requirements on request for waiver of the new eligibility requirement for provider. This requirement aims to allow potential providers to apply for waiver of the new requirement so that these providers may continue to provide VRS on an interim basis until the new certification process becomes effective.

Potential VRS providers wishing to receive a temporary waiver shall provide, in writing, a description of the specific requirement(s) for which it is seeking a waiver, along with documentation demonstrating the applicant's plan and ability to come into compliance with all of these requirements (other than the certification requirement) within a specified period of time, which shall not exceed three months from the date on which the rules become effective. Evidence of the applicant's plan and ability to come into compliance with the new rules shall include the applicant's detailed plan for modifying its business structure and operations in order to meet the new requirements, along with submission of the following relevant documentation to support the waiver request:

- A copy of each deed or lease for each call center operated by the applicant;
- A list of individuals or entities that hold at least a 10 percent ownership share in the applicant's business and a description of the applicant's organizational structure, including the names of its executives, officers, partners, and board of directors;
- A list of all of the names of applicant's full-time and part-time employees;
- Proofs of purchase or license agreements for use of all equipment and/or technologies, including hardware and software, used by the applicant for its call center functions, including but not limited to, automatic call distribution (ACD) routing, call setup, mapping, call features, billing for compensation from the TRS fund, and registration;
- Copies of employment agreements for all of the provider's executives and CAs;
- A list of all financing arrangements pertaining to the provision of Internet-based relay service, including documentation on loans for equipment, inventory, property, promissory notes, and liens;
- Copies of all other agreements associated with the provision of Internet-based relay service; and
- A list of all sponsorship arrangements (*e.g.,* those providing financial support or in-kind interpreting or personnel service for social activities in exchange for brand marketing), including any associated agreements.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary, Office of Managing Director.*

[FR Doc. 2011–9407 Filed 4–18–11; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL RESERVE SYSTEM

### Federal Open Market Committee; Domestic Policy Directive of March 15, 2011

In accordance with Section 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on March 15, 2011.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long-run objectives, the Committee seeks conditions in reserve markets consistent with federal funds trading in a range from 0 to ¼ percent. The Committee directs the Desk to execute purchases of longer-term Treasury securities in order to increase the total face value of domestic securities held in the System Open Market Account to approximately $2.6 trillion by the end of June 2011. The Committee also directs the Desk to reinvest principal payments from agency debt and agency mortgage-backed securities in longer-term Treasury securities. The System Open Market Account Manager and the Secretary will keep the Committee informed of ongoing developments regarding the System's balance sheet that could affect the attainment over time of the Committee's objectives of maximum employment and price stability.

By order of the Federal Open Market Committee, April 6, 2011.

**William B. English,**

*Secretary, Federal Open Market Committee.*

[FR Doc. 2011–9364 Filed 4–18–11; 8:45 am]

**BILLING CODE 6210–01–P**

[1] Copies of the Minutes of the Federal Open Market Committee at its meeting held on March 15, 2011, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, DC 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's Annual Report.

## FEDERAL TRADE COMMISSION

### Department of Justice

### Antitrust Division

### Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

**AGENCY:** FTC; Antitrust Division, DOJ.

**ACTION:** Notice with comment period.

**SUMMARY:** The FTC and DOJ (the "Agencies") are proposing an enforcement policy regarding the application of the antitrust laws to health care collaborations among otherwise independent providers and provider groups, formed after March 23, 2010, the date on which the Patient Protection and Affordable Care Act was enacted, that seek to participate, or have otherwise been approved to participate, as accountable care organizations (ACOs) under the Medicare Shared Savings Program, Section 3022 of the Affordable Care Act (Patient Protection and Affordable Care Act, Public Law 111–48 (2010) and the Health Care and Education Reconciliation Act of 2010, Public Law 111–52 (2010)).

**DATES:** Public comments must be received on or before May 31, 2011.

**ADDRESSES:** Interested parties are invited to submit written comments electronically or in paper form, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gilman, (202) 326–3136 (FTC) or Gail Kursh, (202) 307–5799 (DOJ).

**SUPPLEMENTARY INFORMATION:**

### Proposed 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

[1] Patient Protection and Affordable Care Act, Public Law 111–48 (2010); the Health Care and

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 * * * meeting the criteria specified by the [Department of Health and Human Services] Secretary may work together to manage and coordinate care for Medicare * * * 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]

Recent commentary suggests that health care providers are more likely to integrate their care delivery for Medicare beneficiaries through ACOs if they can also use the ACOs for commercially insured patients.[6] This preference to operate in both the Medicare and commercial markets appears to reflect the significant resources and time required to integrate independent provider practices, a desire to provide more patients—not just Medicare patients—with the benefits of integrated health care, and the intent to develop new delivery and payment systems with commercial purchasers of health care services (including health insurance plans and other private payers).

