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Antitrust Enforcement Agencies Issue Final Guidance on ACOs

Part one in a series of client advisories focusing on the new ACO regulations

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This is the first in our client advisory series on the recent regulatory activities concerning accountable care organizations ("ACOs"). The federal antitrust agencies issued the final statement of their antitrust enforcement policy regarding Accountable Care Organizations participating in Medicare's Shared Savings Program on October 20, 2011.

The final policy statement, issued on the same day the Centers for Medicare & Medicaid Services ("CMS") issued its final ACO regulations, confirms the federal antitrust enforcement agencies will apply the so-called "rule of reason" to combinations of providers meeting CMS eligibility criteria for ACOs participating in the Shared Savings Program rather than the considerably more harsh "per se" rule of illegality reserved for provider collaborations that do not involve significant financial or clinical integration.

Furthermore, ACOs with groups of independent providers who offer common services that cumulatively account for no more than 30% of those services within their primary services areas may fall within a "safety zone" because they "are highly unlikely to raise significant competitive concerns." The agencies will not challenge such ACOs under the antitrust laws, "absent extraordinary circumstances."

ACOs that do not qualify for the safety zone "may be procompetitive and legal" though "not all ACOs are likely to benefit consumers." According to the final policy statement, "under certain conditions ACOs could reduce competition and harm consumers through higher prices or lower quality of care."

The agencies provide a process by which ACOs may receive guidance from the antitrust enforcers on an "expedited" basis. Obtaining such guidance is voluntary, however. In a notable change from the proposed policy issued in March 2011, the final statement does not require any ACO to obtain a mandatory review from the enforcement agencies. ACOs that choose to skip a review by the antitrust agencies are provided with advice on how to operate so as to minimize the possibility of antitrust risk.

Applicability of the Policy Statement

The final policy statement applies to "all collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Medicare Shared Savings Program." The earlier statement proposed to limit applicability to collaborations formed after March 23, 2010.

The agencies recognize many ACOs will provide services to commercially insured patients as well. The policy statement provides a framework under which the agencies will analyze CMS-qualified ACOs when they provide services in the commercial market.

The policy statement does not apply to single, integrated entities, nor does it apply to mergers.

"Rule of Reason" Treatment for Price Negotiations by Qualifying ACOs with Commercial Payors

Under standard antitrust principles, otherwise competing providers who jointly negotiate contracts with commercial payors are fixing prices in violation of Section 1 of the Sherman Act, unless the providers are either clinically or financially "integrated." In antitrust jargon, such joint negotiations are a "per se" violation of Section 1. In the event the providers are "integrated," however, their collaboration is judged under the more lenient "rule of reason." A rule of reason analysis examines both the efficiencies that flow from the collaboration and its anticompetitive effects. An arrangement is unlawful under the rule of reason only if, on balance, the likely anticompetitive effects outweigh the efficiencies.

The two federal antitrust agencies have provided advice elsewhere on what constitutes sufficient financial or clinical integration to escape per se treatment and bring an arrangement under the rule of reason. In particular, the "Statements of Antitrust Enforcement Policy in Health Care," issued by the agencies in 1996, provide useful guidance on how providers might integrate.

The criteria by which financial integration is judged are broadly understood and have caused little controversy. What constitutes acceptable clinical integration, however, has been less well understood. In the final policy statement, the agencies recognize health care providers could benefit from additional guidance in this area. Accordingly, the statement provides that ACOs participating in the Medicare Shared Savings Program will be presumed to be clinically integrated – and thus able to negotiate prices with commercial payors without engaging in per se violations of the antitrust laws – so long as they comply with the CMS eligibility criteria for participation in the Share Savings Program and participate in that program. Such ACOs also must employ in their commercial business "the same governance and leadership structures and the same clinical and administrative processes" used to qualify for and participate in the Shared Savings Program.

The 30% Safety Zone

The policy statement establishes an antitrust "safety zone" for ACOs in the Shared Service Program when market shares of overlapping providers do not exceed 30%. ACOs falling within this safety zone are assured that "absent extraordinary circumstances" the agencies "will not challenge" either their formation or their operation. (There are separate provisions for ACOs that include rural providers and permit market shares in excess of 30% if additional criteria are met.)

If an ACO includes hospitals or ASCs, those facilities must be "non-exclusive" to the ACO to fall within the safety zone. This means the facility must retain the ability to contract or affiliate with other payors or ACOs or the safety zone is lost. The safety zone for physicians applies regardless of whether or not they contract with the ACO on an exclusive basis.

If an ACO wishes to establish that it qualifies for the safety zone it needs to engage in a detailed share calculation. To conduct the required share analysis, the ACO first must determine which services are provided by two or more competing providers (or groups of providers) in the ACO. The ACO then must calculate, for each such "common service," the share all the ACO's providers hold of that service within each provider's primary service area (PSA). For example, if an ACO were to include two otherwise independent groups of cardiologists, the PSA for each group would be separately determined. Then the combined shares of both groups would be calculated within each of the two PSAs.

The guidelines borrow the CMS definition of a PSA as the lowest number of zip codes from which the provider draws a least 75% of its patients for a particular service.

In order to perform these calculations, physician services are defined by a physician's specialty, as defined by the Medicare Specialty Code ("MSC"), hospital inpatient services are identified by Major Diagnostic Categories ("MDCs"), and outpatient services are defined by categories to be identified by CMS.

Shares will be calculated for hospital inpatient services by using all-payor discharge data for the relevant MDCs when they exist at a state level. Physician shares will be calculated using Medicare fee-for-service allowed charges. Outpatient services will be measured by Medicare fee-for-service payment data for hospitals and fee-for-services allowed charges for ambulatory surgery centers. If available, an ACO can use state-level, all-payor discharge data instead.

Guidelines for ACOs Outside the Safety Zone

ACOs that fall outside the 30% safety zone "may be procompetitive and lawful." Such ACOs, however, remain exposed to possible antitrust challenge by the enforcement agencies. The risk of such a challenge will rise with the market power held by an ACO. The policy statement does not give specific guidance as

to when an ACO with a share or shares above 30% may violate the antitrust laws. Nonetheless, the agencies do provide guidance as to how such ACOs may reduce competitive concerns.

The policy statement identifies four types of conduct ACOs "with high PSA shares or other possible indicia of market power" should consider avoiding to minimize the likelihood of an antitrust challenge. Such ACOs should not:

1. Prevent or discourage commercial payors from steering patients to certain providers.

2. Tie sales of the ACO's services to a commercial payor's purchase of other services from providers outside the ACO.

3. Contract on an exclusive basis with ACO participants. There is no exception for primary care physicians.

4. Restrict a commercial payor's ability to share cost, quality, efficiency, and performance information with its enrollees.

Regardless of share size, ACOs should also adopt policies to prevent the sharing of confidential pricing information among its otherwise competing members.

Voluntary Review Program

Any ACO that as of March 23, 2010, had not signed or negotiated contracts with a commercial payor, and had not participated in the Shared Savings Program, may seek an antitrust review from the enforcement agencies through a process specified in the policy statement. Within 90 days of receiving the required information the reviewing agency will inform the ACO that the group's formation and operation "does not likely raise competitive concerns," "potentially raises competitive concerns," or "likely raises competitive concerns." The agency may condition a finding that the ACO does not likely raise competitive concerns on agreement by the ACO to take certain prescribed steps to remedy concerns raised by the agency.

Observations

Data Limitations. The share calculations necessarily are limited to available data. The antitrust agencies recognize that many states collect and publish all-payer discharge data that permit, when hospital services are at issue, share calculations based on these data. But similar data generally are not available for physician services. Accordingly the statement discusses and permits the use of Medicare data for physicians and outpatient services. But this necessarily produces shares based on Medicare revenues, which may or may not necessarily reflect a provider's market power in a region.

Safety Zones Do Not Provide Antitrust Immunity. An ACO that falls within the 30% safety zone or that receives a letter from an agency indicating it does not pose a competitive problem need not fear a challenge from either federal antitrust agency (so long as it does not substantially change the manner in which it does business). Private parties, however, are not bound by the safety zone or an agency letter and are free to sue the ACO, though the risk of such litigation is probably low.

Uncertainty for ACOs that Are Not Qualified by CMS. If an ACO is structured in a way that falls within the safety zone described in the policy statement, but the ACO chooses not to qualify under the Medicare Shared Savings Program and instead focuses on commercial business, it is not clear whether the antitrust enforcement agencies would scrutinize it under the guidelines set forth in the policy statement or under more traditional antitrust principles.

Information to Be Provided and the 90-Day Review Period. The final policy statement promises an expedited 90-day review for an ACO applying for a letter indicating the enforcement intentions of the antitrust agencies. ACOs expecting to hear definitively from an antitrust agency 90 days after they submit their applications must take great care to provide what can be a burdensome and complex amount of data in advance.