

FEDERAL TRADE COMMISSION**DEPARTMENT OF JUSTICE****Antitrust Division****Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program****AGENCIES:** FTC, DOJ.**ACTION:** Final Policy Statement.

SUMMARY: The FTC and DOJ (the “Agencies”) are issuing the final *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (the “Policy Statement”) in conjunction with the final rule issued today by the Centers for Medicare and Medicaid Services (“CMS”) under Section 3022 of the Affordable Care Act (the Patient Protection and Affordable Care Act, Public Law 111–48, 124 Stat. 119 (2010), and the Health Care and Education Reconciliation Act of 2010, Public Law 111–52, 124 Stat. 1029 (2010)).

The final Policy Statement differs from the proposed Policy Statement issued earlier this year, 76 FR 21,894 (Apr. 19, 2011), in two significant respects. First, the entire final Policy Statement—with the exception of the voluntary expedited antitrust review—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 “Shared Savings Program”); its applicability is no longer limited to those collaborations formed after March 23, 2010, the date on which the Patient Protection and Affordable Care Act was enacted. Second, because the Shared Savings Program final rule will no longer require a mandatory antitrust review for certain collaborations as a condition of entry into the Shared Savings Program, the final Policy Statement no longer contains provisions relating to mandatory antitrust review. However, as discussed in the final rule, the Agencies will continue to protect competition in markets served by accountable care organizations (“ACOs”) that participate in the Shared Savings Program, aided by data and information from CMS that will assist the Agencies in monitoring the competitive effects of ACOs. Specifically, CMS will provide the Agencies with aggregate claims data regarding allowed charges and fee-for-service payments for all ACOs accepted

into the Shared Savings Program and also with copies of all of the applications to the Shared Savings Program of ACOs formed after March 23, 2010. The Agencies will vigilantly monitor complaints about an ACO’s formation or conduct and take whatever enforcement action may be appropriate. Additionally, upon request, the Agencies will provide an expedited 90 day review for newly formed ACOs that wish to obtain additional antitrust guidance.

SUPPLEMENTARY INFORMATION:**Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program***I. Introduction*

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, the “Affordable Care Act”) seek to improve the quality and reduce the costs of health care services in the United States by, among other things, encouraging physicians, hospitals, and other health care providers to become accountable for a patient population through integrated health care delivery systems.¹ One delivery system reform is the Affordable Care Act’s Medicare Shared Savings Program (the “Shared Savings Program”), which promotes the formation and operation of Accountable Care Organizations (“ACOs”²) to serve Medicare fee-for-service beneficiaries.³ Under this provision, “groups of providers of services and suppliers meeting criteria specified by the [Department of Health and Human Services] Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an [ACO].”⁴ An ACO may share in some portion of any savings it creates if the ACO meets certain quality performance standards established by the Secretary of Health and Human Services through the Centers for Medicare and Medicaid Services (“CMS”). The Affordable Care Act requires an ACO that wishes to participate in the Shared Savings Program to enter into an agreement with CMS for not less than three years.⁵

¹ Health Care and Education Reconciliation Act of 2010, Public Law 111–52, 124 Stat. 1029 (2010); Patient Protection and Affordable Care Act, Public Law 111–48, 124 Stat. 119 (2010).

² As used in this document, “ACO” refers to Accountable Care Organizations under the Medicare Shared Savings Program, which also may operate in commercial markets. Patient Protection and Affordable Care Act 3022, 124 Stat. at 395–99.

³ *Id.*

⁴ *Id.* at 395.

⁵ *Id.* at 396.

Recent commentary suggests that some health care providers are likely to create and participate in ACOs that serve both Medicare beneficiaries and commercially insured patients.⁶ The Federal Trade Commission and the Antitrust Division of the Department of Justice (the “Agencies”) recognize that ACOs may generate opportunities for health care providers to innovate in both the Medicare and commercial markets and achieve for many other consumers the benefits Congress intended for Medicare beneficiaries through the Shared Savings Program. Therefore, to maximize and foster opportunities for ACO innovation and better health for patients, the Agencies wish to clarify their antitrust enforcement policy regarding collaborations among independent providers that seek to become ACOs in the Shared Savings Program. The Agencies recognize that not all such ACOs are likely to benefit consumers, and under certain conditions ACOs could reduce competition and harm consumers through higher prices or lower quality of care. Thus, the antitrust analysis of ACO applicants to the Shared Savings Program seeks to protect both Medicare beneficiaries and commercially insured patients from potential anticompetitive harm while allowing ACOs the opportunity to achieve significant efficiencies.

To achieve these goals, the Agencies have developed this *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (the “Policy Statement”). The Policy Statement is intended to ensure that health care providers have the antitrust clarity and guidance needed to form procompetitive ACOs that participate in both the Medicare and commercial markets. The Policy Statement describes (1) the ACOs to which the Policy Statement will apply;⁷ (2) when the Agencies will apply rule of reason treatment to those ACOs; (3) an antitrust safety zone; and (4) additional antitrust guidance for ACOs that are outside the safety zone, including a voluntary expedited

⁶ Fed. Trade Comm’n & Dep’t of Health and Human Serv., Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws (Oct. 5, 2010).

