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Association**

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Submitted electronically
May 31, 2011

The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
U. S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Donald M. Berwick, M.D., MPP
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program – Matter V100017

Dear Assistant Attorney General Varney, Chairman Leibowitz and Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health care organizations and the nearly 200,000 employed physicians within those organizations, the American Hospital Association (AHA) submits comments in connection with the Federal Trade Commission (FTC) and Antitrust Division of the Department of Justice (DOJ) (collectively, the Agencies) Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Proposed Statement).

We commend your agencies for working collaboratively to craft a series of regulatory notices on Accountable Care Organizations (ACOs). This historic effort underscores the promise that ACOs have for improving the quality and efficiency of health care delivered to Medicare patients. Below is an overview of our comments concerning the Proposed Statement. Detailed comments are attached.

POSITIVE ASPECTS OF THE PROPOSED STATEMENT

The Proposed Statement has several highlights of note; the foremost of which is the automatic Rule of Reason treatment bestowed upon any ACO that has met the Centers for Medicare &



Medicaid Services (CMS) eligibility criteria for ACOs. Under this approach, ACOs will be secure in their knowledge that if they devote time and expense to developing an ACO plan, the Agencies will not summarily conclude that their structure is *per se* unlawful.

Another welcome provision is the Antitrust Safety Zone for ACOs with a primary service area (PSA) share of below 30 percent. The AHA encourages the Agencies to increase the Safety Zone percentage to 35 percent to sweep in more ACOs that are highly unlikely to present competitive problems. Maintaining the Safety Zone concept provides continuity and comfort for those ACOs least likely to raise antitrust concerns.

Further, the AHA applauds the Agencies for recognizing that exclusivity does not always indicate anticompetitive behavior and in fact can be beneficial in certain cases, such as with primary care physicians. The AHA encourages the Agencies to extend Antitrust Safety Zone protection to hospitals' exclusive arrangements. Such arrangements can have similar procompetitive benefits to those for physicians and do not have an unnecessarily negative impact on competition where there are other hospitals available to contract with payers or participate in other ACOs.

AREAS OF CONCERN

Despite these highlights, the resulting regulations, particularly those applicable to the antitrust laws, are disappointing. The AHA has been in the vanguard of urging the Agencies to provide more user friendly guidance for hospitals, physicians and other caregivers to help them better navigate the antitrust laws for clinically integrated organizations. Unlike other areas of law generally applied to hospitals, antitrust compliance is determined in reference to case law, business review or opinion letters and occasionally guidance in the form of statements on enforcement policy. Such tailored applicability has long been considered one of the antitrust law's greatest strengths. When necessary, in the past, the Agencies have been willing to provide additional guidance to various fields or in specific situations. The 1996 Statements of Antitrust Enforcement Policy in Health Care is a paradigm of useful guidance extended to an entire sector.

Consequently, the Proposed Statement is deeply disappointing in a number of important respects; not the least of which is the lack of actual guidance to aid the hospital field in moving forward with clinically integrated organizations, like ACOs. Our attached comments, which go into much greater detail, highlight the following concerns with the Proposed Statement:

- CMS lacks the legal authority to issue regulations governing the application of the antitrust laws or to delegate to the DOJ or the FTC the authority to block certain ACOs. The first prospective ACO participant to be blocked by the Agencies should have a viable cause of action against CMS as there is no precedent for this kind of backdoor approach to regulation.
- The Proposed Statement inappropriately transforms antitrust enforcement into a regulatory scheme. By incorporating it into the CMS Proposed Rule, CMS and the Agencies have subsumed antitrust enforcement of ACOs within a web of regulation. Without justification,

this conversion to regulation effectively shifts the burden of antitrust review from the government to ACO participants.