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 consumers the benefits Congress intended for Medicare beneficiaries through the Shared Savings Program. Therefore, to maximize and foster opportunities for ACO innovation, the Agencies wish both to clarify the antitrust analysis of newly formed collaborations among independent providers that seek to become ACOs in the Shared Savings Program [7] and to coordinate the antitrust analysis with the CMS review of those ACO applications. 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 must ensure that ACOs have an opportunity to achieve substantial efficiencies, yet the analysis must remain sufficiently rigorous to protect both Medicare beneficiaries and commercially insured patients from potential anticompetitive harm.

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 (l) The ACOs to which the Policy Statement will apply; [8] (2) when the Agencies will apply rule of reason treatment to those ACOs; (3) an antitrust safety zone; (4) the Agency review of ACOs exceeding a 50 percent share threshold mandated by CMS under the Shared Savings Program; and (5) options for ACOs to obtain additional antitrust certainty if they are outside the safety zone and below the mandatory review threshold.[9]

## II. Applicability of the Policy Statement

This Policy Statement applies to collaborations among otherwise independent providers and provider groups,[10] formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate, in the Shared Savings Program. For ease of reference, we refer to such collaborations as ACOs, although they may not yet have been approved to participate as ACOs in the Shared Savings Program. We refer to the otherwise independent providers and provider groups that constitute the ACO as ACO participants. This Policy Statement, including its provisions for streamlined analysis, does not apply to mergers. Merger transactions, including transactions that meet the criteria set forth in Section 1.3 of the *Competitor Collaboration Guidelines,*[11] will be evaluated under the Agencies' *Horizontal Merger Guidelines.*[12]

## 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 substantial 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 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

Education Reconciliation Act of 2010, Public Law 111–52 (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, Public Law 111–48, section 2706 (2010).

[3] *Id.*

[4] *Id.*

[5] *Id.*

[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] "Newly formed competitor collaborations" are those formed in whole or in part after March 23, 2010, the date on which the Patient Protection and Affordable Care Act was enacted. Patient Protection and Affordable Care Act, Public Law 111–48 (2010).

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

[9] This Policy Statement provides guidance to allow ACOs to determine 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.

[10] A "collaboration" comprises a 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), *available at http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.*

[11] *U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for Collaborations Among Competitors* § 1.3 (2000), *available at http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.*

[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.*

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. 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.[13] The Health Care Statements provide examples of financial risk-sharing arrangements that satisfy this standard, but also recognize that other acceptable financial risk-sharing arrangements might develop.[14]

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.[15] 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 provider participants and to create a high degree of interdependence and cooperation among the providers to control costs and ensure quality.[16] Federal Trade Commission staff advisory opinions discuss evidence sufficient to demonstrate clinical integration in specific factual circumstances.[17]

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.[18] CMS has further defined these eligibility criteria through proposed regulations.[19]

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 how they wish to integrate their health care delivery systems to improve quality and lower costs.[20] The Agencies have wished to avoid dictating prescriptions for 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 greater certainty in evaluating whether an ACO that satisfies the CMS eligibility criteria could be subject to an antitrust investigation and potential challenge as per se illegal.

The Agencies have determined that CMS's proposed 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.[21] The Agencies also have determined that organizations meeting the CMS criteria for approval as an ACO are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants' joint efforts. Further, if a CMS-approved ACO provides the same or essentially the same services in the commercial market, the Agencies have determined that the integration criteria are sufficiently rigorous that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO's primary purpose of improving health care services.

Further, CMS will collect and evaluate cost, utilization, and quality metrics annually relating to each ACO's performance in the Shared Savings Program over the three-year agreement period. This extensive monitoring of cost, utilization, and quality metrics will help the Agencies determine the extent to which the proposed CMS eligibility criteria in fact lead to cost savings and improved health care quality and may help inform the Agencies' future analysis of ACOs and other provider organizations.

Therefore, the Agencies will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Shared Savings Program. This rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program. The 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").[22] 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.[23] 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.[24] The Agencies shall

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

[14] *Id.*

[15] *Id.* at 83–87, 110–11.

