FTC and DOJ define "safety zone" for certain ACOs

By Karen Palestini

SUMMARY
The U.S. Federal Trade Commission and the Department of Justice have issued a Policy Statement providing "procompetitive" guidance to ACOs.

In a release coordinated with the Centers for Medicare and Medicaid Services' (CMS') final regulations on the Medicare Shared Savings Program, the U.S. Federal Trade Commission (FTC) and the Department of Justice (DOJ) jointly issued a final Statement of Antitrust Enforcement Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf) ("Policy Statement"). The Policy Statement applies to collaborations among otherwise independent providers and providers groups that are eligible and intend, or have been approved to, participate in the Medicare Shared Savings Program (MSSP). To read an earlier alert on the release of the CMS' Final Rule for ACOs, please visit http://www.saul.com/common/publications/pdf_3046.pdf.

While naked price-fixing and market-allocation agreements among competitors are treated as per se illegal, the Policy Statement confirms that the anti-competitive/pro-competitive effects of ACOs participating in the MSSP instead be evaluated using a "rule of reason" analysis. This use of the "rule of reason" analysis, which is consistent with the FTC/DOJ’s previously-issued Statements of Antitrust Enforcement Policy in Health Care, was driven by the FTC/DOJ’s recognition that CMS’ eligibility criteria and collection and evaluation of quality and cost metrics with regard to ACOs participating in the MSSP are broadly consistent with the clinical and financial integration factors traditionally associated with increased efficiencies that improve quality and reduce costs to health care consumers.

Thus, the FTC and DOJ have stated that they will treat joint negotiations with private payors as reasonably necessary to an ACO’s primary purpose of improving health care delivery. In addition, they will afford rule of reason treatment to an ACO that meets CMS’ eligibility requirements for, and participates in, the MSSP and uses the same governance and leadership structures and clinical and administrative processes it uses in the MSSP to serve patients in the commercial markets. The Policy Statement goes on to provide further guidance as to the application of the rule of reason analysis in certain situations.
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“What keeps you up at night?”

The FTC and DOJ have created a “safety zone” for MSSP ACOs. MSSP ACOs that fall within the safety zone will not face challenge by the FTC/DOJ, absent extraordinary circumstances. For an ACO to fall within this safety zone, independent ACO participants that provide the same service (a “common service”) must have a combined share of 30 percent or less of each common service in each participant’s primary service area (PSA), wherever two or more ACO participants provide that service to patients from that PSA. The Policy Statement sets forth an appendix that demonstrates how to calculate the PSA shares of common services for each ACO participant. There is also a rural exception that may allow certain ACOs that exceed the 30 percent PSA to be included in the safety zone.

Also worth noting is that the availability of the PSA safety zone can be affected by whether certain participants are exclusive to the ACO. For example, hospitals and ambulatory surgery centers must be non-exclusive to the ACO – meaning that they must be allowed to contract with private payors through entities other than the ACO – to fall within the safety zone, regardless of PSA share. Similarly, any ACO participant that has more than a 50 percent share in its PSA with respect to any service that no other ACO participant provides to patients in that PSA, must be non-exclusive to the ACO for the ACO to fall within the safety zone.

The FTC and DOJ did underscore in the Policy Statement that ACOs that fall outside the safety zone may still be pro-competitive and lawful. The Policy Statement specifically identifies conduct the FTC and DOJ view as anti-competitive, and urges ACOs to refrain from engaging in such conduct so as to lessen exposure to antitrust risk.

Finally, the Policy Statement sets forth a process by which MSSP ACOs (or MSSP ACO applicants) can seek a 90 day expedited review and antitrust guidance from the FTC or DOJ relative to the ACO’s formation and planned operations. The Policy Statement details the documents and information that will be both required and subject to the discretion of the ACO desiring expedited review.

Should you have any questions about the Policy Statement’s application to your ACO, or should you desire assistance with ACOs or any other form of provider organization, you may contact the author or any member of the Saul Ewing Health Practice Group.

This Alert was written by Karen Palestini, a member of the firm’s Health Practice Group. Karen can be reached at 609.452.5044 or kpalestini@saul.com. Ms. Palestini serves as a member of the American Health Lawyers Association ACO Task Force and formed one of the first ACOs in New Jersey. This publication has been prepared by the Health Practice Group for information purposes only.

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