⁷ The analytical principles underlying the Policy Statement also would apply to various ACO initiatives undertaken by the Innovation Center within CMS as long as those ACOs are substantially clinically or financially integrated.

antitrust review process for newly formed ACOs.⁸

II. Applicability of the Policy Statement

The Policy Statement applies to collaborations among otherwise independent providers and provider groups⁹ that are eligible and intend, or have been approved, to participate in the Shared Savings Program. For ease of reference, the Policy Statement refers to such collaborations as ACOs, although they may not yet have been approved to participate as ACOs in the Shared Savings Program. The Policy Statement refers to the otherwise independent providers and provider groups that constitute the ACO as ACO participants.¹⁰ The Policy Statement does not apply to mergers. Merger transactions, including transactions that meet the criteria set forth in Section 1.3 of the *Antitrust Guidelines for Collaborations Among Competitors*,¹¹ will be evaluated under the Agencies' *Horizontal Merger Guidelines*.¹² The Policy Statement also does not apply to single, fully integrated entities.

III. The Agencies Will Apply Rule of Reason Analysis to ACOs That Meet Certain Conditions

The antitrust laws treat naked price-fixing and market-allocation agreements among competitors as per se illegal. Joint price agreements among competing health care providers are evaluated under the rule of reason, however, if the providers are financially or clinically integrated and the agreement is reasonably necessary to accomplish the procompetitive benefits of the integration.

A rule of reason analysis evaluates whether the collaboration is likely to have anticompetitive effects and, if so,

whether the collaboration's potential procompetitive efficiencies are likely to outweigh those effects. The greater the likely anticompetitive effects, the greater the likely efficiencies must be for the collaboration to pass muster under the antitrust laws. The Agencies have articulated the standards for both financial and clinical integration in various policy statements, speeches, business reviews, and advisory opinions. For example, the Agencies' *Statements of Antitrust Enforcement Policy in Health Care* (the "Health Care Statements") explain that where participants in physician or multiprovider joint ventures have agreed to share substantial financial risk as defined in the Health Care Statements, their risk-sharing arrangement generally establishes both an overall efficiency goal for the venture and the incentives for the participants to meet that goal.¹³ Accordingly, the setting of price is integral to the venture's use of such an arrangement and therefore warrants evaluation under the rule of reason.¹⁴ The Health Care Statements provide examples of financial risk-sharing arrangements that can satisfy this standard, but also recognize that other acceptable financial risk-sharing arrangements might develop.¹⁵

The Health Care Statements further explain that provider joint ventures also may involve clinical integration sufficient to ensure that the venture is likely to produce significant efficiencies.¹⁶ Clinical integration can be evidenced by the joint venture implementing an active and ongoing program to evaluate and modify practice patterns by the venture's providers and to create a high degree of interdependence and cooperation among the providers to control costs and ensure quality.¹⁷ Federal Trade Commission staff advisory opinions discuss evidence that appears sufficient to demonstrate clinical integration in specific factual circumstances.¹⁸

The Affordable Care Act provides that CMS may approve ACOs that 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.¹⁹ CMS has further defined these eligibility criteria through regulations.²⁰

By contrast, the Agencies have not previously listed specific criteria required to establish clinical integration, but instead have responded to detailed proposals from health care providers who have decided on specific ways to integrate their health care delivery systems to improve quality and lower costs.²¹ The Agencies have chosen to avoid prescribing how clinical integration should take place. Nonetheless, the Agencies recognize that health care providers seeking to create ACOs in the context of the Shared Savings Program could benefit from additional antitrust guidance in evaluating whether an ACO that satisfies the CMS eligibility criteria could be subject to an antitrust investigation and potential challenge as engaging in per se illegal conduct.

The Agencies have determined that CMS's eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements and identified in the context of specific proposals for clinical integration from health care providers.²² The Agencies also have determined that organizations meeting the eligibility requirements for the Shared Savings Program are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care

⁸ The Policy Statement provides guidance to assist ACOs in determining whether they are likely to present competitive concerns. It does not reflect the full analysis that the Agencies may use in evaluating ACOs or any other transaction or course of conduct. "Newly formed ACOs" are defined *infra* at note 23.

⁹ A "collaboration" comprises an agreement or set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in economic activity, and the resulting economic activity. U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for Collaborations Among Competitors* 1.1 (2000) [hereinafter *Collaboration Guidelines*], available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

¹⁰ An ACO participant can be an independent physician solo practice, a fully integrated physician group practice, an inpatient facility, or an outpatient facility. The Policy Statement's definition of ACO participant may differ from CMS's use of the term.

¹¹ *Collaboration Guidelines*, *supra* note 9, 1.3.

¹² U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* (rev. ed. 2010), available at <http://www.justice.gov/atr/public/guidelines/hmg-2010.pdf>.

¹³ U.S. Dep't of Justice & Fed. Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care*, Statements 8 and 9 (1996) [hereinafter *Health Care Statements*], available at <http://www.ftc.gov/reports/hlth3s.pdf>.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ See, e.g., Christine A. Varney, Assistant Attorney Gen., Antitrust Div., U.S. Dep't of Justice, *Antitrust and Healthcare* at 12 (May 24, 2010), available at <http://www.justice.gov/atr/public/speeches/258898.pdf>.