- The Proposed Statement falls short of its own stated goals in many respects:
 - The required analysis is burdensome and costly. The AHA estimates that the *minimum* cost of each overlap calculation that must be performed is \$1,500. **Thus, to perform all the required calculations just to apply to the Agencies for clearance to apply to CMS for ACO designation will cost potentially several hundred thousands of dollars.**
 - Many prospective ACO candidates will be subject to mandatory antitrust review. Based on nationwide, two states and a single medical center's data compiled and analyzed by Compass Lexecon, **we found that in most Metropolitan Statistical Areas (MSAs), an ACO that includes the largest hospitals and any other hospital will be subject to mandatory antitrust review.** In many MSAs, a combination of the second and third largest hospitals also will trigger a review. Even the addition by a highly respected medical center of another hospital to an ACO would likely trigger mandatory review.
- This suggests that those seeking to build the most comprehensive ACO models of the future are the ones most likely to be ensnared in an uncertain, unappealable, burdensome and costly antitrust review *before* their merits as a force to transform health care delivery can be determined by CMS.
- The mandatory review threshold of 50 percent is too low, and the exception for rural providers is too narrow.
 - Basing the required calculations on Medicare fee-for-service data has numerous pitfalls, not the least of which it will be practically unavailable for some services and specialties and even when it is available, is unlikely to produce consistent or reliable estimates.
 - The specified “conduct to avoid” described in the Proposed Statement is too general and, therefore, is likely to discourage procompetitive activity, such as offering payors incentives to keep patients in the ACO.
 - There is no process specified for re-review of an ACO in the event of a “material change” in composition. Not only are the relevant definitions of the circumstances that would trigger a re-review circular and confusing, they do not even make clear whether or not a provider can be added during the mandatory three-year period of operation at all.
- To the extent the Agencies wish to seek legal authority to review ACOs, DOJ already uses a model of review in connections with transactions in the banking industry that would provide a more rational basis for assessing an ACO's competitive potential.

We urge the Agencies to abandon the proposed regulatory scheme in favor of guidance that restores antitrust to, in the words of Justice Breyer, its historic role of “creat[ing] or maintain[ing] the conditions of a competitive marketplace.” Such guidance should build on the highlights in the Proposed Statement. We believe this approach will provide positive incentives for America’s hospitals to both participate in the Medicare Shared Savings Program and move forward to create new models of accountable care organizations on which the transformation of health care delivery is so dependent.

We appreciate your consideration of our comments and look forward to working with the Agencies. If you have any questions, please contact Melinda Hatton, senior vice president and general counsel, at (202) 626-2336 or mhatton@aha.org.

Sincerely,

 /s/
Rick Pollack
Executive Vice President

COMMENTS OF THE AMERICAN HOSPITAL ASSOCIATION RELATED TO THE PROPOSED ANTITRUST ENFORCEMENT OF ACCOUNTABLE CARE ORGANIZATIONS

Matter V100017

On behalf of our more than 5,000 member hospitals, health care organizations and the nearly 200,000 employed physicians within those organizations, the American Hospital Association (AHA) submits the following comments in connection with the Federal Trade Commission (FTC) and Antitrust Division of the Department of Justice (DOJ) (collectively, the Agencies) Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Proposed Statement).

I. Introduction

The AHA is pleased to present these comments in response to the Agencies' Notice with comment period for the Proposed Statement.¹ We commend the Agencies for attempting to create an antitrust regime responsive to the hospital field's collective concern that the antitrust principles to be applied to accountable care organizations (ACOs)² not unduly interfere with the development of innovative and procompetitive arrangements.

The AHA sees a number of positives in the Proposed Statement, the foremost being the automatic Rule of Reason treatment bestowed upon any ACO that has met the Centers for Medicare & Medicaid Services (CMS) eligibility criteria enunciated in the CMS Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule (CMS Proposed Rule or Proposed Rule). Under the proposed framework, ACOs will be secure in their knowledge that if they devote time and expense to developing an ACO plan, the Agencies will not summarily conclude that their structure is *per se* unlawful. This will encourage the formation and ultimate success of ACOs.

Another provision that the AHA welcomes is the Antitrust Safety Zone for ACOs with a primary service area (PSA) share of below 30 percent. The AHA encourages the Agencies to increase the Safety Zone percentage to 35 percent to sweep in more ACOs that are highly unlikely to present competitive problems. Maintaining the Safety Zone concept, which was present in Statement 8 of the 1996 Statements of Antitrust Enforcement Policy in Health Care (1996 Health Care Statements), provides continuity and comfort for those ACOs least likely to raise antitrust concerns.

A third positive aspect of the Proposed Statement is the recognition on the part of the Agencies that exclusivity does not always indicate anticompetitive behavior and in fact can be beneficial in certain cases, such as with primary care physicians. The AHA applauds the Agencies for their recognition that exclusive arrangements may actually promote competition

¹ 76 Fed. Reg. 21894.

² Unless otherwise indicated, ACO here refers to those organizations contemplated under the Medicare Shared Savings Program, not to other integrated organizations providing accountable care.

under certain conditions. We urge the Agencies, however, to eliminate the prohibition in the Safety Zone on exclusivity for hospitals with PSA shares below 30 percent (or for a revised 35 percent Safety Zone). As discussed below, exclusive arrangements with hospitals can have similar procompetitive benefits to those for physicians and do not have an unnecessarily negative impact on competition where there are other hospitals available to contract with payers or participate in other ACOs.