[16] *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.*

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

[18] Patient Protection and Affordable Care Act, Public Law 111–48, section 3022 (2010).

[19] CMS Notice of Proposed Rulemaking, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations (2011) [hereinafter CMS NPRM on ACOs].

[20] *See generally* FTC Staff Advisory Opinions (2002–Present), *available at http://www.ftc.gov/bc/healthcare/industryguide/opinionguidance.htm.*

[21] *See, e.g.,* Tristate Health Partners, Inc. Advisory Opinion from FTC Staff (April 13, 2009) (evaluating Tristate Health Partners' proposal and stating that, if implemented as proposed, Federal Trade Commission staff would not recommend that the Commission challenge the proposed program), *available at http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf.*

[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.

[24] The provisions regarding non-disclosure of competitively sensitive or business confidential

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.[25]

*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.

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.[26] The 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.[27]

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.[28] 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) [29] 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.[30] Likewise, an ACO may include Rural Hospitals [31] 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 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.[32] 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.[33] 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 the ACO needs that proposed share to provide high-quality,

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) (Federal Trade Commission advisory opinions) would generally apply to the expedited review process.

[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.

[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.

[27] Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 FR 16094 (Mar. 26, 2004).

[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.*

[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 CFR 412.92. *See also https://www.cms.gov/MLNProducts/downloads/SoleCommHospfctsht508–09.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 CFR part 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 CFR 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 CFR 50.6.

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:[34]

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

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.[35]

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.[36] 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.

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

[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.

[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.

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.[37]

**Appendix**

This Appendix explains how to calculate the PSA shares of common services discussed in this Policy Statement.[38] 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.[39]

b. For inpatient facilities (*e.g.,* hospitals), a service is an MDC.[40]

c. For outpatient facilities (*e.g.,* ASCs or hospitals), a service is an outpatient category, as defined by CMS.[41]

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.[42]

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 full range of services and the aggregate fee-for-service allowed charges or payments for each service, by zip code. For inpatient services, the ACO applicant 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 applicant 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 necessary data). For those services that are rarely used by Medicare beneficiaries (*e.g.,* pediatrics, obstetrics, and neonatal care), the ACO may use other available data to determine the relevant shares. For example, for services where Medicare data are not applicable, data on the number of actively participating physicians within the specialty and 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 calculating the ACO's shares for each common service.

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 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 PSAs by zip code for orthopedic surgery for each Physician Group. In this example, there will be two PSAs: One for PG A's orthopedic surgery practice ("PSA A") and one for PG B's orthopedic surgery practice ("PSA B").

3. Determine the ACO's share in each of the relevant PSAs. In this example, both PG A's and PG B's orthopedic surgeons serve patients 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 PSAs by zip codes for cardiac care and orthopedic care for each hospital. In this example, there will be four PSAs: Hospital 1 PSA for cardiac care, Hospital 1 PSA for orthopedic care, Hospital 2 PSA for cardiac care, and Hospital 2 PSA for orthopedic care.

[37] CMS NPRM on ACOs.

[38] 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.

[39] 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.

[40] CMS will make publicly available the most current list of MDCs.

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

[42] 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 16094 (Mar. 26, 2004).

3. Determine the ACO's share in each of the relevant PSAs. In this example, Hospital l and Hospital 2 both serve cardiac patients located in each hospital's PSA for cardiac care, and both serve orthopedic patients in each hospital's PSA for orthopedic care. Thus, shares need to be calculated in all four PSAs. 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 l's PSA) divided by the total number of inpatient discharges for MDC 05 for all residents of this PSA. Use the same process for the other three PSAs.

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 PSAs by zip codes for cardiovascular tests/procedures and musculoskeletal procedures for each facility. In this example, there will be four PSAs: Hospital 2 PSA for cardiovascular tests/procedures, Hospital 2 PSA for musculoskeletal procedures, ASC PSA for cardiovascular tests/procedures, and ASC PSA for musculoskeletal procedures.

3. Determine the ACO's share in each of the relevant PSAs. In this example, Hospital 2 and ASC both provide cardiovascular tests/procedures to patients located in each facility's PSA for cardiovascular tests/procedures, and both provide musculoskeletal procedures to patients located in each facility's PSA for musculoskeletal procedures. Thus, shares need to be calculated in all four PSAs. The ACO's share of cardiovascular tests/procedures in Hospital 2's PSA would be the ACO's total Medicare fee-for-service payments for outpatient category 2 (which are Hospital 2's and the ASC's total payments for outpatient cardiovascular tests/procedures for Medicare beneficiaries in Hospital 2's PSA) divided by the total payments for outpatient category 2 for all Medicare beneficiaries in this PSA. Use the same process for the other three PSAs.