¹⁸ See Fed. Trade Comm'n, *Advisory Opinions* (1982–2010), available at <http://www.ftc.gov/bc/healthcare/industryguide/advisory.htm#2010>.

¹⁹ Patient Protection and Affordable Care Act, Public Law 111–48, 3022, 124 Stat. 119, 395–99 (2010).

²⁰ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 42 CFR part 425 (2011) [hereinafter *CMS ACO Rule*].

²¹ See generally FTC Staff Advisory Opinions (2002–Present), available at <http://www.ftc.gov/bc/healthcare/industryguide/opinionguidance.htm>; see also U.S. Dep't of Justice & Fed. Trade Comm'n, *Improving Health Care: Another Dose of Competition* ch. 2 at 34–41 (July 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

²² *Id.* See also, e.g., TriState Health Partners, Inc. Advisory Opinion from FTC Staff (Apr. 13, 2009) (evaluating TriState Health Partners' proposal and stating that, if implemented as proposed, FTC staff would not recommend that the Commission challenge the proposed program), available at <http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf>.

services through their participants' joint efforts.

To assess whether an ACO has improved quality and reduced costs to Medicare, CMS will collect and evaluate cost, utilization, and quality metrics relating to each ACO's performance in the Shared Savings Program. The results of this monitoring will help the Agencies determine whether the CMS eligibility criteria have required a sufficient level of clinical integration to produce cost savings and quality improvements, and may help inform the Agencies' future analysis of ACOs and other provider organizations.

In light of CMS's eligibility criteria, and its monitoring of each ACO's results, the Agencies will treat joint negotiations with private payers as reasonably necessary to an ACO's primary purpose of improving health care delivery, and will afford rule of reason treatment to an ACO that meets CMS's eligibility requirements for, and participates in, the Shared Savings Program and uses the same governance and leadership structures and clinical and administrative processes it uses in the Shared Savings Program to serve patients in commercial markets. The Agencies further note that CMS's regulations allow an ACO to propose alternative ways to establish clinical management and oversight of the ACO, and the Agencies are willing to consider other proposals for clinical integration as well.

IV. The Agencies' Antitrust Analysis of ACOs That Meet CMS Eligibility Criteria

The following Sections provide additional antitrust guidance for ACOs that are eligible and intend, or have been approved, to participate in the Shared Savings Program, including those ACOs that also plan to operate in the commercial market. Section A sets forth a safety zone for certain ACOs that are highly unlikely to raise significant competitive concerns and, therefore, will not be challenged by the Agencies under the antitrust laws, absent extraordinary circumstances.

The Agencies emphasize that ACOs outside the safety zone may be procompetitive and legal. An ACO that does not impede the functioning of a competitive market will not raise competitive concerns. The creation of a safety zone reflects the view that ACOs that fall within the safety zone are highly unlikely to raise significant competitive concerns; it does not imply that ACOs outside the safety zone necessarily present competitive concerns.

Section B offers options for ACOs that seek additional antitrust guidance. It

describes certain conduct all ACOs generally should avoid, other conduct that ACOs with high Primary Service Area ("PSA") shares or other possible indicia of market power may wish to avoid, and the process by which a newly formed ACO²³ may obtain a voluntary expedited antitrust review.

A. The Antitrust Safety Zone for ACOs in the Shared Savings Program

This Section sets forth an antitrust safety zone for ACOs that meet the CMS eligibility criteria for and intend, or have been approved, to participate in the Shared Savings Program and are highly unlikely to raise significant competitive concerns. The Agencies will not challenge ACOs that fall within the safety zone, absent extraordinary circumstances.²⁴

To determine whether it falls within the safety zone, an ACO should evaluate the ACO's share of services in each ACO participant's PSA. Although a PSA does not necessarily constitute a relevant antitrust geographic market, it nonetheless serves as a useful screen for evaluating potential competitive effects.

The Policy Statement focuses on PSA shares for three major categories of services: physician specialties, major diagnostic categories ("MDCs") for inpatient facilities, and outpatient categories, as defined by CMS, for outpatient facilities.²⁵ Although these services are useful in evaluating potential anticompetitive effects, they do not necessarily constitute relevant antitrust product markets. The Appendix to the Policy Statement describes how to calculate an ACO's shares of these services in the relevant PSAs, identifies data sources available for these calculations, and provides illustrative examples.²⁶

For an ACO to fall within the safety zone, independent ACO participants

that provide the same service (a "common service") must have a combined share of 30 percent or less of each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from that PSA.²⁷ As noted above, a service is defined as a primary specialty for physicians, an MDC for inpatient facilities, or an outpatient category for outpatient facilities. The PSA for each participant is defined as "the lowest number of postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients],"²⁸ separately for all physician, inpatient, or outpatient services. Thus, for purposes of determining whether the ACO is eligible for the safety zone, each independent physician solo practice, each fully integrated physician group practice, each inpatient facility (even if part of a hospital system), and each outpatient facility will have its own PSA. In addition, each inpatient facility hospital will have separate PSAs for its (1) inpatient services, (2) outpatient services, and (3) physician services provided by its physician employees, if any.²⁹