Despite these positive aspects of the Proposed Statement, the AHA remains concerned about the process and requirements it creates. Accordingly, this comment will first discuss why the Proposed Statement represents an unauthorized delegation of authority from CMS to the Agencies. Second, it will highlight how the proposed regime improperly converts traditional antitrust enforcement into a regulatory scheme. Third, it will explain how the Proposed Statement consistently undermines many of its stated goals. Finally, it will suggest that if the Agencies wish to secure authority to review ACOs, they consider an alternative model of antitrust review already in use by DOJ.

II. CMS Does Not Have the Authority to Issue Regulations Governing the Application of the Antitrust Laws Nor to Delegate to DOJ or FTC the Authority to Block Certain ACOs.

The AHA contends that the Proposed Statement represents an exercise of power that CMS does not actually possess. The CMS authority to issue this regulation, if that authority exists, could only come from either the *Patient Protection and Affordable Care Act of 2010* (*Affordable Care Act* or *ACA*) or CMS's general regulatory authority in the *Social Security Act* (*SSA*), neither of which grants such authority. Moreover, the scheme created by the CMS Proposed Rule and the Proposed Statement appears to be an improper attempt by CMS to interpret the antitrust laws.

An agency must have some source of statutory authority in order to lawfully issue regulations. Specifically, a regulation is considered legally binding only “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.”³ If properly authorized, a “regulation is binding on the courts,” and ultimately binding on the affected parties, “unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute.”⁴ If an agency acts outside of its authority, then its regulation does not have the force of law and is not binding on the courts or on the parties to whom it is directed.⁵

³ *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001).

⁴ *Id.* at 227.

⁵ *See, e.g., FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000) (striking down FDA regulation of tobacco where the FDA's professed “authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA”).

CMS, as part of the Department of Health and Human Services,⁶ has general regulatory authority under the SSA. The relevant provision of the SSA states: “The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter.”⁷ And “this subchapter” includes the section of the ACA governing ACOs.

The Affordable Care Act does not provide CMS with any additional authority to issue regulations governing ACOs. To be sure, the ACA states that CMS “shall establish a shared savings program,”⁸ and CMS can do so through regulation. But this regulatory power comes from the already existing authority in the SSA,⁹ not from the ACA. The reason for this distinction is that the ACA section governing ACOs does not provide any particular grant of authority to issue regulations. Indeed, where Congress wanted to give regulatory authority in the *Affordable Care Act*, it did so explicitly.¹⁰ Thus, the absence of this authority for CMS with respect to ACOs means that the ACA does not give CMS any regulatory authority beyond its general regulatory authority in the SSA.

The question, then, is whether the CMS Proposed Rule falls within CMS’ general authority to issue regulations to administer insurance programs (including the ACO program). There is nothing in the *Affordable Care Act* that suggests the administration of ACOs is related to the antitrust laws, aside from the definition of the program itself, which recognizes that it involves “groups of providers . . . work[ing] together to manage and coordinate care.”¹¹ Moreover, the only statutory requirements for ACO eligibility concern the structure of the ACO, the quality of care offered by the ACO, and various administrative duties.¹² Nonetheless, for the antitrust section of its proposed rule, CMS purports to be interpreting two provisions of the ACA.

The first provision states that “[t]he ACO shall enter into an agreement with the Secretary to participate in the program for not less than a 3-year period.”¹³ CMS claims that its Proposed Rule “ensures that ACOs participating in the Shared Savings Program will not present competitive problems that could subject them to antitrust challenge that may prevent them from

⁶ For ease of reference, this comment will refer to CMS throughout, though the AHA recognizes that the Department of Health and Human Services is the entity to which the ACA actually refers.

⁷ 42 U.S.C. § 1395hh(a)(1).

⁸ ACA § 1899(a)(1).

⁹ 42 U.S.C. § 1395hh(a)(1).

¹⁰ See, e.g., ACA §§ 2714(b) (“The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).”); id. § 2715(g) (“The Secretary shall, by regulation, provide for the development of standards for the definitions of terms used in health insurance coverage, including the insurance-related terms described in paragraph (2) and the medical terms described in paragraph (3).”).

¹¹ ACA § 1899(a)(1).

¹² See *id.* § 1899(b).

