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Subject: *Federal Antitrust Policy: Stakeholders' Perspectives Differed on the Adequacy of Guidance for Collaboration among Health Care Providers*

Health care delivery in the United States generally is fragmented, with care delivered by multiple providers and in multiple care settings, often without systematic coordination across providers and settings.<sup>1</sup> This can lead to inefficient care delivery, poor quality of care, and patient dissatisfaction. There is a growing consensus among providers, researchers, and policymakers that collaboration among health care providers is essential to addressing these problems. Collaborative arrangements can take a variety of forms, including collaborations among independent physician groups—called physician arrangements—or among multiple types of independent providers—called multiprovider arrangements. For example, a physician arrangement could involve a network of primary care physicians and specialists, such as cardiologists and radiologists, who contract collectively with health plans. Similarly, a multiprovider arrangement could involve a hospital collaborating with groups of physicians to contract collectively with health plans. Collaborative arrangements may be able to address problems associated with fragmented care delivery because providers generally have greater resources and ability to coordinate care when collaborating with each other than when acting separately. For example, providers within a collaborative arrangement could pool resources to use electronic health records (EHR) to obtain timely and relevant clinical information and enable them to coordinate patient care across various care settings, potentially improving efficiency and quality of care. Or providers collaborating with each other could negotiate capitated rates with health plans to give these providers a financial incentive to furnish care efficiently.<sup>2</sup>

While collaborative arrangements can have potential benefits, such arrangements may lead to higher prices. In a competitive health care market, consumers are able to choose from a wide variety of competing providers that have an incentive to

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<sup>1</sup>Some patients, particularly those with multiple conditions, may receive care from multiple primary and specialty providers across different settings, including physician offices and hospitals.

<sup>2</sup>A capitated rate is a fixed amount that health plans pay per patient that covers a specific bundle of services for a period of time, such as 1 month, regardless of the amount of these services a patient uses. Providers in collaborative arrangements that are paid at a capitated rate have a financial incentive to provide care efficiently because they keep the difference if a patient's actual cost of services is less than the capitated amount and lose money if the actual cost of care exceeds the capitated amount.

furnish the highest-quality services at the lowest cost. However, the providers in a collaborative arrangement may be able to negotiate higher prices with health plans than would otherwise be expected in a competitive market merely because they have agreed to act together in setting fees. While higher prices benefit providers, consumers are adversely affected if higher prices for providers result in higher health plan premiums. Furthermore, when collaborating providers have the ability to negotiate prices in excess of competitive levels, the arrangement may violate federal antitrust laws, which are designed to promote market competition.<sup>3</sup>

The Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ), the agencies that are responsible for enforcing federal antitrust laws, have issued general guidance for the business community, and specific guidance for health care providers, on the application of these laws.<sup>4</sup> One aspect of this guidance by the FTC and DOJ (the agencies) describes the analysis they undertake to determine whether to challenge a particular collaborative arrangement among competing health care providers as unlawful.<sup>5</sup> The agencies also issued guidance in October 2011 describing their approach to antitrust policy for certain collaborative arrangements, called Accountable Care Organizations (ACO), that are eligible to participate in the Medicare Shared Savings Program (SSP).<sup>6</sup> The SSP is intended to promote provider collaboration to reduce costs and improve quality of care for Medicare beneficiaries by allowing ACOs to receive a portion of the net savings realized as a result of their efforts.<sup>7</sup> You asked us to examine how federal antitrust guidance may affect the ability of health care providers to collaborate to improve health care quality. In this report, we describe the perspectives of stakeholders—health care industry groups and experts in antitrust law—on key aspects of federal antitrust guidance related to collaboration among health care providers.

To address this research objective, we interviewed officials from the agencies and reviewed agency guidance on federal antitrust policy for collaborative arrangements in health care. We focused our analysis on physician and multiprovider arrangements among providers that (1) were actual or potential competitors and

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<sup>3</sup>The federal antitrust laws include the Sherman Act, 15 U.S.C. §§ 1-7; the Clayton Act, 15 U.S.C. §§ 12-27; and the Federal Trade Commission Act, 15 U.S.C. §§ 41-58.

<sup>4</sup>For example, see FTC and DOJ, *Antitrust Guidelines for Collaborations Among Competitors* (Washington, D.C.: April 2000), and *Statements of Antitrust Enforcement Policy in Health Care* (Washington, D.C.: August 1996), statements 8 and 9.

<sup>5</sup>This report discusses “unlawful” arrangements in the limited context of the agencies’ analysis as described in statements 8 and 9 of the *Statements of Antitrust Enforcement Policy in Health Care*.

<sup>6</sup>FTC and DOJ, Final Policy Statement, *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, 76 Fed. Reg. 67026 (Oct. 28, 2011).

<sup>7</sup>Section 3022 of the Patient Protection and Affordable Care Act required the establishment of the SSP no later than January 1, 2012. The Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services, is responsible for overseeing the SSP. In order to participate in the SSP and share in savings resulting from its cost control and quality improvement efforts, an ACO must enter into an agreement with CMS for at least 3 years. If the ACO demonstrates that it has satisfied the quality performance standards, and meets all other applicable requirements, the ACO would be eligible to receive any shared savings. Pub. L. No. 111-148, §§ 3022, 10307, 124 Stat. 119, 395, 940 (2010) (codified at 42 U.S.C. § 1395jjj).

