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ACOs

Antitrust Regulators Issue Policy Statement On ACO Formation Criteria, Review Options

The Department of Justice and the Federal Trade Commission March 31 issued a proposed statement of antitrust enforcement policy for accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP) established under the health reform law.

The statement of enforcement policy enunciates the agencies' general view of how ACOs can successfully participate in the U.S. health care delivery system—with respect to government and private payers—without harming competition or consumers.

It also establishes a framework for how the agencies will assess and review ACOs and says that they will share responsibility for enforcement in this area. DOJ and FTC will accept comment through May 31.

The major component of the proposed enforcement policy is the agencies' position that compliance with ACO eligibility criteria proposed by the Centers for Medicare & Medicaid Services will be deemed ''reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants' joint efforts.''

ACOs that have the same governance, leadership structure, and clinical and administrative processes as are required by CMS for program participation will be evaluated, with respect to their contracting with private payers, under the ''rule of reason'' analytical framework, the antitrust regulators said.

A rule of reason analysis asks whether a collaboration of competitors ''is likely to have substantial anticompetitive effects and, if so, whether the collaboration's potential procompetitive efficiencies are likely to outweigh those effects,'' FTC and DOJ noted.

This approach is consistent with the antitrust agencies' longstanding position, memorialized in part in their 1996 Statements of Antitrust Enforcement Policy in Health Care, that joint contracting by groups of financially and/or clinically integrated health care providers does not run afoul of antitrust laws as long as the joint contracting ''is reasonably necessary to accomplish the procompetitive benefits of the integration,'' the agencies said.

The title of the DOJ-FTC document is ''Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.''

Formal Legal Structure. CMS, in its proposed rule, is requiring that ACOs have a formal legal structure that allows them to receive and distribute payments for shared savings, leadership and management structures that include clinical and administrative processes, processes to promote evidence-based medicine and patient engagement, a system for reporting on quality and cost measures, and the ability to provide coordinated care for beneficiaries.

''The Agencies have determined that CMS's proposed eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements and identified in the context of specific proposals for clinical integration from health care providers,'' FTC and DOJ said.

The MSSP also will provide CMS with cost, utilization, and quality metrics on an annual basis relating to each ACO's performance, the FTC and DOJ noted.

''This extensive monitoring . . . will help the Agencies determine the extent to which the proposed CMS eligibility criteria in fact lead to cost savings and improved health care quality and may help inform the Agencies' future analysis of ACOs and other provider organizations,'' the agencies added.

'Safety Zone.' The policy statement establishes what the agencies described as an antitrust enforcement ''safety zone,'' which will apply to those ACOs that obtain CMS approval; describes mandatory and voluntary agency review options; and sets forth a ''streamlined'' analytical process the agencies will use to determine whether a specific ACO raises ''significant competitive concerns.''

The policy statement said the agencies will look to evaluate an ACO's share of services in each ACO participant's Primary Service Area (PSA), which the proposal likened to a geographic market assessment used to determine potential anticompetitive effects. The agencies will assume the higher the PSA share, the greater the risk an ACO might be anticompetitive.

''An ACO with high PSA shares may reduce quality, innovation, and choice for Medicare and commercial patients, in part by reducing the ability of competing equally or more efficient ACOs to form. High PSA shares also may allow the ACO to raise prices to commercial health plans above competitive levels,'' the agencies noted.

Based on this PSA-based approach, the agencies said, they will not normally challenge CMS-approved ACOs in which ''independent ACO participants (e.g., physician group practices) that provide the same service (a 'common service') . . . have a combined share of 30 percent or less of each common service in each partici-

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pant's PSA, wherever two or more ACO participants provide that service to patients from that PSA.''

The policy statement also requires that a hospital or ambulatory surgery center (ASC) participating in an ACO ''must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share.'' In the non-exclusive context, ''a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers,'' the proposal said.

FTC and DOJ also set forth a ''rural exception,'' which allows non-exclusive arrangements with certain physicians in rural areas, even though the inclusion of that physician would cause the ACO to exceed the 30 percent common service threshold, and a ''dominant provider limitation,'' which applies a ''non-exclusivity'' requirement to any ACO participant with greater than a 50 percent share in its PSA of any service that no other ACO participant provides.

Agency Reviews. The DOJ and FTC detailed mandatory review requirements applicable to ACOs, other than those in rural areas, with participants whose shares exceed the 50 percent threshold, and voluntary review opportunities for ACOs falling between the 30 and 50 percent thresholds that desire ''certainty'' regarding the antitrust implications of their configuration in a particular market.

The agencies said reviews would be coordinated by an interagency work group and performed on an expedited basis—with an aim to completion within a 90-day period—for mandatory and voluntary review requests.