*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 hospital inpatient and outpatient services 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.

*Application to the Mandatory Review Threshold:* If only one of the ten PSA shares in this example exceeds 50 percent, the ACO would be required to obtain an antitrust review from one of the Agencies before participating in the Shared Savings Program. In other words, mandatory review is necessary even if the share for only one common service exceeds 50 percent in any PSA in which another ACO participant provides that service.

## V. Request for Comments

The Agencies seek public comment from health care providers, payers, consumers, antitrust practitioners, and other stakeholders on the following:

1. Whether and, if so, why the guidance in the proposed Policy Statement should be changed in any respect;

2. Whether other sources of data exist that ACO applicants could use to determine relevant PSA shares (as identified in Step 3 of the Appendix) for:

(a) Physician services rarely used by Medicare beneficiaries (*e.g.,* pediatrics, obstetrics, and neonatal care); and

(b) Inpatient hospital services located in states where all-payer hospital discharge data are not available.

3. Whether providing the documents and information required to obtain an expedited antitrust review will present an undue burden on ACO applicants—specifically, the Agencies seek comment on:

(a) The necessity of and practical utility for the proposed collection of information;

(b) The accuracy of the estimated time and cost to prepare responses to the requested collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden of collecting the information on those who are to respond.

Interested parties are invited to submit written comments electronically or in paper form. Comments should state "Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017" both in the text and on the envelope. Please note that your comment, including your name and your state, will be placed on the public record of this proceeding, including on the publicly accessible FTC Web site, at *http://www.ftc.gov/os/comments/aco-comments/index.shtm.*

Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and Commission Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form and clearly labeled "Confidential."

Because mail delivered to the FTC by the U.S. Postal Service is subject to delay due to heightened security screening, please consider submitting your comments electronically. Comments filed electronically should be submitted by using the following Web link: *https://ftcpublic.commentworks.com/ftc/acoenforcementpolicy* (and following the instructions on the web-based form). To ensure that the Agencies consider an electronic comment, you must file it on the web-based form at the Web link *https://ftcpublic.commentworks.com/ftc/acoenforcementpolicy.* If this Notice appears at *http://www.regulations.gov/#!home,* you may also file an electronic comment through that Web site. The Agencies will consider all comments that regulations.gov forwards to the Commission. You may also visit the FTC Web site at *http://www.ftc.gov/opp/aco/* to read the Notice and the news release describing it.

A comment filed in paper form should reference the "Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017" both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex W), 600 Pennsylvania Avenue, NW., Washington, DC 20580. The FTC requests that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to

delay due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Agencies will consider all timely and responsive public comments, whether filed in paper or electronic form. Comments received will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov/os/comments/aco-comments/index.shtm.* As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at *http://www.ftc.gov/ftc/privacy.shtm.*

**Paperwork Reduction Act**

The Medicare Shared Savings Program is exempt from the Paperwork Reduction Act.[43] Nonetheless, the Agencies are seeking comments relevant to the utility and burden of the submission of documents and information (collectively, "information") required in connection with requests for expedited antitrust review as described above.[44] The Agencies are providing this opportunity for public comment regarding the utility of the information to be provided in support of an ACO request for antitrust review and steps to minimize the burden of collecting and submitting that information. Specific questions regarding these considerations are included in the Request for Comment part of the Supplementary Information section above.

Subject to further refinement by public comment, calculating the projected overall burden of collecting and submitting the required information necessarily entails estimating the number of ACOs that will apply for expedited review, and the average time necessary per applicant to respond. To help inform some of these estimates, the FTC has drawn upon CMS's notice of proposed rulemaking regarding the Medicare Shared Savings Program, published simultaneously with this **Federal Register** notice.[45]

CMS has estimated that some 1.5 to 4 million Medicare beneficiaries will be aligned with a participating ACO during the first three years of the Shared Savings Program.[46] Moreover, the amendments to the Social Security Act that gave rise to the Program specify that, at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it in order to be eligible to participate in the Shared Savings Program.[47] Thus, by extrapolation, there may be a range of 300 to 800 ACOs.