As described below, the availability of the PSA safety zone differs in some cases depending on whether an ACO participant is exclusive or non-exclusive to the ACO. To participate in an ACO on a non-exclusive basis, a participant must be allowed to contract with private payers through entities other than the ACO, including contracting individually or through other ACOs or analogous collaborations. The ACO must be non-exclusive in fact and not just in name. Exclusivity may be present explicitly or implicitly, formally or informally, through a written or de facto agreement as shown by conduct.³⁰

Hospitals and Ambulatory Surgical Centers. Any hospital or ambulatory surgery center ("ASC") participating in

²³ "Newly formed ACOs" are those ACOs that, as of March 23, 2010, the date on which the Patient Protection and Affordable Care Act was enacted, had not yet signed or jointly negotiated any contracts with private payers, and have not yet participated in the Shared Savings Program. Patient Protection and Affordable Care Act, Public Law 111-48, 124 Stat. 119 (2010). An ACO is not newly formed if it comprises only the same, or a subset of the same, providers that signed or jointly negotiated contracts with private payers on or before March 23, 2010.

²⁴ Extraordinary circumstances could include, for example, ACO participants engaging in collusion or improper exchanges of price information or other competitively sensitive information with respect to their sale of competing services outside the ACO. See *infra* IV(B)(1)(a).

²⁵ The Policy Statement does not apply to other types of providers (e.g., clinical laboratories or nursing homes). Nonetheless, the Agencies recognize that those providers may participate in ACOs.

²⁶ The ACO may send questions regarding PSA share calculations to aco_psa_questions@ftc.gov.

²⁷ Thus, if two otherwise independent physician group practices form an ACO and each includes cardiologists and oncologists, each physician group practice would be an independent participant in the ACO, and cardiology and oncology would be common services. If, on the other hand, one physician group practice consists only of cardiologists and the other only of oncologists, then there would be no common services and the ACO would fall within the safety zone regardless of its share, subject to the dominant participant limitation described below.

²⁸ Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 FR 16,094 (Mar. 26, 2004).

²⁹ See Appendix to the Policy Statement.

³⁰ The Health Care Statements further explain the indicia of non-exclusivity that the Agencies consider relevant to this evaluation. Health Care Statements, *supra* note 13, at 66-67.

an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share.

Physicians. The safety zone for physicians (regardless of whether the physicians are hospital employees) does not differ based on whether the physicians are exclusive or non-exclusive to the ACO, unless they fall within the rural exception or dominant participant limitation described below.

1. Rural Exception

An ACO that exceeds the 30 percent PSA share may still fall within the safety zone if it qualifies for this rural exception. The rural exception allows such an ACO to include one physician or physician group practice³¹ per specialty from each rural area³² on a non-exclusive basis and still fall within the safety zone, provided the physician's or physician group practice's primary office is in a zip code that is classified as "isolated rural" or "other small rural."³³ Thus, an ACO may qualify for the safety zone as long as it includes only one physician or physician group practice per specialty for each county that contains at least one "isolated rural" or "other small rural" zip code, even if the inclusion of

these physicians causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA.

Likewise, an ACO may include Rural Hospitals³⁴ on a non-exclusive basis and qualify for the safety zone, even if the inclusion of a Rural Hospital causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA.

2. Dominant Participant Limitation

The dominant participant limitation applies to any ACO that includes a participant with a greater than 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA. Under these conditions, the ACO participant must be non-exclusive to the ACO for the ACO to fall within the safety zone.³⁵ In addition, to fall within the safety zone, an ACO with a dominant participant cannot require a private payer to contract exclusively with the ACO or otherwise restrict a private payer's ability to contract or deal with other ACOs or provider networks.

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The safety zone will remain in effect for the duration of an ACO's agreement with CMS, provided the ACO continues to meet the safety zone's requirements. An ACO will not lose its safety zone status solely because it attracts more patients.

B. ACOs Outside the Safety Zone

ACOs that fall outside the safety zone may be procompetitive and lawful. An ACO that does not impede the

functioning of a competitive market will not raise competitive concerns.³⁶

Nonetheless, there may be circumstances in which an ACO would raise competitive concerns. This section describes some types of conduct by an ACO that, under certain circumstances, may raise competitive concerns and outlines how an ACO may obtain further antitrust guidance from the Agencies.

1. Conduct To Avoid

a. Improper Sharing of Competitively Sensitive Information

Regardless of an ACO's PSA shares or other indicia of market power, significant competitive concerns can arise when an ACO's operations lead to price-fixing or other collusion among ACO participants in their sale of competing services outside the ACO. For example, improper exchanges of prices or other competitively sensitive information among competing participants could facilitate collusion and reduce competition in the provision of services outside the ACO, leading to increased prices or reduced quality or availability of health care services.³⁷ ACOs should refrain from, and implement appropriate firewalls or other safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO.³⁸

b. Conduct by ACOs With High PSA Shares or Other Possible Indicia of Market Power That May Raise Competitive Concerns

For ACOs with high PSA shares or other possible indicia of market power, the Agencies identify four types of conduct that may raise competitive concerns.³⁹ The Agencies recognize that

³⁶ The Agencies emphasize that PSA shares are useful as a screening device and that alternative data and information also may be useful in evaluating the likely competitive significance of a particular ACO. The Agencies recognize that an ACO may have reliable evidence other than PSA shares from which the ACO may reasonably conclude that the ACO is unlikely to raise competitive concerns.

