

## Levels of antitrust scrutiny for ACOs

*Feds propose a tiered system of review for health care provider groups under the new affordable care law*



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The Department of Justice and Federal Trade Commission recently proposed new guidelines regarding antitrust enforcement of accountable care organizations — the new health care delivery model mandated by the 2010 Patient Protection and Affordable Care Act (PPACA) pursuant to its “shared savings program.” This statement was issued in conjunction with the Department of Health and Human Services’ Centers for Medicare and Medicaid Services’ (CMS) proposed regulations implementing the shared savings program, as part of a coordinated inter-agency effort to facilitate health care provider participation in the shared savings program, so as to achieve the cost savings and improvement in quality of care Congress intended.

Accountable care organizations (ACOs) are, in essence, collaborations of independent health care providers and/or provider groups (including physician practice groups, hospitals, physician-hospital organizations and any other provider groups that CMS deems appropriate) centered around the concept of enhanced coordination of care to improve both the quality

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and cost of care. ACOs are to be accountable for the overall care of a defined population of Medicare beneficiaries, and upon meeting certain performance standards set by CMS, awarded some portion of any savings realized (in addition to traditional fee-for-service payments). The statement is intended to ensure that providers have the antitrust clarity and guidance necessary to form pro-competitive ACOs, while also ensuring against the unintended effect of reducing competition and harming consumers through higher prices or lower quality of care. To that end, it sets forth varying levels of antitrust scrutiny applicable to: (1) ACOs with “primary service area (PSA) shares” of “common services” (defined below) of 30 percent or less; (2) ACOs with PSA shares of common services greater than 50 percent; and (3) ACOs with PSA shares of common services greater than 30 percent but less than or equal to 50 percent.

This three-tiered structure is premised on the assumption that the higher the PSA share, the greater the risk that the ACO will be anti-competitive. The statement notes that while a PSA does not necessarily constitute a relevant antitrust geographic market, it nonetheless provides a useful tool for evaluating potential competitive effects: “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 [of] more efficient ACOs to form. High PSA shares also may allow the ACO to raise prices to commercial health plans above competitive levels.”

The statement applies to collaborations formed subsequent to the PPACA’s enactment that seek to participate in the shared savings program. It does not apply to mergers, to which the antitrust agencies’ existing horizontal merger guidelines continue to apply. Furthermore, while the shared savings program contemplates formation of ACOs to care for Medicare ben-

eficiaries, the statement accounts for the economic reality that providers are more likely to invest the significant resources to integrate independent provider practices if they can also use the ACOs to service commercial purchasers such as health insurance plans and other private payers.

### ACOS WITH PSA SHARES LESS THAN 30 PERCENT

The statement delineates an antitrust “safety zone” for ACOs whose independent ACO participants, which provide a “common service,” have a combined share of 30 percent or less of each such common service in each participant’s PSA, wherever two or more ACO participants provide that service to patients from that PSA.

As set forth in the appendix to the statement, there are three major steps to calculating the PSA shares. First, each service provided by at least two independent ACO participants (the common service) must be identified. For physician participants, a service is the physician’s primary specialty; for inpatient facilities, such as hospitals, a service is a major diagnostic category (MDC); and for outpatient facilities, such as ambulatory surgery centers and hospitals, a service is an outpatient category as defined by CMS. (It should be noted that this method of identifying a “common service” strongly suggests regulatory recognition of a distinct “market” for outpatient ambulatory surgery centers, overlapping with hospitals to the extent they provide outpatient surgical services.) Second, the PSA for each common service for each ACO participant, which is defined as the lowest number of contiguous postal ZIP codes from which the participant draws at least 75 percent of its patients for that service, must be identified. Third, the ACO’s PSA share for each common service in each PSA from which at least two ACO participants serve patients for that service must be calculated. For physician services, for example, an ACO applicant’s

shares of Medicare fee-for-service allowed charges should be calculated for the most recent calendar year for which data are available. These calculations require CMS to make available the necessary underlying data, such as the aggregate fee-for-service allowed charges or payments for each service, by ZIP code. Finally, it should be noted, that in those states that do not prohibit the corporate practice of medicine, services provided by a hospital's employed physicians, if any, would also need to be taken into account in calculating the ACO's shares for each common service. Additionally, hospitals or ambulatory surgery centers participating in ACOs must be nonexclusive (i.e., able to contract individually or affiliate with other ACOs or commercial payers) to qualify for the safety zone. The statement also provides a "rural exception" wherein an ACO may include one physician per specialty from each rural county or a "rural hospital" on a nonexclusive basis and still qualify for the safety zone, even if the inclusion of that physician or rural hospital causes the ACO's PSA share to exceed 30 percent for that service. Lastly, a "dominant provider limitation" requires any "dominant provider" ACO participant (one with a greater than 50 percent PSA share of any service that no other ACO participant provides to patients in that PSA) to be nonexclusive to qualify for the safety zone. And an ACO with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer's ability to deal with other ACOs or provider networks.

### **ACOS WITH PSA SHARES GREATER THAN 50 PERCENT**

An ACO whose share for any common service that two or more independent ACO participants provide to patients in the same PSA exceeds 50 percent (and does not qualify for the rural exception) must obtain mandatory review, on an expedited basis, from the DOJ or FTC. A FTC/DOJ ACO Working Group will be established to allow ACOs to rely on the expertise of both agencies and ensure efficient, cooperative and expeditious reviews.

The mandatory review would evaluate the legality of joint price agreements and

other concerted action among the otherwise independent ACO participants. While joint price agreements, without more, are per se illegal under the antitrust laws, it is now generally accepted (and reaffirmed in this statement) that multiprovider health care networks are to be evaluated under the more lenient "rule of reason" standard if there is sufficient financial or clinical integration, in which the ultimate determination of legality requires weighing the ACO's pro-competitive benefits with its anti-competitive potential. The antitrust agencies have previously articulated some standards regarding financial and clinical integration, which will certainly apply to ACO reviews — in the form of various statements (including the 1996 Health Care Statements), speeches and a series of nonprecedential actions to specific factual situations in the form of business review letters, advisory opinions and consent decrees. But these are hardly specific, bright-line rules that ACOs may rely on.

Significantly, while this statement endorses ACO eligibility criteria set forth in the PPACA (and further defined by CMS's proposed regulations) as reliable indicia of sufficient integration to merit rule of reason analysis, the DOJ and FTC again decline to provide further specific, concrete guidance in their "wish[]" to avoid dictating prescriptions for how clinical integration should take place."

As explained in CMS's proposed regulations, mandatory antitrust review ensures: (i) that ACOs participating in the shared savings program will not present competitive problems that could subject them to antitrust challenge, preventing them from completing the minimum three-year term mandated by the program; and (ii) competition will be maintained for the benefit of Medicare beneficiaries by reducing the potential for the creation of ACOs with market power. Competition in the marketplace benefits Medicare beneficiaries by promoting quality of care and protecting access to a variety of providers. Competition also ensures the opportunity for the formation of two or more ACOs in a given area, which in turn could accelerate advancements in quality and efficiency through competition on nonprice dimensions.

If, at the conclusion of the mandatory review, the reviewing agency determines it is likely to challenge the ACO as anti-competitive, that ACO may not participate in the shared savings program.

### **ACOS WITH PSA SHARES BETWEEN 30 AND 50 PERCENT**

The statement explains that ACOs outside the safety zone, but below the mandatory review threshold, frequently may be competitive and may proceed without first obtaining antitrust review. The statement provides further guidance to ACOs within this tier by identifying the following five types of conduct that they can avoid to significantly reduce their antitrust exposure:

(1) Discouraging commercial payers from directing or incentivizing patients to choose certain providers through "anti-steering," "guaranteed inclusion," "product participation," "price parity" or other similar contractual provisions.

(2) Tying sales of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO, and vice versa (for example, requiring a purchaser to contract with all the hospitals in the same network as the hospital that belongs to the ACO).

(3) Contracting with providers (other than primary care physicians) on an exclusive basis, thus preventing them from contracting outside the ACO.

(4) Restricting a commercial payer's ability to make available cost, quality, efficiency and performance information to aid enrollees in evaluating and selecting providers in the health plan.

(5) Sharing among the ACO's provider participants competitively sensitive pricing or other data that could be used to set prices or other terms for services provided outside the ACO. An ACO that desires further certainty may also seek expedited review from the DOJ or FTC. If, upon elective review, the reviewing antitrust agency determines it is likely to challenge the ACO as anti-competitive, that ACO may not participate in the shared savings program.

The DOJ and FTC are currently accepting public comments on the proposed statement.