Not all of these ACO applicants will be covered by the Policy Statement, however, because the Statement applies only to collaborations among otherwise independent providers and provider groups[48] formed after March 23, 2010, the date of passage of the Patient Protection and Affordable Care Act; it does not apply to such collaborations formed earlier or to ACOs created through merger.[49] Our general understanding is that a number of long-existing institutions will apply to become ACOs, but also that a number of ACO applicants are likely to be newly formed. Accordingly, we estimate that roughly one-half of ACO applicants will be covered, yielding a range of 150 to 400 ACOs likely to be covered by the Policy Statement.

Not all ACO applicants covered by the Policy Statement will need to seek expedited antitrust review, however; only ACO applicants not qualifying for the rural exception and having a share over 50 percent for any common service provided to patients by two or more independent ACO participants in the same PSA must do so. Other ACO applicants that are not required to obtain an antitrust review and do not fall within the Policy Statement's Safety Zone nonetheless may obtain a review if they wish additional antitrust certainty. For the purposes of this burden analysis, we estimate that the number of submissions for expedited antitrust review, both required and voluntary, will range from roughly one-quarter to one-half of all ACO applications covered by the Policy Statement. This yields an estimated range of 38 to 200 ACO applicants that will seek antitrust review. Erring conservatively, the following burden estimate will use the upper bound estimate, *i.e.,* 200 submissions.

In developing an estimate of the time necessary for applying ACOs to collect and review and submit the information for antitrust review, we note that the Policy Statement asks for the application the ACO has submitted or plans to submit to CMS, information that will already have been gathered and organized. Other required information is similar in nature to that required when submitting a pre-merger notification filing under the Hart-Scott-Rodino Act ("HSR");[50] the basic burden estimate for HSR premerger notification filings, OMB Control No. 3084–0005, is 39 hours. Accordingly, we estimate that, in the aggregate, ACOs and their antitrust counsel likely will devote approximately 30 to 50 hours to retrieving, reviewing, and submitting the information. This estimate is conservative, since submitters may submit information about the relevant markets in a format of their choosing. There is no prescribed notification and report form as there is for a submission under the HSR Rules.[51]

**Estimated Labor Costs**

It is not possible to calculate with precision the labor costs associated with providing the required information, because responses will entail participation by management and support staff at various compensation levels within many different entities. Individuals within some or all of those labor categories may be involved in the information-collection process. Nonetheless, the FTC has assumed that executive-level personnel and outside legal counsel will handle most of the

[43] The Patient Protection and Affordable Care Act provides: "Chapter 35 of title 44, United States Code [44 U.S.C. 3501 *et seq.,* the Paperwork Reduction Act] shall not apply to the [Medicare Shared Savings] program." Patient Protection and Affordable Care Act, Public Law 111–48, section 3022 (2010) (codified at 42 U.S.C. 1395jjj(e)).

[44] *Cf.* Paperwork Reduction Act, 44 U.S.C. 3501–3521.

[45] CMS NPRM on ACOs.

[46] *Id.,* preamble to proposed rule.

[47] Section 3022 of the Affordable Care Act amended Title XVIII of the Social Security Act (42 U.S.C. 1395 *et seq.*) by adding new section 1899 to establish "a shared savings program * * * that promotes accountability for a patient population and coordinates items and services under [Medicare] Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery." Patient Protection and Affordable Care Act, Public Law 111–48, section 3022 (2010) (codified at 42 U.S.C. 1395jjj(a)(1). Section 1899(b)(2)(D) (codified at 42 U.S.C. 1395jjj(b)(2)(D)) specifies the minimum number of beneficiaries per eligible program participant.

[48] A "collaboration" comprises a 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), *available at http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.*

[49] Merger transactions, including transactions that meet the criteria set forth in Section 1.3 of the *Competitor Collaboration Guidelines,* will be evaluated under the Agencies' *Horizontal Merger Guidelines. See U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for Collaborations Among Competitors* § 1.3 (2000), *available at http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf; 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.*

[50] See Section 7A of the Clayton Act, 15 U.S.C. 18a, as amended by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Public Law 94–435, 90 Stat. 1390.

[51] See 16 CFR 801–803 (2010).

tasks involved in gathering and producing the responsive information, and has applied an average hourly wage of $460/hour for their labor. Thus, the labor costs per applicant for expedited review should range from approximately $13,800 to $23,000.

**Estimated Annual Capital or Other Non-Labor Costs**

The capital or other non-labor costs associated with the information requests will be minimal. Industry members should already have in place the means to store information of the volume requested. In addition, respondents may have to purchase office supplies such as file folders, computer CDs or DVDs, photocopier toner, or paper in order to comply with the Commission's requests. The FTC estimates that such costs will be minimal.

