Agencies further note that CMS’s proposed regulations allow an ACO to propose alternative ways to establish clinical integration, 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

As an initial step in determining whether an ACO is likely to raise competitive concerns, the Agencies will use a streamlined analysis that evaluates the ACO’s share of services in each ACO participant’s Primary Service Area (“PSA”). The higher the PSA share, the greater the risk the ACO will be anticompetitive. An ACO with high PSA shares may reduce quality, innovation, and choice for Medicare and commercial patients, in part by reducing the ability of competing equally or more efficient ACOs to form. High PSA shares also may allow the ACO to raise prices to commercial health plans above competitive levels. On the other hand, if there are already other competing ACOs, or sufficient suitable unaffiliated physicians and hospitals to form competing ACOs, it is less likely that the ACO would raise significant competitive concerns.

The following Sections describe how the Agencies will treat ACO applicants that meet CMS eligibility criteria for the Shared Savings Program, based on different ranges of PSA shares. Depending on an ACO’s range of PSA shares, CMS may mandate, or an ACO may choose to seek, an expedited antitrust review. An ACO will submit its request for expedited review to both Agencies, and the Agencies will then determine which Agency will be the reviewing Agency and will notify the applicant of such. 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.

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 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. ACOs in the safety zone, therefore, have no obligation to contact the Agencies.

22 While a PSA does not necessarily constitute a relevant antitrust geographic market, it nonetheless provides a useful tool for evaluating potential competitive effects.
23 We expect ACOs to maintain, for the duration of the agreement period with CMS, the data on which they relied to calculate their PSA shares.
25 For example, it has been standard practice for the Agencies to share with each other their 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.
The Agencies emphasize that ACOs outside the safety zone are not presumptively unlawful. Indeed, ACOs outside the safety zone frequently may be procompetitive and lawful. Rather, the creation of a safety zone simply reflects a view that ACOs that fall within it are highly unlikely to raise significant competitive concerns, so no initial competitive review is necessary.

For an ACO to fall within the safety zone, independent ACO participants (e.g., physician group practices) 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. For each service is defined as “the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]” for that service.

Any hospital or ambulatory surgery center (“ASC”) participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share. In a non-exclusive ACO, a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers. The safety zone for physician and other provider services (regardless of whether the physicians or other providers are hospital employees) does not differ based on whether the physicians or other providers are exclusive or non-exclusive to the ACO, unless they fall within the rural exception or dominant provider limitation described below.

The Appendix to this Policy Statement describes how, and identifies the data sources available, to calculate an ACO’s shares of services (i.e., physician specialties, major diagnostic categories (“MDCs”) for inpatient facilities, and outpatient categories for outpatient facilities) in the relevant PSAs and provides examples.

**Rural Exception**: An ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis and qualify for the safety zone, 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 for that service. Likewise, an ACO may include Rural Hospitals on a non-exclusive basis and

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26 For example, if two physician group practices form an ACO and each includes cardiologists and oncologists, 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 are no common services and the ACO falls within the safety zone regardless of its share, subject to the dominant provider limitation, described below.


28 The ACO must be non-exclusive in fact and not just in name. The Health Care Statements explain the indicia of non-exclusivity that the Agencies consider relevant to this evaluation. HEALTH CARE STATEMENTS, supra note 9, at 66-67.

29 While these services do not necessarily constitute relevant antitrust product markets, they nonetheless provide a useful tool for evaluating potential competitive effects.

30 The definition and list of rural counties are available at [http://www.census.gov/geo/www/ua/2010urbanruralclass.html](http://www.census.gov/geo/www/ua/2010urbanruralclass.html).
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 for that service.

**Dominant Provider Limitation**: This 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 (a “dominant provider”) must be non-exclusive to the ACO to fall within the safety zone. In addition, to fall within the safety zone, an ACO with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer’s ability to contract or deal with other ACOs or provider networks.

The safety zone will remain in effect for the duration of an ACO’s agreement with CMS, unless there is a significant change to the ACO’s provider composition. An ACO that is not within the rural exception and later exceeds the 30 percent share limitation solely because it attracts more patients will not lose its safety zone status.