(2) shared pricing information or agreed on fees or other terms they would accept from health plans.<sup>8</sup> The guidance we reviewed included the following:

- statements 8 and 9 in the *Statements of Antitrust Enforcement Policy in Health Care*, jointly issued by the agencies in 1996 (1996 Statements), which describe the agencies' antitrust analysis for determining whether physician and multiprovider arrangements are unlawful;<sup>9</sup>
- selected advisory opinions, which contain the assessment of FTC staff of whether a collaborative arrangement's specific proposed conduct is likely to raise antitrust concerns;<sup>10</sup>
- other forms of guidance, including a report by the agencies that elaborates on their approach to antitrust enforcement policy for collaborative arrangements in health care, agency guidelines for collaborative arrangements that apply to all industries, including health care, and court cases;<sup>11</sup> and
- the Centers for Medicare & Medicaid Services' (CMS) regulations for the SSP and the *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (Policy Statement), issued jointly by the agencies in 2011.<sup>12</sup> We also asked agency officials about the implications, if any, that this statement may have for collaborative arrangements outside the SSP.

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<sup>8</sup>Provider groups that furnish similar services—for example, two groups of primary care physicians—could be considered competitors. However, different types of providers may also compete with each other. For example, a hospital that provides diagnostic imaging services may compete with a radiology practice that provides similar services. Antitrust guidance that applies to independent provider groups that merge to form a single entity was beyond the scope of this report.

<sup>9</sup>The 1996 Statements contain agency guidance on mergers and various joint activities in health care. We use the term 1996 Statements to refer to the statement addressing physician arrangements (statement 8) and the statement addressing multiprovider arrangements (statement 9). The 1996 Statements updated joint statements that the agencies had issued in 1993 and 1994.

<sup>10</sup>The FTC issues Commission or staff advisory opinions, and DOJ issues business review letters, in response to a request to review specific proposed conduct of a collaborative arrangement. According to agency officials, the review of a given collaborative arrangement is generally done by the agency with the most expertise with that type of arrangement. Advisory opinions and business review letters are applicable only to the parties that requested the review and include DOJ's or the FTC's present enforcement intentions with regard to the proposed conduct. Neither agency is bound by the views expressed in an advisory opinion or business review letter, and each reserves the right to rescind it later. Our review included the following FTC advisory opinions, which are notable in part because they describe the FTC's assessment of activities, identified by the proposed collaborative arrangements, that might be evidence of clinical integration: *TriState Health Partners, Inc. Advisory Opinion* (2009); *Greater Rochester Independent Practice Association Advisory Opinion* (2007); *Suburban Health Organization, Inc. Advisory Opinion* (2006); and *MedSouth, Inc. Advisory Opinion* (2002 and 2007). DOJ officials noted that there were no favorable business review letters for clinical integration because most requests for such information went to the FTC.

<sup>11</sup>For example, see FTC and DOJ, *Improving Health Care: A Dose of Competition* (2004); *Antitrust Guidelines for Collaborations Among Competitors*; *Arizona v. Maricopa County Medical Soc.*, 457 U.S. 332 (1982); and *North Texas Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008).

<sup>12</sup>See CMS, Final Rule, *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, 76 Fed. Reg. 67802 (Nov. 2, 2011).

To obtain the perspectives of providers on key aspects of federal antitrust guidance related to collaboration among health care providers, we interviewed representatives from three national industry groups representing health care providers, including physicians and hospitals. In addition, because health plans play a critical role in health care markets, we spoke with representatives from a national industry group of health plans.<sup>13</sup> We also spoke with six experts in antitrust law related to collaborative arrangements in health care.<sup>14</sup> In addition, we reviewed publications from these industry groups and experts that addressed antitrust policy for physician and multiprovider arrangements.

We identified aspects of federal antitrust guidance that were of concern to stakeholders through interviews and a review of their publications. We then focused our description of their perspectives on these aspects of the guidance and included the agencies' perspectives in our description. We did not examine stakeholders' perspectives on antitrust guidance for collaborative arrangements participating in the SSP because the Policy Statement containing this guidance had not been issued when we conducted our interviews with stakeholders.

We conducted this performance audit from October 2010 through March 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings based on our audit objective.

## **Results in Brief**

Stakeholders—health care industry groups and experts in antitrust law—had different perspectives on the adequacy of three key aspects of antitrust guidance for health care provider collaboration. First, stakeholders' perspectives differed on the sufficiency of guidance on clinical integration, which involves integrating clinical activities across providers in a collaborative arrangement. Clinical integration is one way for a collaborative arrangement to satisfy the requirement that the arrangement demonstrate the potential to yield significant benefits, such as reduced costs or improved quality, in order to be able to jointly negotiate prices. Five of the six experts and one of the four industry groups said that agency guidance was sufficient, while one expert and two industry groups asserted that agency guidance on clinical integration was inadequate. Second, stakeholders' perspectives differed as to whether the agencies should permit greater use of exclusive collaborative arrangements, which restrict the ability of providers within a collaborative arrangement to contract with other arrangements or health plans. The use of exclusive arrangements has the potential to improve or reduce competition,

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<sup>13</sup>We interviewed representatives from the following health care industry groups: the American Medical Association, which represents physicians; the American Hospital Association; America's Health Insurance Plans; and Premier Inc., which is an alliance of health care providers and health systems that promotes collaboration as a way to improve health care delivery.