Mandatory review is required under the CMS proposal before an ACO with participants whose shares exceed the 50 percent threshold may qualify for MSSP participation.

The agencies set forth extensive documentation requirements and described the information that an ACO will have to show to earn antitrust agency approval. Voluntary review may be obtained following the same procedures outlined with respect to mandatory review, the agencies said.

Voluntary review may be unnecessary, however, if the ACO avoids five specifically delineated types of conduct set forth in the proposal, the agencies said. That conduct includes:

- preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers;
- tying sales of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO;
- except in the case of primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs, or other providers on an exclusive basis;
- restricting the ability of commercial payers to make information on cost, quality, efficiency, and performance available to its health plan enrollees; and
- sharing competitively sensitive pricing information or other data among the ACO's provider participants.

Antitrust Practitioner Reaction. Douglas Ross, with Davis Wright Tremaine LLP in Seattle, said the statement by the federal antitrust agencies will create challenges for antitrust attorneys who will help ACOs navigate the new requirements and could tax the agencies themselves.

The agencies' policy ''is a full employment act for health care antitrust lawyers'' and, with provisions mandating pre-approval ACO review, has DOJ and the FTC, which traditionally have seen themselves as enforcement agencies, taking a ''big step towards being traditional regulatory agencies,'' Ross said.

''With the exception of the Hart-Scott-Rodino premerger process and the FTC's enforcement of the Robinson-Patman Act, DOJ and the FTC enforce the antitrust laws when they discover violations; they typically do not have to grant permission before something can be done,'' Ross said. ''That's changing now—and it is an odd result for agencies that are charged with ensuring that a free market prevails.''

Ross said the promise of expedited review is welcome, but ''it remains to be seen how often applicants will be able to submit all required information without having the agencies come back, again and again, asking for more. If that happens, the idea that an expedited, 90-day review will work is in serious jeopardy.''

Ross said the 30 percent threshold in the proposal is ''generous to providers, by the agencies' previous standards, which included a safety zone for provider networks only up to 20 percent of market share.'' On the other hand, ''the rural exception that permits an ACO to enlist one physician per specialty without forcing an antitrust review if he or she is the only one in the specialty is far too conservative,'' Ross said.

He said it was ''extremely interesting'' that the agencies decided to rely on PSAs as a proxy for delineating the relevant antitrust market.

''The agencies concede in the proposal that a PSA is not the same as a relevant geographic market for antitrust purposes, but implicitly realize that, if they were to try to define antitrust markets, the administrative process would be unworkable,'' he said.

''So this is the compromise,'' he said. ''But sometimes, the area defined by the PSA and the relevant geographic market are very different things.''

Interagency Coordination 'Unprecedented.' In announcing the proposal, FTC Chairman Jon Leibowitz said four agencies—CMS/Health and Human Services, DOJ, FTC, and the Treasury Department/IRS—engaged in an ''unprecedented, collaborative effort . . . [to] ensure that ACOs meet their goals of improving quality and lowering costs while minimizing the regulatory burden on health care providers.''

The agencies said in a statement that they ''recognize that ACOs may generate opportunities for health care providers to innovate in both the Medicare and commercial markets to achieve the cost savings Congress intended'' in establishing MSSP.

The agencies said they also understand that collaborations among competitors—as will occur through the formation of ACOs—may raise concerns about competition.

The FTC voted 4-1 to approve the proposed policy statement on antitrust, with Commissioner J. Thomas Rosch the lone dissenter. Rosch said in a statement that, although he agrees generally with the analytical framework described in the proposal, he disagrees with the decision to have both antitrust agencies involved in ACO formation review.

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According to the FTC statement, ''Rosch believes that responsibility for reviewing the formation of ACOs should remain with the Commission because: 1) the Antitrust Division currently has far less expertise or experience than the Commission in reviewing the formation of ACOs or applying the antitrust laws to them; and 2) the Antitrust Division is more susceptible than the Commission, an independent agency, to lobbying and other political pressure.''

The statement said Rosch believes ''the evaluation of some ACOs by the Antitrust Division represents a victory for physicians and hospital—as well as their lobbyists and political supporters—which have opposed Commission review and antitrust enforcement of clinically-integrated health care providers.''

The proposal includes a request for comment on the suggested components of antitrust review of ACOs and asks for guidance on obtaining data needed to calculate PSA shares for certain physician services, such as pediatrics and obstetrics, rarely used by Medicare beneficiaries and data for inpatient hospital services in states where all-payer hospital discharge data are unavailable.

The agencies also asked whether being required to provide the documents and information needed to obtain expedited antitrust review will present an undue burden on ACO applicants.

BY PEYTON STURGES

The FTC-DOJ statement on enforcement policy is available at http://op.bna.com/hl.nsf/r?Open=psts-8fgren.