For the Antitrust Division of the Department of Justice.

**Sharis A. Pozen,**

*Chief of Staff and Deputy Assistant Attorney General.*

For the Federal Trade Commission.

By direction of the Commission, Commissioner Rosch dissenting.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 2011–9466 Filed 4–18–11; 8:45 am]

**BILLING CODE 6750–01–P**

## DEPARMENT OF HEALTH AND HUMAN SERVICES

### Privacy Act of 1974; Report of a New System of Records

**AGENCY:** Office of Grants and Acquisition Policy and Accountability (OGAPA), Assistant Secretary for Financial Resources (ASFR), Department of Health and Human Services (HHS).

**ACTION:** Notice of New System of Records (SOR).

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, the HHS OGAPA is proposing to establish a new system titled, "HHS Consolidated Acquisition Solution (HCAS), System No. 09–90–0411." As an IT investment, HCAS is monitored by the HHS IT Investment Review Board (ITIRB). In addition to the ITIRB oversight, HCAS is monitored by the HHS/ASFR Office of Grants and Acquisition Policy and Accountability (OGAPA).

At HHS, there were seven different systems in place to support the people who make buying—procurement—possible. The HHS Consolidated Acquisition System (HCAS) is an initiative to reduce the number of duplicative acquisition systems, thereby streamlining and standardizing our procurement processes and systems across the Department. The use of disparate systems complicates all interfaces to financial, inventory, and other systems that HHS has or will employ.

HCAS replaced varying Procurement Request Information System (PRISM) configurations that existed across HHS, and replaced legacy acquisition systems and manual processes necessary for capturing HHS acquisition transactions for integration with the Unified Financial Management System (UFMS). We are also proposing routine uses for this system of records.

**DATES:** *Effective Dates:* The HHS ASFR/OGAPA filed a new system report with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on April 8, 2011. To ensure that all parties have adequate time in which to comment, the new SOR, including routine uses, will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless HHS/ASFR/OGAPA receives comments that require alterations to this notice. Although the Privacy Act requires only that the HHS/ASFR/OGAPA provide an opportunity for interested persons to comment on the proposed routine uses, the HHS/ASFR/OGAPA invites comments on all portions of this notice.

**FOR FURTHER INFORMATION OR COMMENTS CONTACT:** The public should address comments to Kowanna Parran at HHS Office of the Secretary, Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Hubert H. Humphrey Building, 200 Independence Avenue, Washington, DC 20201. Ms. Parran can be reached by telephone at (202) 205–0722 or via e-mail at *kowanna.parran@hhs.gov.* Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., Eastern Time zone.

**SUPPLEMENTARY INFORMATION:** The HCAS system itself collects information necessary to support a procurement relationship between HHS and the vendor community. Information is collected on HHS Contracting Officers, and HHS vendors. There are limited instances where an individual's information in identifiable form (IIF) will be collected in order to facilitate a transaction in HCAS. HCAS collects and maintains IIF for service fellows and sole proprietorships that provide vendor services as individuals. Acquisition processes supported by HCAS include acquisition planning, solicitation, contract creation and approval, contract award and award closeout, and contract performance and management. To support these business processes, IIF contained in HCAS may include the following: vendor and contracting officer names, vendor mailing addresses, phone numbers, vendor financial account information, legal documents, Web URLs, e-mail addresses, vendor education records, and vendor tax ID numbers (TIN) or Social Security numbers.

The Privacy Act allows information disclosure without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a "routine use." The Government will only release HCAS information that can be associated with an individual as provided for under "Section III. Proposed Routine Use Disclosures of Data in the System." Both identifiable and non-identifiable data may be disclosed under a routine use. We will only collect the minimum personal data necessary to achieve the purpose of HCAS. We are proposing to establish the following routine use disclosures of information maintained in the system:

(1) To agency contractors or consultants who have been engaged by the agency to assist in the accomplishment of the HCAS Operations and Maintenance (O&M) function relating to the purposes for this system and who need to have access to the records in order to assist the OGAPA and HCAS O&M Federal leadership.

We contemplate disclosing information under this routine use only in situations in which OGAPA and HCAS O&M Federal leadership enters into a contractual or similar agreement with a third party to assist in accomplishing a HCAS function relating to purposes for this system.

The HHS Program Support Center (PSC) Financial Enterprise Systems Management (FESM) Operations and Maintenance (O&M) must be able to give a contractor or consultant whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting