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Antitrust Enforcement Agencies Issue Proposed Guidance on ACOs

Part two in a series of client advisories focusing on the proposed ACO regulations

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Accountable Care Organizations wishing to participate in the Medicare Shared Savings Program would have to engage in a detailed analysis of their shares in defined markets and, when those shares exceed 50 percent, would be required to obtain approval from the federal antitrust enforcement agencies before the Centers for Medicare & Medicaid Services would qualify them for participation in the Shared Savings Program, under a proposal announced by the antitrust enforcement agencies on March 31, 2011.

The proposal, contained in a Policy Statement issued by the Department of Justice and the Federal Trade Commission the same day that CMS issued its proposed regulations on ACOs, departs in several significant ways from traditional antitrust analysis of provider joint ventures. While the antitrust agencies signal a willingness to relax the standards by which providers forming an ACO could establish "clinical integration," the agencies impose significant burdens on all ACOs seeking CMS qualification to establish that they do not create market power.

The Policy Statement would create a "safety zone" for ACOs with shares under 30 percent. These ACOs would apply directly to CMS to qualify under the Shared Savings Program without seeking approval from the antitrust agencies first.

ACOs with shares falling between 30 percent and 50 percent would not have to seek a review from the antitrust agencies before applying to CMS, though they could do so if they wanted to forestall the possibility of subsequent enforcement action by those agencies. ACOs in this middle zone that chose to skip a review by the antitrust agencies would be provided with advice on how to operate so as to minimize the possibility of a later antitrust enforcement action.

Although the Policy Statement is expressly intended to provide criteria for participation in the Shared Savings Program, the agencies recognize many ACOs will provide services for commercially insured patients as well. If adopted, the Policy Statement will provide a framework under which the agencies will analyze CMS-qualified ACOs when they provide services in the commercial market.

The Policy Statement would apply to ACOs formed after March 23, 2010, among otherwise independent providers that seek to participate in, or have otherwise been approved to participate in, Medicare's Shared Savings Program.

The agencies are soliciting public comments on the proposed rules until May 31, 2011.

Calculation of shares

The antitrust agencies propose to differentiate among ACOs according to their shares of defined markets. The Policy Statement would require mandatory review by the antitrust agencies of ACOs with shares exceeding 50 percent. Such ACOs would have to receive a letter from one of the agencies that it has no present intention to mount an antitrust challenge before CMS would qualify it to participate in the Medicare Shared Savings Program.

The Policy Statement would establish an antitrust safety zone for ACOs with shares below 30 percent, meaning they would not need to undergo review by the antitrust agencies before applying to CMS. ACOs with shares falling between the 30 percent and 50 percent thresholds could seek an antitrust clean bill of health from the agencies, though they would not be required to do so. The Policy Statement publishes guidelines ACOs in this middle zone could follow if they were to decide not to seek an antitrust review but nonetheless wished to minimize the possibility of a later challenge from one of the antitrust agencies.

To conduct the required share analysis, every ACO first would determine which services are provided by two or more competing providers (or groups of providers). The ACO then would calculate, for each such service, the share of ***all*** ACO providers 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 contiguous zip codes from which the provider draws a least 75 percent of its patients for a particular service.

- Physician services are defined by a physician's specialty, as defined by its Medicare Specialty Code (MSC). Hospital inpatient services are identified by Major Diagnostic Categories (MDCs). Outpatient services are defined by categories to be identified by CMS.

- Shares would be calculated for hospitals by using all payor discharge data for the relevant MDCs. Physician shares would be calculated using Medicare fee-for-service allowed charges. Outpatient services would be measured by Medicare fee-for-service payment data. For services not captured in Medicare payment data, such as pediatrics, obstetrics, and neonatal care, ACO applicants would be directed to use "other available data."

An appendix to the Policy Statement provides detailed examples for calculating shares. The crucial point, however, is that under the proposal applicants themselves would need to conduct this analysis before applying for participation in the Shared Savings Program.