¹³ *Id.* § 1899(b)(2)(B).

completing the term of their 3-year agreement with us.”¹⁴ However, a possible antitrust challenge does not affect whether the agreement is for three years, which is all that the statute requires. In fact, the ACA recognizes that an agreement can be terminated before the end of the three-year period.¹⁵

The second provision CMS relies upon states that an eligible ACO must “have in place a leadership and management structure that includes clinical and administrative systems.”¹⁶ CMS asserts that the antitrust limitations serve this provision because they “maintain[] competition for the benefit of Medicare beneficiaries by reducing the potential for the creation of ACOs with market power.”¹⁷ However, whether there is a leadership and management structure in place does not affect competition or market power. Simply put, the antitrust part of the proposed CMS regulation does not actually interpret either of the provisions that CMS cites.

Indeed, it appears from the content of the CMS Proposed Rule that CMS is actually interpreting the antitrust laws, not the ACA. CMS does not only reference the antitrust laws in its Proposed Rule; it provides specific antitrust requirements for ACOs. In particular, as discussed below, an ACO applicant with more than a 50 percent PSA for a common service must receive a letter from the FTC or DOJ confirming that it has no intent to challenge the proposed ACO.¹⁸ The 50 percent PSA share test reflects a substantive determination of when an ACO potentially violates the antitrust laws, and the requirement of preapproval by the antitrust agencies reflects a decision about how the antitrust laws should be enforced against potential violators. Even more to the point, in the Proposed Statement itself, the Agencies refer to the requirements therein as “an application of the antitrust laws.”¹⁹

CMS has no authority to interpret the antitrust laws. The case law is clear that an agency does not act with the force of law (or receive deference) in interpreting a statute that it lacks authority to administer.²⁰ This is especially true given that CMS is interpreting something completely outside of its expertise. Just as *Gonzales* rejected the “conclusion that the Attorney

¹⁴ 76 Fed. Reg. 19630.

¹⁵ ACA § 1899(d)(4).

¹⁶ Id. § 1899(b)(2)(F).

¹⁷ 76 Fed. Reg. 19630.

¹⁸ 76 Fed. Reg. 19629.

¹⁹ 76 Fed. Reg. 21894.

²⁰ See, e.g., *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-650 (1990) (holding that the Secretary of Labor’s interpretation of a statute’s enforcement provisions is not entitled to deference because “[n]o such delegation regarding [those] provisions is evident in the statute”); *Gonzales v. Oregon*, 546 U.S. 243, 263-64 (2006) (holding that the Attorney General has no authority to define the terms at issue in the Controlled Substances Act, and therefore he does not receive deference in his interpretation); *Dobbs v. Anthem Blue Cross and Blue Shield*, 600 F.3d 1275, 1284 n.9 (10th Cir. 2010) (“[W]e need not defer to the IRS’ interpretation of a statute it does not administer.”).

General has authority to make quintessentially medical judgments,”²¹ courts would likely be skeptical of the conclusion that CMS has authority to make judgments regarding antitrust law.

While the agencies with expertise—the DOJ and FTC—have cooperated with CMS in creating the Proposed Rule, this should not change the analysis. CMS issued the Proposed Rule, and it is therefore CMS’ authority that must be examined. In addition, the Agencies’ enforcement guidelines do not have the force of law.²² Thus, the policy guidelines at issue here are not, by themselves, regulations with the force of law. Effectively, all of the agencies are attempting to effectuate the antitrust guidelines by bootstrapping the guidelines to a CMS regulation. However, if CMS has no authority to issue the Proposed Rule, it certainly has no authority to delegate that non-existent power to another agency. There is no precedent to support this kind of back-door approach to regulation.

Furthermore, it is unclear how an agency decision not to issue a letter, and the concomitant CMS decision not to authorize an ACO, could be reviewed in court. The decision might not be considered final agency action, and thus might not be amenable to judicial review at all. The CMS decision would presumably be final agency action, but its decision would be premised solely on the opinion of the Agencies, and there is a question as to whether and how that opinion could be challenged in a proceeding against CMS. Indeed, the proposed CMS regulation states that “[t]here is no reconsideration, appeals, or other administrative or judicial review” of “[a] determination made by the reviewing antitrust agency that it is likely to challenge or recommend challenging the ACO.”²³ However, this limitation on review seems to go beyond the statutory limit, which shields from review only specific determinations, *e.g.*, assessment of quality of care, that do not include antitrust determinations.²⁴ These problems for judicial review provide another reason why CMS’ approach seems to go beyond the normal regulatory approach that agencies follow, and from which the ACA shows no intent to depart.

Finally, the lone provision of the ACA concerning antitrust laws further suggests that CMS does not have authority here. That provision states: “Nothing in this title (or an amendment made by this title) shall be construed to modify, impair, or supersede the operation of any of the antitrust laws.”²⁵ The CMS Proposed Rule claims to abide by this restriction.²⁶ Nonetheless, it does appear to “modify” the “operation” of the antitrust laws because it is substantively wrong on antitrust policy and procedurally wrong on the need for the Agencies’ preapproval.