<sup>14</sup>To determine which experts to interview, we identified individuals who have published on the topic, and we solicited recommendations from individuals with expertise in this area.

depending on the circumstances. Four of the experts said that the agencies' guidance on exclusive arrangements was reasonable, while three industry groups stated that the agencies should permit greater use of exclusive arrangements. Third, stakeholders' perspectives differed on the adequacy of guidance related to which collaborative arrangements are exempt from the antitrust analysis and therefore are presumed to be lawful—known as being within a safety zone. One of the four industry groups and one of the six experts said the size and scope of the safety zones outlined in the 1996 Statements were appropriate, while three industry groups and three experts contended that the safety zones should be expanded to include a wider range of arrangements.

## **Background**

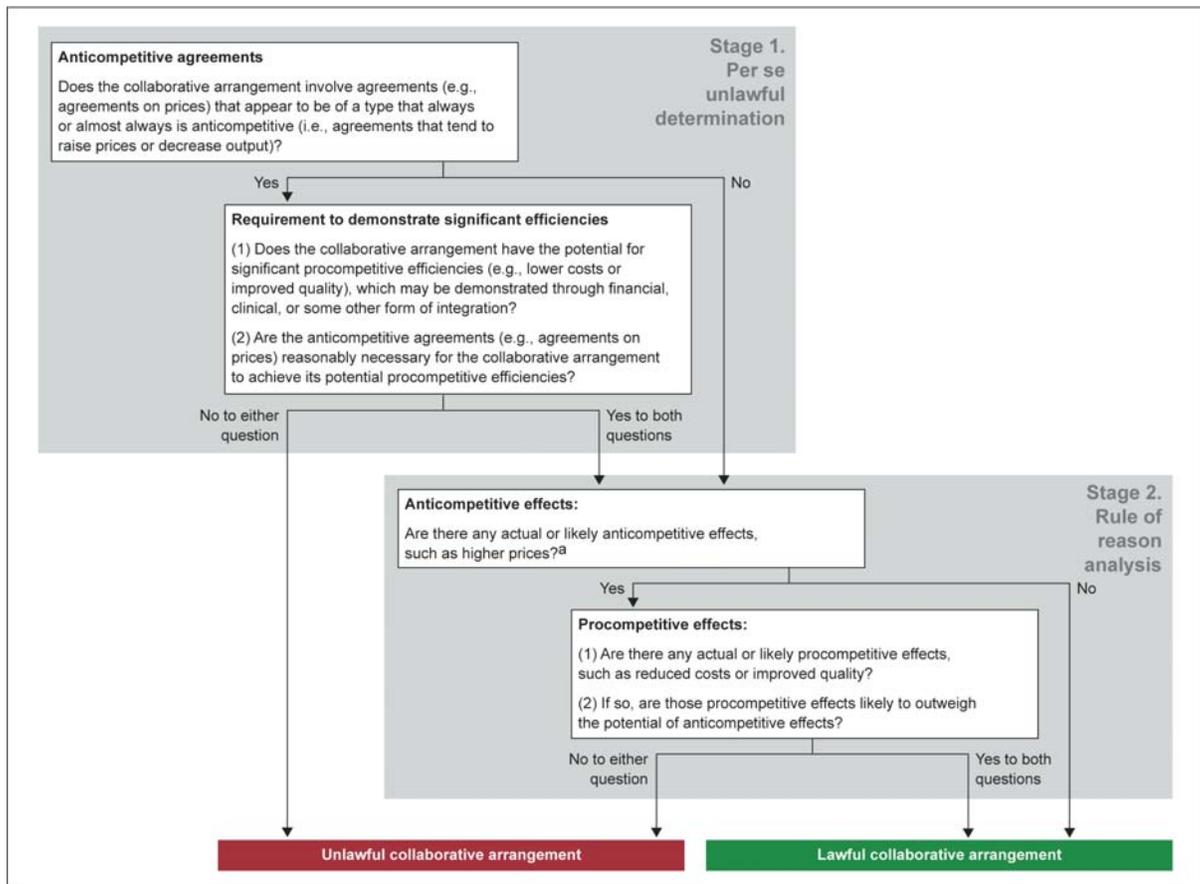
### Antitrust Analysis

The agencies generally conduct their antitrust analysis in response to a complaint, at their own discretion, or at the request of a specific proposed collaborative arrangement. This analysis is described in the 1996 Statements and consists of two key stages.<sup>15</sup> In the first stage, the agencies determine whether the collaborative arrangement is inherently anticompetitive, or “per se unlawful.” The second stage, triggered when collaborative arrangements are determined not to be per se unlawful in the first stage, involves the rule of reason analysis to determine the arrangement's anticompetitive effects. The antitrust agencies may bring antitrust enforcement actions to challenge collaborative arrangements that appear unlawful. (See fig. 1.)

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<sup>15</sup>This analysis applies to collaborative arrangements examined by the agencies in response to requests made for advisory opinions or business review letters, through complaints from health plans or other providers, or as the result of agency-initiated reviews.

**Figure 1: Federal Antitrust Analysis of Collaborative Arrangements among Health Care Providers That Are Actual or Potential Competitors**



Sources: GAO analysis of guidance from DOJ and the FTC on federal antitrust enforcement policy for physician and multiprovider arrangements in health care and interviews with officials from these agencies.

<sup>a</sup>To determine whether the collaborative arrangement would have potential anticompetitive effects, the agencies would consider, among other things, the arrangement’s market share as well as whether the arrangement involves exclusive contracting, which could hinder the ability of other providers to form competing arrangements.