**B. Mandatory Antitrust Agency Review of ACOs Exceeding the 50 Percent PSA Share Threshold**

As described in the CMS regulations, an ACO that does not qualify for the rural exception cannot participate in the Shared Savings Program if its share exceeds 50 percent for any common service that two or more independent ACO participants provide to patients in the same PSA, unless, as part of the CMS application process, the ACO provides CMS with a letter from one of the Agencies stating that the reviewing Agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws. This 50 percent share threshold for mandatory review provides a valuable indication of the potential for competitive harm from ACOs with high PSA shares. When conducting a review, however, the Agencies will consider any information or alternative data suggesting that the PSA shares may not reflect the ACO’s likely market power, and also will consider any substantial procompetitive justification for why

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31 For the purposes of this Policy Statement, a Rural Hospital is defined as a Sole Community Hospital or a Critical Access Hospital. A Sole Community Hospital is a hospital that is paid under the Medicare hospital inpatient prospective payment system and is either located more than 35 miles from other like hospitals or is located in a rural area, and meets the criteria for Sole Community Hospital status as specified at 42 C.F.R. § 412.92. See also [https://www.cms.gov/MLNProducts/downloads/SoleCommHospfactsht508-09.pdf](https://www.cms.gov/MLNProducts/downloads/SoleCommHospfactsht508-09.pdf). A Critical Access Hospital is a rural community hospital that has been certified as a Medicare Critical Access Hospital, based on the criteria described in 42 C.F.R. § 485 Subpart F.

32 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 commercial payer’s ability to contract or deal with other ACOs or provider groups.

33 CMS NPRM on ACOs. 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 C.F.R. § 1.1(b). When the Antitrust Division is the reviewing Agency, the Assistant Attorney General in charge of the Antitrust Division or her delegate will sign the letter. 28 C.F.R. § 50.6.
the ACO needs that proposed share to provide high-quality, cost-effective care to Medicare beneficiaries and patients in the commercial market.

The Agencies are committed to providing an expedited review of ACOs that exceed the 50 percent PSA share threshold. To obtain this expedited review, however, the ACO must submit the following documents and information to the reviewing Agency:  

1. The application and all supporting documents that the ACO plans to submit, or has submitted, to CMS or that CMS requires the ACO to retain as part of the Shared Savings Program application process

2. Documents or agreements relating to the ability of the ACO participants to compete with the ACO, either individually or through other ACOs or entities, or to any financial or other incentives to encourage ACO participants to contract with CMS or commercial payers through the proposed ACO

3. Documents discussing the ACO’s business strategies or plans to compete in the Medicare and commercial markets and 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

4. Documents showing the formation of any ACO or ACO participant that was formed in whole or in part, or otherwise affiliated with the ACO, after March 23, 2010

5. Information sufficient to show the following:
   a. The ACO’s PSA share calculations for each common service, as described in the Appendix, and the ACO’s PSA share calculations for each common service provided to commercial customers where those shares differ significantly from the PSA share calculations based on Medicare data (e.g., PSA share calculations for pediatricians or obstetricians)
   b. Restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge commercial payers that do not contract through the ACO
   c. The identity, including points of contact, of the five largest commercial health plans or other payers, actual or projected, for the ACO’s services

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34 The ACO must represent in writing that it has undertaken a good-faith search for the documents and information specified in this Policy Statement and, where applicable, provided all responsive material. Moreover, the Agencies may request additional documents and information where necessary to evaluate the ACO.
d. The identity of any other existing or proposed ACO known to operate, or known to plan to operate, in any PSA in which the ACO will provide services

All of the above documents and information must be received by the reviewing Agency at least 90 days before the last day on which CMS has stated that it will accept ACO applications to participate in the Shared Savings Program for the relevant calendar year.  

Within 90 days of receiving all of the above documents and information, the reviewing Agency will advise the ACO that the Agency

1. has no present intent to challenge or recommend challenging the ACO, as described in the documents provided and, if appropriate, conditioned on the ACO’s written agreement to take specific steps to remedy concerns raised by the Agency; or

2. is likely to challenge or recommend challenging the ACO if it proceeds.

Pursuant to CMS regulations, CMS will not approve for the Shared Savings Program an ACO that has received a letter stating that the reviewing Agency is likely to challenge or recommend challenging the ACO if it proceeds. ACOs that exceed the 50 percent threshold can reduce the likelihood of antitrust concern by avoiding the conduct set forth in Section IV.C (1) through (5) below.

C. ACOs Below the 50 Percent Mandatory Review Threshold and Outside the Safety Zone

ACOs that are outside the safety zone and below the 50 percent mandatory review threshold frequently may be procompetitive. The key issue is whether the ACO, on balance, will provide consumers with high-quality, cost-effective health care or, instead, increase price and reduce consumer choice and value. An ACO in this category that does not impede the functioning of a competitive market and that engages in procompetitive activities will not raise competitive concerns and may proceed without Agency scrutiny. As is current practice, however, if it appears that an ACO’s formation or conduct may be anticompetitive, one of the Agencies may investigate the ACO and, if appropriate, take enforcement action at any time during the ACO’s participation in the Shared Savings Program.

35 For example, if CMS sets November 1, 2011, as the last date for accepting applications to begin participation in the Shared Savings Program on January 1, 2012, then the Agency must receive all of the above documents and information on or before August 3, 2011.

36 Moreover, if at any time during the ACO’s agreement period with CMS there is a significant change to the ACO’s provider composition such that the ACO exceeds the 50 percent threshold or is materially different than what was initially reviewed, the ACO must seek antitrust review as set forth above. However, an ACO that exceeds the 50 percent threshold solely because it attracts more patients will not be required to seek antitrust review. CMS NPRM on ACOs.
To provide additional antitrust guidance for ACOs that fall below the mandatory review threshold and outside the safety zone, the Agencies identify five types of conduct that an ACO can avoid to reduce significantly the likelihood of an antitrust investigation. Specifically, the Agencies believe that an ACO in this category is highly unlikely to present competitive concerns if the ACO avoids the conduct set forth in (1) through (5) below. Avoiding the first four types of conduct is important to facilitate payers’ ability to offer insurance products that differentiate among providers based on cost and quality. Avoiding the final type of conduct ensures that the ACO does not facilitate collusion involving ACO participants that contract with payers outside the ACO.

1. Preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through “anti-steering,” “guaranteed inclusion,” “product participation,” “price parity,” or similar contractual clauses or provisions

2. Tying sales (either explicitly or implicitly through pricing policies) of the ACO’s services to the commercial 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 may not require a purchaser to contract with all the hospitals in the same network as the hospital that belongs to the ACO)

3. With an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs, or other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks

4. Restricting a commercial 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, quality, efficiency, and performance measures used in the Shared Savings Program

5. Sharing among the ACO’s provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO

An ACO that desires further certainty regarding the application of the antitrust laws to its formation and planned operation can seek an expedited review from one of the Agencies, similar to the mandatory review for ACOs above the 50 percent threshold described in Section IV.B above. The reviewing Agency will complete the review within 90 days of receiving all of the necessary documents and information (as described in the mandatory review above and according to the same deadlines) and will inform the ACO of the outcome of the review. The reviewing Agency will advise the ACO of the Agency’s intention according to the options described in Section IV.B above. Pursuant to CMS regulations, CMS will not approve for the Shared Savings Program an ACO that
has received a letter stating that the reviewing Agency is likely to challenge or recommend challenging the ACO if it proceeds.\footnote{CMS NPRM on ACOs.}

\section*{Appendix}

This Appendix explains how to calculate the PSA shares of common services discussed in this Policy Statement.\footnote{Any ACO participant that wants to determine whether it meets the dominant provider limitation of the safety zone should calculate its PSA share in a similar manner.} 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:
   
   \begin{itemize}
   \item[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.\footnote{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 this Policy Statement.}
   \item[b.] For inpatient facilities (e.g., hospitals), a service is an MDC.\footnote{CMS will make publicly available the most current list of MDCs.}
   \item[c.] For outpatient facilities (e.g., ASCs or hospitals), a service is an outpatient category, as defined by CMS.\footnote{CMS will make publicly available a list of applicable outpatient categories as well as data necessary to assign procedure codes to the appropriate category.}
   \end{itemize}

2. Identify the PSA for each common service for each participant (e.g., physician group, inpatient facility, or outpatient facility) in the ACO. For each common service and each participant, the PSA is defined as the lowest number of contiguous postal zip codes from which the participant draws at least 75 percent of its patients for that service.\footnote{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 Fed. Reg. 16094 (Mar. 26, 2004).}

3. Calculate the ACO’s PSA share for each common service in each PSA from which at least two ACO participants serve patients for that service. For physician services, the ACO applicant 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. For outpatient services, the ACO applicant should calculate its shares of Medicare fee-for-service payments during the most recent calendar year for which data are available. CMS will make public the data necessary to identify the

\footnote{CMS will make publicly available the most current list of MDCs.}