October 2014 interim rule. However, as discussed in Part 1 of this Health Capital Topics series, entitled “Definitions of Commercial Reasonableness and ACOs,” these waivers have never been adopted in finalized regulations, resulting in uncertainty relating to the ongoing permissibility of these waivers. In addition to these varying perspectives, both the OIG and, more recently, the U.S. Department of Justice (DOJ), are intensifying their regulatory scrutiny toward individual corporate executives for corporate regulatory violations, which may force individual executives to pay fines or face time in prison.

For the reasons listed above, maintaining compliance with federal healthcare fraud and abuse laws is becoming an even more pressing issue for ACOs. Healthcare executives and ACO board members may be well-served to monitor the compensation arrangements, joint ventures, and acquisitions within the ACO to verify that they comply with certain regulatory thresholds, particularly the threshold of commercial reasonableness (CR). This second installment of the three-part Health Capital Topics series will address the uncertainty surrounding the continued viability of the fraud and abuse waivers going forward, as well as the need for a CR opinion related to ACOs to protect both the health system and the board of directors in today’s heightened regulatory environment.

As introduced above, CMS and OIG released waivers of certain fraud and abuse laws for ACO participants in November 2011, and extended these waivers in its October 2014 interim rule. There are five types of waivers; the broadest of these waivers are the ACO Pre-Participation and ACO Participation waivers. The ACO Participation and Pre-Participation waivers remove the requirements of the Stark Law and Anti-Kickback Statute, including the requirement of CR thresholds required under the Stark Law.

Although the ACO fraud and abuse waivers may potentially place many arrangements outside the scope of the Stark Law, Anti-Kickback Statute, and civil monetary penalties, sole reliance on the waivers for compliance with these regulations may be unwise. First, both CMS and the OIG have indicated that these waivers may be narrowed in the future, potentially placing many arrangements outside the scope of the Stark Law, Anti-Kickback Statute, and civil monetary penalties. Additionally, ACO decision makers should note that the extension of the fraud and abuse waivers are set to expire on November 2, 2015, unless a final waiver rule (or additional extension) becomes effective on an earlier date. Owing to this uncertainty regarding the continuation of the protections provided by the waivers, ACO participants may be well served to ensure that any arrangements relying on an ACO fraud and abuse waiver to retain legal validity also receive the added protection afforded by satisfying the regulatory thresholds required under the federal healthcare fraud and abuse laws, including CR threshold, to which an ACO may become exposed should the waivers be allowed to expire.

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Additionally, ACO participants and/or outside investors who invest capital in an ACO will likely expect a return on their investment. Such an arrangement between an ACO and its investors may better withstand regulatory scrutiny if the arrangement meets the thresholds of fair market value (FMV) and CR to avoid potential regulatory sanctions. The valuation consulting assignment that is commonly requested by legal counsel for an ACO client is the development and reporting of a certified opinion related to whether certain transactional elements involved in ACO capital formation activities, e.g., integration, affiliation, acquisition, and/or divestiture, of the various healthcare enterprises, assets, and services, meet the separate and distinct thresholds of FMV and CR.

In developing a certified opinion of FMV and CR, certain financial analyses may be required, including, e.g., the development of:

1. Requisite due diligence;
2. Economic and demographic analyses and trend reports;
3. Patient utilization demand forecasts;
4. Reimbursement yield and payor mix reports;
5. Forecasts, budgets, and provider income/shared savings distribution plans; and,
6. Financial projections and pro forma reports.

In light of recent regulatory trends and uncertainty surrounding the ongoing permissibility of the ACO waivers, including the growing willingness of the U.S. Department of Justice (DOJ) to target both the corporate owner of a health system but also the individual executives for corporate civil and criminal violations, a certified opinion, prepared in compliance with professional standards by an independent, credentialed valuation professional, and supported by adequate documentation that each of the proposed elements of the transaction are within the range of FMV and are commercially reasonable, will significantly enhance the likelihood of the ACO establishing a risk averse, defensible position that the ACO, and its individual corporate executives, can withstand regulatory scrutiny, even in the absence of ACO waivers.

The third and final article in this three-part Health Capital Topics series will discuss the responsibilities of the board members of an ACO and participating hospitals in determining whether or not a proposed arrangement is commercially reasonable.
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