The two key stages of the analysis are as follows:

- **Stage 1: Per se unlawful determination.** In this stage, the agencies assess whether collaborating providers have entered into agreements that are per se unlawful. To make this determination, the agencies first evaluate whether the collaborative arrangement involves agreements—such as jointly agreeing on prices—that are inherently anticompetitive. If so, the arrangement must demonstrate the following to avoid being determined per se unlawful:
  1. the arrangement has the potential to yield significant benefits—or “significant efficiencies”—for consumers (e.g., reduced costs or improved quality) and
  2. the arrangement’s anticompetitive agreements and practices are subordinate to and reasonably necessary to achieve these potential efficiencies.

The 1996 Statements describe forms of integration among providers in a collaborative arrangement that can demonstrate that an arrangement is likely to produce significant efficiencies. These forms include financial integration, which

is the sharing of substantial financial risk by participating providers, and clinical integration, which involves integration of providers' clinical activities.

**Financial integration.** A collaborative arrangement can demonstrate that it is financially integrated by sharing financial risk across providers in the arrangement. Sharing financial risk could involve negotiating capitated rates with health plans or subjecting providers to substantial financial penalties based on whether they meet the arrangement's cost or utilization targets.<sup>16</sup>

**Clinical integration.** The agencies provided broadly descriptive examples in the 1996 Statements of the types of clinical activities that collaborating providers might undertake to demonstrate clinical integration. For example, the 1996 Statements noted that a collaborative arrangement involving a physician network could demonstrate clinical integration by implementing "an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality."<sup>17</sup> The 1996 Statements elaborated on this point by noting that such a program could include, for example, the establishment of mechanisms to monitor and control utilization of health care services that are designed to control costs and ensure quality of care.<sup>18</sup> Multiprovider arrangements may also demonstrate clinical integration in ways such as this.<sup>19</sup> The 1996 Statements also included descriptions of how the agencies would analyze hypothetical physician and multiprovider arrangements, some of which would be clinically integrated.

In addition to financial and clinical integration, the 1996 Statements indicate that collaborative arrangements can demonstrate the potential for significant efficiencies in other ways but did not specify such additional forms of integration. If the collaborative arrangement demonstrates the potential for significant procompetitive efficiencies through integration, the agencies then analyze whether the anticompetitive agreements, such as agreements on prices, are reasonably necessary for the collaboration to achieve these efficiencies. For example, in a 2002 advisory opinion for a physician arrangement, FTC staff

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<sup>16</sup>See statement 8, pp. 68-69, and statement 9, p. 109.

<sup>17</sup>See Statement 8, pp. 72-73.

<sup>18</sup>The 1996 Statements also noted that activities to demonstrate clinical integration could include (1) selectively choosing network physicians who are likely to further the arrangement's objectives to control costs and ensure quality and (2) having a significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.

<sup>19</sup>The agencies also noted that these types of activities may not be relevant to all multiprovider arrangements, given the wide range of providers that could participate in such arrangements. As a result, the agencies noted that they would consider the particular nature of the services provided through the multiprovider arrangement in assessing whether it has the potential to produce efficiencies that warrant rule of reason analysis. See statement 9, pp. 110-111.

found that joint price agreements were reasonably necessary to ensure provider participation in order for the physician arrangement to operate effectively to achieve its efficiencies.<sup>20</sup>

- **Stage 2: Rule of reason analysis.** For collaborative arrangements that the agencies determine are not per se unlawful, the agencies proceed to the rule of reason analysis to determine whether these arrangements are unlawful. The rule of reason analysis primarily involves an assessment of whether a collaborative arrangement is likely to have anticompetitive effects—for example, result in prices above competitive levels—and if so, whether these potential effects are outweighed by any procompetitive efficiencies, such as lower prices and higher quality. When assessing potential anticompetitive effects, the agencies examine whether providers are capable of raising, and likely to raise, prices in their market above competitive levels. The agencies also consider whether a collaborative arrangement is likely to prevent or impede the formation or operation of other provider collaborations or health plans. In doing this analysis, the agencies consider whether providers must contract only through the collaborative arrangement—called an exclusive collaborative arrangement—or are able and willing to contract independently with payers or through other collaborations.<sup>21</sup> When assessing potential procompetitive efficiencies, the agencies may examine issues such as the extent to which collaborative arrangements are financially or clinically integrated and may also look for other sources of quality improvement and cost savings.

Not all collaborative arrangements among health care providers are subject to the agencies' full antitrust analysis. Under the 1996 Statements, if physician arrangements fall within a "safety zone," the agencies will not challenge them absent any extraordinary circumstances because they consider these arrangements highly unlikely to have anticompetitive effects. To be in a safety zone, a physician arrangement must be financially integrated. The safety zone thresholds differ based on whether a physician arrangement is exclusive. Exclusive physician arrangements fall within a safety zone if they are financially integrated and constitute 20 percent or less of the physicians in each medical specialty in the relevant market.<sup>22</sup> This

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<sup>20</sup>The staff advisory opinion observed that "In order to establish and maintain the on-going collaboration and interdependence among physicians from which the projected efficiencies flow, the doctors need to be able to rely on the participation of other members of the group in the network and its activities on a continuing basis." FTC Staff Advisory Opinion, *MedSouth, Inc.* (2002).

<sup>21</sup>Arrangements that do not explicitly restrict providers in this way may also be considered exclusive if providers do not actually contract outside the arrangement.