³⁷ Health Care Statements 4, 5, and 6 relate to the sharing of data and information among competing providers. The Health Care Statements set forth safety zones for providers' collective provision of fee- and non-fee-related information to health care purchasers and participation in exchanges of price and cost information. The Health Care Statements also provide further guidance on the distinctions between legitimate information sharing and information sharing that may facilitate collusion or otherwise raise competitive concerns. Health Care Statements, *supra* note 13, at 40–52.

³⁸ ACOs within the safety zone should also refrain from this conduct. *See supra* note 24.

³⁹ ACOs with high PSA shares or other possible indicia of market power also should consider the

³¹ To qualify for the rural exception, the physician group practice must be treating patients as a fully integrated practice group as of the date of the Policy Statement. The practice group can add or eliminate physicians and still remain in the safety zone, as long as the number of full-time equivalent physicians in the practice group does not increase during the ACO's Shared Savings Program agreement period. For the purposes of the Policy Statement, Federally Qualified Health Centers and Rural Health Clinics, as defined by the Social Security Act, are considered physician group practices. 42 U.S.C. 1396d (2006); 42 U.S.C. 1395x(aa) (2006). A physician or physician group practice that qualifies for the rural exception may obtain "call coverage" from other physicians in the same rural area without losing its safety zone status as long as those physicians do not participate in the ACO.

³² For the purposes of the Policy Statement, a "rural area" means any county containing at least one zip code that has been classified as "isolated rural," or "other small rural," according to the WWAMI Rural Health Research Center of the University of Washington's seven category classification. <http://depts.washington.edu/uwruca/ruca-maps.php>. These are zip codes that have a Rural Urban Commuting Area ("RUCA") code of 10.0, 10.2–10.6, 8.0, 8.2–8.4, or 9.0–9.2 as developed by the WWAMI Rural Health Research Center of the University of Washington and the U.S. Department of Agriculture's Economic Research Service. <http://www.ers.usda.gov/briefing/Rurality/RuralUrbanCommutingAreas/>. The RUCA code for any particular zip code can be found at <http://depts.washington.edu/uwruca/ruca-download.php>.

³³ A physician's or physician group practice's primary office is the office in which the majority of the physician's or physician group practice's patient visits take place. If no office serves a majority of a physician's patients, the majority of patient visits must take place in offices located in "isolated rural" or "other small rural" zip codes to qualify for the rural exception.

³⁴ For the purposes of the Policy Statement, a Rural Hospital is defined as a Sole Community Hospital, a Critical Access Hospital, or any other acute care hospital located in a rural area that has no more than 50 acute care inpatient beds and is located at least 35 miles from any other inpatient acute care hospital. A Sole Community Hospital is a hospital that is paid under the Medicare hospital inpatient prospective payment system and meets the criteria for Sole Community Hospital status as specified at 42 CFR 412.92. *See also* Dep't of Health and Human Servs., Ctrs. for Medicare & Medicaid Servs., Sole Community Hospital, Rural Health Fact Sheet Series (Oct. 2010), available at <https://www.cms.gov/MLNProducts/downloads/SoleCommHospFctshst508-09.pdf>; Social Security Act, 42 U.S.C. 1395ww(d)(5)(D)(iii) (2006). A Critical Access Hospital is a hospital that has been certified as a Medicare Critical Access Hospital, as described in 42 CFR part 485 subpart F. *See also* 42 U.S.C. 1395i–4(c)(2).

³⁵ For example, a physician group participating in the ACO may comprise a specialty not found in any other ACO participant. In this case, the ACO may be eligible for the safety zone even if the physician group's share exceeds 50 percent, but only if the physician group participates in the ACO on a non-exclusive basis and the ACO does not restrict a private payer's ability to contract or deal with other ACOs or provider groups.

some of the conduct described in (1) through (4) below may be competitively neutral or even procompetitive, depending on the circumstances, including whether the ACO has market power. For example, an ACO that requires its participants to contract exclusively through the ACO to increase the ACO's efficiency is generally less likely to raise competitive concerns the greater the number of competing ACOs or independent providers available to contract with private payers or to participate in competing ACOs or other analogous collaborations.

An ACO with high PSA shares or other possible indicia of market power may wish to avoid the conduct set forth in (1) through (4) below. Depending on the circumstances, the conduct identified below may prevent private payers from obtaining lower prices and better quality service for their enrollees:

1. Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "anti-tiering," "guaranteed inclusion," "most-favored-nation," or similar contractual clauses or provisions.

2. Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the private payer's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (e.g., an ACO should not require a purchaser to contract with all of the hospitals under common ownership with a hospital that participates in the ACO).

3. Contracting on an exclusive basis with ACO physicians, hospitals, ASCs, or other providers, thereby preventing or discouraging those providers from contracting with private payers outside the ACO, either individually or through other ACOs or analogous collaborations.⁴⁰

4. Restricting a private payer's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost,

likely competitive effects of other types of conduct in which they engage.