Antitrust safety zone for certain ACOs

The Policy Statement proposes to establish an antitrust safety zone for certain ACOs unlikely to pose competitive threats. ACOs that fall within this safety zone would have no reporting obligation to the agencies. Of course, an ACO first would have to conduct a market analysis to determine whether it fits within the safety zone.

The safety zone would apply to an ACO that combines providers with shares of no more than 30 percent in any overlapping service line. If an ACO were to include hospitals or ambulatory surgery centers, those facilities would have to be nonexclusive to the ACO to fall within the safety zone—hospitals and ambulatory surgery centers would have to retain the ability to contract or affiliate with other ACOs or payors if the applicant ACO wished to qualify for the safety zone. This does not mean, should the Policy Statement become final, that an ACO cannot contract with a hospital or ASC on an exclusive basis. It means simply that ACOs entering into such exclusive arrangements would not fall within the safety zone and therefore would remain exposed to an antitrust challenge from the agencies.

- **Rural exception (physicians).** If an ACO in a rural area (as defined by the Census Bureau) were to include one physician in a specialty, and if that took the ACO over the 30 percent threshold (because, for example, there are only two physicians in the specialty), the ACO nonetheless would qualify for the safety zone as long as the physician was not exclusive to the ACO.

- **Rural exception (hospitals).** An ACO could include a "Rural Hospital" (defined as a Sole Community Hospital or Critical Access Hospital under CMS regulations) on a nonexclusive basis and still qualify for the safety zone even if the resulting shares for hospital services were to exceed 30 percent.

- **Dominant Provider Limitation.** If a provider with a share greater than 50 percent were to be included in an ACO, the ACO would still qualify for the safety zone if the provider were included on a nonexclusive basis within the ACO and if no other providers of the same service were to be included.

Except as set forth in the rural exception and the dominant provider limitation, an ACO could require its physicians to provide their services on an exclusive basis, and still qualify for the safety zone, so long as the 30 percent thresholds are not exceeded.

To qualify for the safety zone, unless the rural exception applies, an ACO could not exceed 30 percent in any of the service lines in which it combined competing providers. While failing to qualify for the safety zone would not mean the ACO had run afoul of antitrust law, falling outside the safety zone could impose additional administrative burdens, as discussed below.

Mandatory agency review of ACOs creating greater than 50 percent shares

ACOs that include two or more competing providers with an aggregate share of more than 50 percent would have to apply to the antitrust agencies for clearance before they could participate in the Shared Savings Program. CMS has stated in its proposed regulations that it will not approve an application from such an ACO without a letter from one of the antitrust agencies signaling no intention to challenge the organization.

In order to obtain such a letter from an antitrust agency, the proposal requires an ACO applicant to submit the following:

1. The application and supporting documents to CMS for participation in the Shared Savings Program.

2. "Documents or agreements relating to the ability of the ACO participants to compete with the ACO."

3. Documents discussing the ACO's business strategies or plans to compete and the ACO's impact on quality or price.

4. Documents showing the ACO's formation.

5. Information about the ACO's share calculations, proof of restrictions on exchanging price information among ACO participants, payor contacts, and the identities of other ACOs in the market.

Under the proposal, an ACO would submit this information to both antitrust agencies at least 90 days before the ACO's application to CMS otherwise would be due. The agencies then would decide which agency would review the information. The Policy Statement would commit the antitrust agencies to provide responses within 90 days after receipt of the required information. The agencies, however, would reserve the right to request additional information "where necessary to evaluate the ACO." The two antitrust agencies also state they will establish a joint working group "to collaborate and discuss issues arising out of the ACO reviews."

These mandatory reporting requirements would apply only to ACOs that choose to participate in the Medicare Shared Savings Program. ACOs that choose not to participate in that program, but instead seek to establish an ACO for commercial patients only, would not face these mandatory disclosures. Such entities, of course, may face scrutiny from the agencies later.