<sup>22</sup>To fall within a safety zone, the arrangement's physicians in a given specialty must constitute 20 percent or less of the physicians with active hospital staff privileges in that specialty in their relevant market.

percentage is greater—30 percent—for nonexclusive physician arrangements.<sup>23,24</sup> To calculate this market share, providers in a physician arrangement first determine the geographic market for each of their physician specialties and then determine the arrangement's market share for each specialty. Safety zones do not apply to physician arrangements that are not financially integrated or multiprovider arrangements of any type. Collaborative arrangements that fall outside a safety zone are not presumptively unlawful. Rather, these arrangements may be subject to the antitrust analysis to determine whether they are unlawful.

### Medicare Shared Savings Program

In October 2011, CMS issued regulations for the operation of ACOs under the SSP.<sup>25</sup> To participate in the program, ACOs must accept responsibility for at least 5,000 Medicare beneficiaries and must meet certain eligibility criteria, including (1) a formal legal structure that allows the ACO to receive and distribute payments for shared savings, (2) a leadership and management structure that includes clinical and administrative processes, (3) processes to promote evidence-based medicine and patient engagement, (4) reporting on quality and cost measures, and (5) coordinated care for beneficiaries.<sup>26</sup> CMS monitors an ACO's performance to ensure compliance with eligibility and program requirements, among other things, by analyzing claims data and quality data and by performing beneficiary surveys. ACOs that meet CMS's quality performance standards are eligible to receive a share of the savings that are below their expenditure benchmarks.<sup>27</sup> CMS also holds certain ACOs accountable for sharing losses by holding these ACOs liable for a portion of expenditures above their benchmarks. CMS may terminate its agreements with ACOs that fail to comply with eligibility and program requirements.

The agencies' Policy Statement provides guidance detailing how the agencies analyze under antitrust laws ACOs that are eligible and intend or have been approved to participate in the SSP.<sup>28</sup> The agencies noted that CMS's eligibility

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<sup>23</sup>In markets with fewer than five physicians in a given specialty, an exclusive physician arrangement otherwise qualifying for a safety zone may include one physician from that specialty and still qualify for a safety zone even if it exceeds the 20 percent threshold. Similarly, in markets with fewer than four physicians in a given specialty, a nonexclusive physician arrangement otherwise qualifying for a safety zone may include one physician from that specialty and still qualify for a safety zone even if it exceeds the 30 percent threshold.

<sup>24</sup>Criteria the agencies use to determine whether a given arrangement is nonexclusive include, for example, whether the arrangement limits participating providers' ability to contract outside the network and whether participating providers actually participate in, or contract with, other arrangements or managed care plans.

<sup>25</sup>See CMS, Final Rule, *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, 76 Fed. Reg. 67802 (Nov. 2, 2011).

<sup>26</sup>ACOs may include the following types of groups of providers and suppliers of Medicare-covered services: ACO professionals (e.g., physicians or physician assistants) in group practice arrangements, networks of individual practices of ACO professionals, partnerships or joint ventures between hospitals and ACO professionals, hospitals employing ACO professionals, or other Medicare providers and suppliers as determined by CMS.

<sup>27</sup>The expenditure benchmark is an estimate of what expenditures would have been in the absence of the SSP for beneficiaries assigned to an ACO.

<sup>28</sup>See DOJ and FTC, Final Policy Statement.

criteria are broadly consistent with the guidance on clinical integration contained in the 1996 Statements and the FTC’s advisory opinions. Therefore, ACOs meeting CMS’s eligibility requirements would qualify for the rule of reason analysis as long as they participate in the program and use the same legal structure and clinical and administrative process used for the SSP for their private, non-Medicare patients. The agencies established a safety zone for those ACOs meeting CMS’s eligibility criteria that intend to participate or have been approved to participate in the SSP and are highly unlikely to have anticompetitive effects. For an ACO to fall within a safety zone, independent ACO providers that furnish the same service, such as a physician specialty, must have a combined share of 30 percent or less of each type of these services in each provider’s primary service area (PSA).<sup>29</sup> This safety zone threshold does not vary based on whether the ACO involves exclusive contracting among its physicians. However, any hospital or ambulatory surgical center within an ACO must be nonexclusive for the ACO to fall within a safety zone.<sup>30</sup>

### **Stakeholders’ Perspectives Differed on the Adequacy of Antitrust Guidance for Health Care Provider Collaboration Related to Clinical Integration, Exclusive Collaborative Arrangements, and Safety Zones**

Stakeholders we interviewed differed in their assessment of whether federal antitrust guidance related to clinical integration, exclusive collaborative arrangements, and the size and scope of safety zones was adequate.

#### Stakeholders Differed on Sufficiency of Guidance for Clinically Integrated Arrangements

Five of the six experts in antitrust law and one of the four industry groups said that agency guidance was sufficient to enable providers to structure their clinically integrated collaborative arrangements to demonstrate the potential for significant procompetitive efficiencies. Three of these experts noted that the guidance was not impeding providers’ ability to collaborate. In addition, two of the experts stated that providers demonstrate the procompetitive efficiencies contemplated by the guidance when they take meaningful steps to improve the health of patients through clinical integration. Another expert noted that the agencies’ use of broadly descriptive examples to illustrate possible ways for providers to clinically integrate gave providers the flexibility to develop innovative forms of clinical integration. However, two of these five experts observed that although the guidance is sufficient, it would be helpful for the agencies to update the 1996 Statements to reflect provider practices that have been developed since the statements were issued. For example, one expert suggested that the 1996 Statements could be updated to include specific

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<sup>29</sup>These criteria apply to PSAs in which two or more providers furnish that service to patients in that PSA. The PSA for each provider is defined as the lowest number of postal zip codes from which the ACO provider draws at least 75 percent of its patients.