⁴⁰ Note that, although CMS requires the physician practice through which physicians bill for primary care services and to which Medicare beneficiaries are assigned to contract exclusively with one ACO for the purposes of beneficiary assignment, CMS does not require either those individual physicians or physician practices to contract exclusively through the same ACO for the purposes of providing services to private health plans' enrollees. CMS ACO Rule, *supra* note 20.

quality, efficiency, and performance measures used in the Shared Savings Program.

2. Availability of Expedited Voluntary Antitrust Review

Any newly formed ACO⁴¹ that desires further antitrust guidance regarding its formation and planned operation can seek expedited 90 day review from the Agencies.⁴² During expedited review, the reviewing Agency will examine whether the ACO will likely harm competition by increasing the ACO's ability or incentive profitably to raise prices above competitive levels or reduce output, quality, service, or innovation below what likely would prevail in the absence of the ACO.⁴³ To the extent possible in the 90 day review period, the Agency will consider factors in the rule of reason analysis as explained in the *Antitrust Guidelines for Collaborations Among Competitors* and the Health Care Statements.⁴⁴

The ACO should submit its request for expedited review, along with a completed cover sheet (available on the Agencies' Web sites), to both Agencies before its entrance into the Shared Savings Program, and the Agencies will then promptly determine, and notify the applicant, which Agency will be the reviewing Agency.⁴⁵ As soon as the Agencies notify the applicant which Agency will be the reviewing Agency, the applicant should provide all of the documents and information listed below to the reviewing Agency. The Agencies shall establish a Federal Trade Commission/Department of Justice ACO Working Group to collaborate and discuss issues arising out of the ACO reviews. This process will allow ACOs to rely on the expertise of both Agencies and ensure efficient, cooperative, and expeditious reviews.⁴⁶

⁴¹ See *supra* note 23.

⁴² When the Federal Trade Commission is the reviewing Agency, Commission staff will perform the ACO review pursuant to the Commission's authorization of its staff in 16 CFR 1.1(b). When the Antitrust Division is the reviewing Agency, the Assistant Attorney General in charge of the Antitrust Division or the Assistant Attorney General's delegate will sign the review letter. 28 CFR 50.6.

⁴³ See Collaboration Guidelines, *supra* note 9, 1.2.

⁴⁴ See *id.* 3.3; Health Care Statements, *supra* note 13, Statements 8 and 9.

⁴⁵ A request for an expedited review must be submitted in writing to either (1) the Office of the Assistant Attorney General, Antitrust Division, Department of Justice, Main Justice Building, Room 3109, 950 Pennsylvania Avenue NW., Washington, DC 20530 (for non-U.S. Postal Service deliveries, use ZIP code 20004), and to the Federal Trade Commission, Bureau of Competition, Premerger Notification Office, Room 303, 600 Pennsylvania Avenue NW., Washington, DC 20580 or (2) acorequest@usdoj.gov and acorequest@ftc.gov.

⁴⁶ For example, it has been standard practice for the Agencies to share with each other their

To start the 90 day review, the reviewing Agency must receive all of the following documents and information:⁴⁷

1. The application and all supporting documents that the ACO plans to submit, or has submitted, to CMS, including a sample of each type of participation agreement and each type of document that reflects a financial arrangement between or among the ACO and its participants, as well as the ACO's bylaws and operating policies.

2. Documents discussing

a. the ACO's business strategies or plans to compete in the Medicare and commercial markets, including those relating to the ACO's likely impact on the prices, cost, or quality of any service provided by the ACO to Medicare beneficiaries, commercial health plans, or other payers; and

b. the level and nature of competition among participants in the ACO, and the competitive significance of the ACO and ACO participants in the markets in which they provide services.

3. Information sufficient to show the following:

a. The common services that two or more ACO participants provide to patients from the same PSA, as described in the Appendix, and the identity of the ACO participants or providers providing those services.

b. The PSA of each ACO participant, and either PSA share calculations the ACO may have performed or other data that show the current competitive significance of the ACO or ACO participants, including any data that describe the geographic service area of each participant and the size of each participant relative to other providers serving patients from that area.

c. Restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge private payers that do not contract through the ACO.

d. The identity, including points of contact, of the five largest commercial health plans or other private payers, actual or projected, for the ACO's services.

e. The identity of any other existing or proposed ACO known to operate, or

proposed health care business review and staff advisory opinion letters before issuing them in final form to ensure application of consistent standards of antitrust review.

⁴⁷ The ACO must represent in writing that it has undertaken a good-faith search for the documents and information specified in the Policy Statement and, where applicable, provided all responsive material. Moreover, the Agencies may request additional documents and information where necessary to evaluate the ACO. A request for additional documents and information, however, will not extend the 90 day review period.

known to plan to operate, in any market in which the ACO will provide services.

Moreover, the ACO may submit any other documents and information that it believes may be helpful to the Agency in assessing the ACO's likely impact on competition. The documents and information may include anything that may establish a clearer picture of competitive realities in the market, including:

1. evidence that the ACO is not likely to have market power in the relevant market;
2. any substantial procompetitive justification for why the ACO needs its proposed composition to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market; and
3. if relevant, an explanation as to why the ACO engaging in any of the four types of conduct listed in Section IV.B of the Policy Statement would not be anticompetitive or might even be procompetitive.

Within 90 days of receiving all of the above documents and information,⁴⁸ the reviewing Agency will advise the ACO that the ACO's formation and operation, as described in the documents and information provided to the Agency,

1. does not likely raise competitive concerns or, if appropriate, does not likely raise competitive concerns conditioned on the ACO's written agreement to take specific steps to remedy concerns raised by the Agency;
2. potentially raises competitive concerns; or
3. likely raises competitive concerns.

As is current practice, both the request letter and the reviewing Agency's response will be made public consistent with applicable confidentiality provisions.⁴⁹ Also, consistent with current practice, if it appears that an ACO's formation or conduct may be anticompetitive, the Agency may investigate the ACO and, if appropriate, take enforcement action at any time before or during the ACO's

participation in the Shared Savings Program.

Appendix

This Appendix explains how to calculate the PSA shares of common services discussed in the Policy Statement.⁵⁰ There are three steps:

1. Identify each service provided by at least two independent ACO participants (i.e., each common service). A service is defined as follows:

- a. For physicians, a service is the physician's primary specialty, as designated on the physician's Medicare Enrollment Application. Each specialty is identified by its Medicare Specialty Code ("MSC"), as defined by CMS.⁵¹

- b. For inpatient facilities (e.g., hospitals), a service is an MDC.⁵²

- c. For outpatient facilities (e.g., ASCs or hospitals), a service is an outpatient category, as defined by CMS.⁵³

2. Identify the PSA(s) for each participant (e.g., physician group, inpatient facility, or outpatient facility) in the ACO that provides any common service. For each participant, the PSA is defined as the lowest number of postal zip codes from which the participant draws at least 75 percent of its patients.⁵⁴ Each independent physician solo practice, each fully integrated physician group practice, each inpatient facility (even if part of a hospital system), and each outpatient facility will have its own PSA. In addition, each inpatient facility will have a separate PSA for inpatient services, outpatient services, and physician services provided by its physician employees.

3. Separately for each common service, calculate the ACO's PSA share in the PSA of each participant that provides that service if at least two participants provide that service to patients from that PSA. If an entity owned by an ACO participant provides services in a PSA, those services should be included in the share calculation regardless of whether the affiliated organization participates in the ACO.

- a. For physician services, the ACO should calculate its shares of Medicare fee-for-service allowed charges (i.e., the amount that a provider is entitled to receive for the service provided) during the most recent calendar year for which data are available.

⁵⁰ Any ACO participant that wants to determine whether it meets the dominant participant limitation of the safety zone should calculate its PSA share in a similar manner.

⁵¹ CMS will make publicly available the most current list of applicable specialties. Specialty Codes 01 (general practice), 08 (family practice), 11 (internal medicine), and 38 (geriatric medicine) are considered "Primary Care" specialties, and are treated as a single service for the purposes of the Policy Statement.

⁵² CMS will make publicly available the most current list of MDCs.

⁵³ CMS will make publicly available a list of applicable outpatient categories as well as data necessary to assign procedure codes to the appropriate category.

⁵⁴ This PSA calculation is based on the Stark II regulations. Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 FR 16,094 (Mar. 26, 2004).

CMS will make public the data necessary to identify the full range of services and the aggregate fee-for-service allowed charges for each service, by zip code.

- b. For inpatient services, the ACO should calculate its shares of inpatient discharges, using state-level all-payer hospital discharge data where available, for the most recent calendar year for which data are available. For ACOs located in a state where all-payer hospital discharge data are not available, the ACO should calculate its shares of Medicare fee-for-service payments during the most recent federal fiscal year for which data are available. CMS will make public the data necessary to identify the full range of services and the aggregate fee-for-service payments for each service, by zip code.

- c. For outpatient services, the ACO should calculate its shares of Medicare fee-for-service payments for hospitals and fee-for-services allowed charges for ASCs during the most recent calendar year for which data are available, or the ACO can use state-level all-payer claims data, if available. CMS will make public the data necessary to identify the full range of services and the aggregate fee-for-service payments and allowed charges for each service, by zip code.

For those services that are rarely used by Medicare beneficiaries (e.g., pediatrics, obstetrics, gynecology, and neonatal care) and for which all-payer data are not available, the ACO may use other available data to determine the relevant shares. For example, for those services, data on the number of active physicians within the specialty and located within the PSA may be a reasonable alternative for the purposes of calculating shares of physician services.

Example of How To Calculate an ACO's PSA Shares

The following example illustrates how to calculate the ACO's relevant PSA shares. Assume that two independent physician practices, two independent hospitals, and an ASC propose to form an ACO. For purposes of this example, further assume that the hospitals do not directly employ physicians. If they do, then services provided by the hospitals' employed physicians would need to be taken into account in determining the PSA and calculating the ACO's shares for each common physician service where at least two participants provide that service to patients from the same PSA.

For the physician groups:

1. Identify the physician groups' common MSCs. In this example, Physician Group A ("PG A") has physicians with general surgery (MSC 02) and orthopedic surgery specialties (MSC 20). Physician Group B ("PG B") has physicians with orthopedic surgery (MSC 20) and cardiology (MSC 06) specialties. The only common service is orthopedic surgery, not general surgery or cardiology, because PG A does not have cardiologists and PG B does not have general surgeons.

2. Identify the zip codes that make up the PSA for each physician group. In this example, there will be two PSAs: one for PG A ("PSA A") and one for PG B ("PSA B").

3. Determine the ACO's share in each of the PSAs. In this example, both PG A's and PG B's orthopedic surgeons serve patients

⁴⁸ Upon the applicant's request, the reviewing Agency may extend the review beyond 90 days, subject to the availability of resources or other discretionary considerations.

⁴⁹ The provisions regarding public access to review information, non-disclosure of competitively sensitive or business confidential information, and retention of review information set forth in 28 CFR 50.6 (2010) (U.S. Department of Justice business review letters) and 16 CFR 1.1–1.4 (2010) (FTC advisory opinions) will generally apply to the expedited review process. Requesters should follow applicable Agency procedures governing the designation of competitively sensitive business information and other information the requesters wish not to be made public in connection with a review request. See 28 CFR 50.56 (U.S. Department of Justice procedures); 16 CFR 4.2, 4.9, and 4.10 (FTC procedures).

located in both PSAs. Thus, shares need to be calculated in PSA A and PSA B. The ACO's share of orthopedic surgery in PSA A would be the total Medicare allowed charges for claims billed by the ACO's orthopedic surgeons (which are PG A's and PG B's total allowed charges for claims billed by orthopedic surgeons for Medicare beneficiaries in PSA A's zip codes) divided by the total allowed charges for orthopedic surgery for all Medicare beneficiaries in PSA A. Likewise, the ACO's share of orthopedic surgery services in PSA B would be the total Medicare allowed charges for claims billed by the ACO's orthopedic surgeons (which are PG A's and PG B's total allowed charges for claims billed by orthopedic surgeons for Medicare beneficiaries in PSA B's zip codes) divided by the total allowed charges for orthopedic surgery for all Medicare beneficiaries in PSA B.

For the inpatient services:

1. Identify the hospitals' common MDCs. In this example, Hospital 1 and Hospital 2 each provide services in 10 MDCs, but only two are common services: cardiac care (i.e., services related to diseases and disorders of the circulatory system—MDC 05) and orthopedic care (i.e., services related to diseases and disorders of the musculoskeletal system and connective tissue—MDC 08).

2. Identify the zip codes that make up the PSA for inpatient services for each hospital. In this example, there will be two PSAs: Hospital 1's PSA and Hospital 2's PSA.

3. Determine the ACO's share in each of the PSAs. In this example, Hospital 1 and Hospital 2 both serve cardiac patients located in each hospital's PSA and both serve orthopedic patients in each hospital's PSA. Thus, shares need to be calculated in both

PSAs, resulting in four shares. This hypothetical ACO is located in a state for which all-payer hospital discharge data are available, so the ACO's share of cardiac care in Hospital 1's PSA would be the ACO's total number of inpatient discharges for MDC 05 (which are Hospital 1's and Hospital 2's total inpatient discharges for cardiac care in Hospital 1's PSA) divided by the total number of inpatient discharges for MDC 05 for all residents of this PSA. Use the analogous process to calculate the ACO's share of cardiac care in Hospital 2's PSA, the ACO's share of orthopedic care in Hospital 1's PSA, and the ACO's share of orthopedic care in Hospital 2's PSA.

For the outpatient services:

1. Identify the hospitals' and ASC's common outpatient categories. In this example, Hospital 1 does not provide outpatient services, while Hospital 2 and the ASC each provide services in 10 outpatient categories, but only two are common services: cardiovascular tests/procedures (outpatient category 2) and musculoskeletal procedures (outpatient category 5).

2. Identify the zip codes that make up the PSA for outpatient services for Hospital 2 and the ASC. In this example, there will be two PSAs: Hospital 2's PSA for outpatient services and the ASC's PSA.

3. Determine the ACO's share in each of the PSAs. In this example, Hospital 2 and the ASC both provide cardiovascular tests/procedures to patients located in each facility's PSA, and both provide musculoskeletal procedures to patients located in each facility's PSA. Thus, shares need to be calculated in both PSAs, resulting in four shares. The ACO's share of cardiovascular tests/procedures in Hospital

2's PSA would be the ACO's total Medicare fee-for-service payments/charges for outpatient category 2 (which are Hospital 2's total payments and the ASC's total allowed charges for outpatient cardiovascular tests/procedures for Medicare beneficiaries in Hospital 2's PSA) divided by the total payments/charges for outpatient category 2 for all Medicare beneficiaries in this PSA. Use the analogous process to calculate the ACO's share of cardiovascular tests/procedures in the ASC's PSA, the ACO's share of musculoskeletal procedures in Hospital 2's PSA, and the ACO's share of musculoskeletal procedures in the ASC's PSA.

Application to the Safety Zone: In this example, the ACO would calculate ten PSA shares. If all of the shares are 30 percent or below, and the hospitals and the ASC are non-exclusive to the ACO, then the ACO would fall within the safety zone. In other words, the 30 percent threshold must be met in each relevant PSA for each common service. If that condition is not met, then the ACO does not fall within the safety zone, unless it qualifies for the rural exception.

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