Guidelines for ACOs outside the safety zone but not subject to mandatory reporting

ACOs that fall above the 30 percent safety zone threshold and below the 50 percent mandatory reporting threshold would not be compelled to seek clearance from one of the antitrust agencies before qualifying for the Shared Savings Program. Such ACOs could seek expedited review of their programs, however, similar to the review under the mandatory reporting program. An ACO would need to submit the same information, and the agencies again propose to respond within 90 days.

For those ACOs that fall in this middle zone, but do not want to seek an antitrust review, the Policy Statement identifies five types of conduct they should avoid in order to minimize the likelihood of an antitrust investigation. Such ACOs should not:

1. Include "anti-steering" (or similar) clauses in commercial payor contracts. The agencies state that "directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO" can be "important to facilitate payers' ability to offer insurance products that differentiate among providers based on cost and quality."

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

3. Contract with ACO participants on an exclusive basis, with a stated exception for primary care physicians.

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

5. Share competitively sensitive pricing information among ACO participants.

Price negotiations by CMS-sanctioned ACOs with commercial payors

ACOs frequently will include competing providers of the same service. Unless these providers are "integrated," however, an ACO's price negotiations with commercial payors are likely to violate the antitrust laws. The Policy Statement refers to the "Statements of Antitrust Enforcement Policy in Health Care," issued by the antitrust agencies in 1996, for guidance on how providers might integrate—either financially or clinically—in order to avoid condemnation of their price negotiations under the antitrust laws.[1]

The question of how to integrate clinically has generated controversy. Until now, the antitrust agencies have resisted setting out specific criteria required to establish clinical integration. Instead, in the years since the issuance of the 1996 antitrust enforcement advice, the FTC has issued a number of staff advice letters explaining what does, and does not, qualify as clinical integration sufficient to permit joint price setting.

In an important departure from this history, the Policy Statement proposes that ACOs that participate in the Medicare Shared Savings Program no longer need prove separately to the antitrust agencies they are clinically integrated in order to negotiate prices with commercial payors. Instead, the antitrust agencies would defer to determinations made by CMS. If an ACO shows it "uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Shared Savings Program," the antitrust agencies would deem it clinically integrated. This is because, according to the antitrust agencies, CMS' eligibility criteria "are broadly consistent with the indicia of clinical integration."

Therefore, so long as an ACO were to participate in the Shared Savings Program and keep the same governance and clinical structures in place as existed at the time of CMS approval of its application for participation in the Program, the ACO's negotiations with commercial payors would not be considered by the antitrust agencies as per se violations of the antitrust laws.

Observations

In several significant respects, the Policy Statement represents a sharp departure from how the antitrust agencies have operated in the past and it sets out some principles that are in tension with traditional antitrust analysis.

Change in the role of the antitrust agencies. In a marked departure from how the antitrust laws are enforced today, the Policy Statement would force providers to engage in detailed market analysis and to seek permission from the antitrust agencies before they may provide their services (as CMS qualified ACOs) in the marketplace. At the same time, the Policy Statement, if it becomes final, will convert the antitrust enforcement agencies into regulatory bodies charged with granting or denying applications from would-be market participants, instead of simply observing provider behavior and instituting law enforcement actions when believed necessary.

Distinction between PSAs and antitrust relevant geographic markets. The Policy Statement expressly notes a PSA is not necessarily equivalent to a relevant geographic market used in traditional antitrust analysis and it nowhere states that the calculations providers make will result in "market shares." Nonetheless, for the purposes of the Shared Savings Program, the Policy Statement would consider a PSA a proxy for an antitrust relevant geographic market. As a matter of antitrust law, however, a PSA at best is only a rough approximation of a relevant geographic market. At worst it bears no resemblance at all to a relevant geographic market, and market analyses based on PSAs will yield incorrect antitrust conclusions.[2]

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 are not generally available for physician services. Accordingly the agencies would mandate the use of Medicare fee-for-service allowed charges (and for outpatient services, Medicare fee-for-service payments). But this will produce shares of Medicare revenues. Not all physicians in the same specialty take Medicare, however, and of those who do, not all do so in equal proportions. Consequently, share calculations based on Medicare data may be either higher or lower than calculations based on all-payer data—which, the agencies acknowledge, is preferable to Medicare data. And the preference makes sense. If the goal is to estimate market power, comprehensive data is more likely to lead to accurate results. Incomplete data (such as Medicare reimbursement data only) may lead to incorrect conclusions.

Safety zones do not provide antitrust immunity. While an ACO that applied for antitrust review and received a letter from an antitrust agency indicating the agencies would not take an enforcement action could proceed safe in the knowledge that those agencies would not prosecute it (so long as it did not substantially change the manner in which it did business), it would have no such protection from private litigants. Similarly, if an ACO were to fall within the 30 percent "safety zone," this would protect it only from an enforcement action by the agencies. Private parties would be free to sue the ACO. And courts would not necessarily follow the Policy Statement, as it does not express antitrust law.

Uncertainty for ACOs that are not qualified by CMS. If an ACO were structured in a way that would fall within the safety zone described in the Policy Statement, but the ACO chose not to qualify under the Medicare Shared Savings Program and instead focused 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 Policy Statement promises an expedited 90-day review for an ACO applying for a letter indicating the enforcement intentions of the antitrust agencies. Whether the agencies have sufficient staff to follow through on this promise remains to be seen, especially as the volume—and complexity—of ACO applications is unknown and difficult now to predict. ACOs expecting they will 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. ACOs should also take note of the admonition in the Policy Statement that the agencies reserve the right to request additional information. Should this occur, presumably the agencies would not necessarily respond to a request within 90 days of when the request initially was submitted.

Different criteria for clinical integration? The effect of the deferral by the antitrust agencies to CMS to determine when otherwise competing providers are clinically integrated is uncertain. Despite the hopeful statement in the Policy Statement that CMS' eligibility criteria "are broadly consistent with the indicia of clinical integration," it remains to be seen whether, in the event, CMS finds ACOs to be eligible for the Shared Savings Program that previously would not have satisfied the FTC (or DOJ) they were clinically integrated. The possibility that CMS' criteria will be different from—and more relaxed than—those applied until now by the antitrust agencies is a real one.

In our ongoing series, we will be issuing a number of separate advisories focusing on specific topics raised by the new regulations and the affiliated guidance and requests for comments including:

- Structure and governance
- Fraud and abuse, and waivers
- Beneficiary attributions and safeguards
- Quality metrics
- Shared savings calculations
- State law restrictions
- When things go wrong or circumstances change

Please also see our first installment in this series, " The New ACO Regs: They're Here (Well, Sort of ...)."

Stay tuned … and in the meantime, if you have any questions, please contact us.

FOOTNOTES

1 The 1996 Statements are here: www.ftc.gov/bc/healthcare/industryguide/policy/index.htm. In general, examples of sharing financial risk include accepting capitation or setting a fee schedule with a substantial risk withhold. Clinical integration is evidenced by the implementation by a network of an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and the creation of a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. Networks that are clinically integrated may set prices jointly, so long as such price setting is reasonably necessary to achieve the promised efficiencies.

2 Courts and antitrust commentators alike repeatedly have warned against confusing the area from which a seller obtains its customers with a relevant geographic market. "[A] court would often be mistaken to conclude that a seller's 'trade area,' or the area from which it currently draws its customers, constitutes a relevant geographic market. In fact, the 'trade area' and the 'relevant market' are precisely reverse concepts." *Bathke v. Casey's General Stores, Inc.,* 64 F.3d 340, 346 (8th Cir. 1995) (quoting H. Hovenkamp, FEDERAL ANTITRUST POLICY § 3.6d, at 113-14); see also *Federal Trade Commission v. Freeman Hosp.*, 69 F.3d 260, 268 (8th Cir. 1995).