<sup>30</sup>The agencies will allow ACOs to include one physician or physician group per specialty from each rural county on a nonexclusive basis and qualify for a safety zone, even if the inclusion of these physicians causes the ACO’s PSA share for that service to exceed 30 percent provided that the physician’s or physician group’s primary office is in an “isolated rural” or “other small rural” zip code. They will also allow an ACO to qualify for a safety zone in instances where a participant in the ACO has more than a 50 percent PSA share with no other participants within that PSA, as long as it contracts on a nonexclusive basis.

examples of clinically integrated arrangements that incorporate advances in the use and understanding of evidence-based medicine and quality measures. In addition, the industry group and one expert believed the agencies would risk stifling innovation by channeling providers into the forms of clinical integration specified by the agencies if they provided additional guidance. Finally, one expert acknowledged that the guidance on clinical integration was clear to experts in antitrust law, but also asserted that it may be less clear for providers as well as for lawyers with less experience in this area.

In contrast to stakeholders who believed guidance on clinical integration was adequate, two of the four industry groups and one of the six experts said that agency guidance on clinical integration was inadequate. In particular, two industry groups noted that what they perceived as inadequate guidance may have discouraged provider collaboration. These two industry groups also noted that providers were often uncertain about how to clinically integrate in ways that would demonstrate sufficient clinical integration. For example, one industry group said that it was not clear, based on antitrust guidance, whether a collaborative arrangement needed to address all clinical conditions and include all types of providers or whether it was permitted to focus on certain conditions, such as diabetes or stroke. Similarly, the expert noted that the outdated nature of the guidance made it difficult to advise collaborating providers as to whether their current practices would be sufficient. Moreover, this expert said that advisory opinions and business review letters were of limited value to providers because they focused on specific circumstances and were not necessarily generalizable to other collaborative arrangements.

Another industry group said that agency guidance related to clinical integration was problematic because it was indicative of a restrictive approach to antitrust policy. In contrast to the 1996 Statements, guidelines for collaborative arrangements in other industries do not mention clinical and financial integration as specific ways to demonstrate the potential for significant efficiencies.<sup>31</sup> According to this group, the agencies should focus on the potential for collaborative arrangements to achieve efficiencies more broadly, as is the case for other industries, rather than focusing on financial and clinical integration.

Agency officials contended that their guidance on clinical integration is sufficient. They said that in providing this guidance, they were attempting to give sufficient information on how they will assess clinical integration without being overly prescriptive and thus limiting the ways in which collaborative arrangements clinically integrate. According to the officials, there are many ways to clinically integrate, and the ways in which providers do so continue to evolve. In addition, because the FTC and DOJ are enforcement, not regulatory, agencies, it would not be appropriate or desirable for them to be prescriptive about how providers should integrate their clinical operations, a task for which they believed health professionals were better suited. Instead of issuing a list of requirements, the agencies issued guidance in the 1996 Statements that contained broadly descriptive examples of clinical integration and also noted the types of questions they ask when assessing such

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<sup>31</sup>See FTC and DOJ, *Antitrust Guidelines for Collaborations Among Competitors*, for guidelines that apply to health care as well as other industries.

arrangements.<sup>32</sup> The agencies made the guidance sufficiently broad to account for new types of clinically integrated collaborative arrangements, and noted that providers have used this flexibility to form numerous arrangements intended to improve care coordination and interdependence among providers. Furthermore, the guidance explicitly noted that collaborative arrangements could integrate in ways other than clinical or financial integration to demonstrate the potential for significant efficiencies. However, agency officials were not aware of, nor had providers proposed, an integrated collaborative arrangement among health care providers with significant potential to reduce costs and improve quality that did not involve either clinical or financial integration.

In addition to guidance on clinical integration in the 1996 Statements, arrangements may obtain guidance through advisory opinions, business review letters, and elsewhere. For example, in a 2007 advisory opinion FTC staff described what they viewed as evidence of clinical integration, which included clinical activities such as the use of evidence-based practice guidelines and EHRs.<sup>33</sup> In addition, the agencies noted that the eligibility criteria for the SSP, which CMS recently included in its Final Rule for the program, serve as another source of guidance upon which providers can draw when structuring their clinically integrated collaborative arrangements. The Policy Statement notes that these criteria are generally consistent with the agencies' guidance on clinical integration.<sup>34</sup> However, agency officials noted that fulfilling the SSP eligibility criteria did not automatically mean that the agencies would consider a collaborative arrangement as clinically integrated if it was not participating in the program, which requires regular monitoring and public reporting of each collaborative arrangement's quality and cost data, among other things. Furthermore, agency officials stated that providers should also draw on other sources—such as the 1996 Statements and the advisory opinions—when structuring the form of clinical integration that would be most effective in addressing potential antitrust concerns.

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<sup>32</sup>The questions asked by the agencies when assessing whether a clinically integrated arrangement has the potential for significant efficiencies address (1) what the collaborative arrangement proposes to do, (2) how it would accomplish its efficiency goals, and (3) how joint contracting with health plans would help the arrangement accomplish those goals. See FTC and DOJ, *Improving Health Care: A Dose of Competition*.

<sup>33</sup>The proposed collaborative arrangement identified activities that evidenced clinical integration, including (1) development of a collaborative network of independent primary care and specialty care physicians to provide seamless, coordinated care; (2) the monitoring of adherence to evidence-based practice guidelines; (3) the sharing of clinical information related to patients receiving care from providers in the arrangement; and (4) a decrease in the administrative burden by reducing paperwork and time needed to process treatment information. FTC staff concluded that it appeared that the arrangement's proposed program would involve substantial integration. FTC, *Advisory Opinion for Greater Rochester Independent Practice Association, Inc.* (2007).

<sup>34</sup>FTC and DOJ, Final Policy Statement.

## Stakeholders Differed as to Whether Agencies Should Permit Greater Use of Exclusive Collaborative Arrangements

Stakeholders generally acknowledged that exclusive collaborative arrangements could be procompetitive or anticompetitive, depending on the specific circumstances. For example, one of the four industry groups noted that exclusive arrangements could make it easier to adhere to clinical guidelines and care processes because providers would follow a single set of guidelines as opposed to potentially having to follow several different sets if they contracted with multiple collaborative arrangements. Furthermore, this industry group noted that without the use of exclusive arrangements, a collaborative arrangement that invests capital in a clinical integration program may be at risk of others profiting from this investment—called free riding. One example of free riding could involve an arrangement that charges health plans higher fees to help finance EHRs designed to facilitate care coordination and reduce the provision of duplicative services. If the arrangement is nonexclusive, the health plan could benefit from this investment without paying the higher fee by contracting at lower rates with individual providers in the arrangement. Because of the risk of free riding, providers in a nonexclusive arrangement may have less incentive to make investments to improve care provision than providers in an exclusive arrangement.

Stakeholders also noted that exclusive collaborative arrangements could be anticompetitive. For example, one expert in antitrust law noted that an exclusive arrangement containing a large portion of providers in a market could be anticompetitive by prohibiting its providers from contracting with other arrangements. This prohibition could allow the exclusive arrangement to charge higher prices for its services by limiting the ability of providers in the market to form competing arrangements.

While stakeholders generally agreed that exclusive collaborative arrangements could either be procompetitive or anticompetitive, they differed in their perspectives on whether the agencies should give collaborative arrangements greater flexibility to use such arrangements. Four of the experts we interviewed said that the agencies' guidance on exclusive arrangements was reasonable. In particular, three of these experts stated that what they viewed as the agencies' current preference for nonexclusive arrangements was appropriate given the risks of exclusive arrangements. Furthermore, one of these experts asserted that the guidance allowed for the use of exclusive arrangements in ways that were procompetitive. This expert noted that the use of exclusive arrangements among primary care physicians had helped a certain multiprovider network achieve some of its clinical benefits. In addition, another expert stated that while the lower threshold for the safety zone for exclusive physician arrangements was reasonable, agencies should be more flexible when evaluating exclusive physician arrangements that operate in competitive markets. Specifically, this expert noted that it would be appropriate for the agencies to grant additional flexibility to exclusive physician arrangements with up to 30 percent market share if there were at least two other arrangements within a given market.

In contrast to the four experts who believed that the agencies' guidance on exclusive collaborative arrangements was reasonable, three industry groups stated that the agencies should be more receptive to such arrangements and should expand safety zones to allow for exclusive arrangements with larger market share.<sup>35</sup> One industry group observed that the agencies have not acknowledged the efficiencies that can result from exclusive arrangements in the 1996 Statements or in other guidance. This group observed that free riding, which was more likely to occur with nonexclusive arrangements, can prevent arrangements from realizing potential benefits associated with clinical integration. In addition, one legal expert noted that he had advised his clients not to use exclusive arrangements because of the greater scrutiny that such arrangements receive from the agencies.

Agency officials asserted that antitrust guidance gave arrangements sufficient flexibility to use exclusive arrangements in ways that promote competition and that numerous organizations currently do so. In particular, the 1996 Statements expressly state that the impact of exclusive arrangements on competition varies greatly and that exclusive arrangements, under certain circumstances, could increase providers' incentives to achieve their arrangements' efficiencies.<sup>36</sup> In addition, agency officials pointed out that exclusive arrangements could promote competition in several ways. For example, such arrangements could be procompetitive by increasing providers' incentives to invest in improvements—such as EHRs—that are designed to improve efficiency and quality. Agency officials also noted that they had spoken with numerous collaborative arrangements about how to use exclusive arrangements in ways that were procompetitive. However, agency officials said they had not been asked for an advisory opinion or business review letter for an exclusive arrangement.

While exclusive collaborative arrangements have potential benefits, the agencies have also cautioned providers about the potential anticompetitive effects from such arrangements, particularly from those arrangements that have the ability, and are likely to, raise prices in their markets above competitive levels. In addition, in a 2009 advisory opinion for a collaborative arrangement with a large market share, FTC staff stated that the nonexclusive nature of the arrangement was of critical importance to the agency's conclusion that the arrangement was unlikely to harm competition.<sup>37</sup> Finally, in the 1996 Statements, the agencies also have accounted for the potential of anticompetitive effects associated with exclusive arrangements by establishing a lower safety zone threshold for financially integrated exclusive physician arrangements.

The safety zone set forth in the Policy Statement for the SSP, unlike those in the 1996 Statements, does not differ based on whether the physicians in the ACOs are exclusive or nonexclusive to the ACO. Under the 1996 Statements, the safety zone threshold is lower for exclusive arrangements than the threshold for nonexclusive

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<sup>35</sup>One industry group also stated that nonexclusive collaborative arrangements should almost always be found lawful under the rule of reason analysis because such arrangements are very unlikely to be anticompetitive.

<sup>36</sup>See statement 8, pp. 78-79.

<sup>37</sup>FTC, *Advisory Opinion for TriState Health Partners, Inc.* (Apr. 13, 2009).

arrangements. Agency officials noted that having the same safety zone threshold for exclusive and nonexclusive ACOs under the SSP did not indicate that they had reassessed their approach to exclusive contracting for collaborative arrangements outside the SSP. They also noted that the safety zone thresholds for the 1996 Statements and the SSP are not comparable because of the different methodologies used to determine whether a collaborative arrangement or an ACO falls within a safety zone.

### Stakeholders Differed on Whether Size and Scope of Safety Zones Were Appropriate

One of the four industry groups and one of the six experts in antitrust law we interviewed said the size and scope of the safety zones outlined in the 1996 Statements were appropriate. The industry group stressed the need for empirical evidence to support any expansion of the safety zones and noted that being in a safety zone is not required for a collaborative arrangement to achieve procompetitive benefits. While the expert agreed with the current size and scope of the safety zones, she noted that the agencies should consider evaluating whether changes in provider practice since the safety zones were established in 1996 warranted any changes in this area.

In contrast to the stakeholders above, three industry groups and four experts questioned whether the current safety zones were appropriate. In particular, the three industry groups and three of the four experts said that the current safety zones should be expanded by including clinically integrated and multiprovider arrangements, and the industry groups also said the safety zones should include collaborative arrangements with larger market shares. For example, one of these groups stated that it was necessary to include a broad range of clinically integrated providers—including hospitals, primary care physicians, and specialists—to develop a collaborative arrangement that was effective at reducing costs and improving quality. However, this group noted that providers were reluctant to develop such arrangements because of the lack of a safety zone for clinically integrated or multiprovider arrangements. Similarly, this group noted that a safety zone for multiprovider networks would be more viable today than when the 1996 Statements were issued because these types of arrangements are much more common and well established. In addition, two of these experts noted that expanding the safety zones to include additional types of arrangements could give more certainty to providers. However, they also stated that despite the lack of a safety zone for clinically integrated or multiprovider arrangements, it would be surprising if the agencies challenged whether such arrangements were lawful if they were below the current safety zone thresholds.

Agency officials emphasized that collaborative arrangements that fall outside a safety zone are not presumptively unlawful and, further, would not necessarily be challenged if these arrangements did not reduce competition or if they ultimately generated procompetitive benefits, such as reduced costs and improved quality, that outweighed any anticompetitive effects. Additionally, agency officials said that they were reluctant to expand the safety zones to account for multiprovider and clinically integrated arrangements. In particular, they noted that multiprovider arrangements

were highly variable and could include combinations of provider specialties with which the agencies are less familiar. They also stated that applying the safety zone to clinically integrated arrangements would be problematic because the most effective forms of clinical integration were not yet well established and were continually evolving. Furthermore, they noted that unlike ACOs under the SSP, collaborative arrangements outside the SSP will not be subject to regular monitoring and public reporting. Agency officials also said they did not plan to increase the market share thresholds for the safety zones under the 1996 Statements because the potential for anticompetitive effects generally rises as arrangements' market shares increase. Furthermore, they noted that exclusive collaborative arrangements within a safety zone may exclude as many as 20 percent of providers from contracting with other arrangements in a given market. Increasing this threshold to a 30 percent market share could lead to a market with only three exclusive arrangements available, which they thought might not be sufficiently competitive.

The safety zone outlined for the SSP in some ways may give ACOs greater flexibility than the safety zones in the 1996 Statements, but the agencies noted that this additional flexibility reflected the structure of the SSP, with its monitoring and reporting requirements, and was not an indication that the agencies had reassessed the safety zones in the 1996 Statements. Agency officials noted that in contrast to the safety zones outlined in the 1996 Statements, the safety zone for the SSP includes both multiprovider and clinically integrated arrangements. Agency officials said they included clinically integrated arrangements in the safety zone for the SSP because clinical integration is a key focus of the program. Furthermore, they said they included multiprovider arrangements in the safety zone because many ACOs would likely include types of providers, such as hospitals, in an effort to more effectively coordinate care. Finally, agency officials noted that a key reason for the different safety zone in the SSP was that unlike collaborative arrangements in the private market, ACOs in the SSP are subject to quality and cost reporting requirements and monitoring that do not exist for arrangements outside this program.

### **Agency Comments**

We received technical comments on a draft of this report from DOJ and the FTC, which we incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Attorney General, the Chairman of the Federal Trade Commission, and interested congressional committees. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure I.

A handwritten signature in black ink, appearing to read 'James C. Cosgrove', written in a cursive style.

James C. Cosgrove  
Director, Health Care

Enclosure

*List of Requesters*

The Honorable Max Baucus  
Chairman  
Committee on Finance  
United States Senate

The Honorable Michael F. Bennet  
United States Senate

The Honorable Al Franken  
United States Senate

The Honorable Kirsten Gillibrand  
United States Senate

The Honorable Kay Hagan  
United States Senate

The Honorable Mark Udall  
United States Senate

The Honorable Tom Udall  
United States Senate

The Honorable Mark R. Warner  
United States Senate

Enclosure I

## **GAO Contact and Staff Acknowledgments**

### **GAO Contact**

James C. Cosgrove, (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov)

### **Staff Acknowledgments**

In addition to the contact named above, Christine Brudevold, Assistant Director; William Black; William A. Crafton; Erica Pereira; Monica Perez-Nelson; and Roseanne Price made key contributions to this report.

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