²¹ 546 U.S. at 267.

²² *See, e.g., Fruehauf Corp. v. FTC*, 603 F.2d 345, 353-54 (2d Cir. 1979) (holding that courts need not follow the FTC merger guidelines).

²³ 76 Fed. Reg. 19650.

²⁴ *See* ACA § 1899(g).

²⁵ *Id.* § 1560.

²⁶ 76 Fed. Reg. 19629.

As a substantive matter, the 50 percent threshold does not have a firm legal basis.²⁷ Moreover, the Agencies recognize that the geographic area being used to determine the PSA-share percentage “does not necessarily constitute a relevant antitrust geographic market.”²⁸ As a procedural matter, the Agencies do not have general authority to require notification or preapproval for potentially anticompetitive conduct. Instead, the Agencies require advance notification only in the context of certain mergers and acquisitions, and this authority did not come from the agencies’ general enforcement authority under the antitrust laws. Rather, Congress granted authority to require premerger notification in a separate statute, the *Hart-Scott-Rodino Act*,²⁹ and Hart-Scott-Rodino does not cover ACOs. Indeed, the authority to require preapproval, which the Agencies seek to impose here, goes far beyond the specific statutory authority in the *Hart-Scott-Rodino Act*, which provides for advance notice and a 30-day waiting period, but not preapproval. Thus, to require preapproval for ACOs, the Agencies would need specific congressional authorization. By granting this authority without congressional authorization, CMS has effectively changed the enforcement of the antitrust laws, in conflict with Congress’s insistence that the ACA would make no such changes.

III. The Proposed Statement, as Incorporated into the CMS Proposed Rule, Inappropriately Transforms Antitrust Enforcement into a Regulatory Scheme

The lack of authority on the part of CMS is even more apparent in light of the effects of incorporating the Agencies’ enforcement guidelines into the CMS Proposed Rule. Although the AHA applauds the increased coordination between CMS and the Agencies, CMS’ decision to make its approval of a proposed ACO contingent on that ACO obtaining antitrust clearance crosses the line from antitrust enforcement into regulation. Enforcement has long been distinct from regulation, particularly with regard to antitrust. While still a law professor, Justice Stephen Breyer commented:

[I]n principle the antitrust laws differ from classical regulation both in their aims and in their methods. The antitrust laws seek to create or maintain the conditions of a competitive marketplace rather than replicate the results of competition or correct for the defects of competitive markets. In doing so, they act negatively, through a few highly general provisions prohibiting certain forms of private conduct. They do not affirmatively order firms to behave in specified ways; for the most part, they tell private firms what not to do.³⁰

As Justice Breyer explains, antitrust agencies operate through enforcement. That is, they take a market as it is and monitor whether certain actors are engaging in wrongdoing. If the

²⁷ See Section IV *infra*.

²⁸ 76 Fed. Reg. 21896, n. 22.

²⁹ 15 U.S.C. § 18a.

³⁰ Stephen Breyer, *Regulation and Its Reform*, 156-57 (1982).

agency uncovers a violation, it will bring an enforcement action to stop the illegal conduct. By contrast, regulation involves creating rules that apply to all actors and that are meant to discourage or stop wrongdoing before it occurs. The Agencies themselves recognize this distinction, stressing their mission as one of enforcement rather than of regulation.³¹

In practice, whether dealing with relatively borderline anticompetitive behavior or the most egregious instances of price-fixing, the Agencies generally do not proscribe certain conduct *ex ante*; rather, they wait for market participants to fix prices, and then bring a case against them. Further, even in instances where antitrust enforcement admittedly looks more regulatory in nature, such as in Hart-Scott-Rodino filings in the merger context, the Agencies must still go to court to stop a merger – it is not a decision that can be made by the Agencies alone. In short, an antitrust system predicated on regulation is contrary to United States antitrust law.

By incorporating the Proposed Statement into the CMS Proposed Rule, CMS and the Agencies have subsumed antitrust enforcement of ACOs within a web of regulation. Without justification, this conversion to regulation effectively shifts the burden of antitrust review from the government to ACO participants. And ACO participants bear a greater burden than in a typical antitrust investigation, because the Proposed Statement does not appear to contemplate submission of information by third parties.

Even accepting that there may exist some circumstances in which it is appropriate to make antitrust enforcement more regulatory in nature, adopting a regulatory scheme for antitrust review of ACOs is not one of those circumstances. Most participants in the health care field have the sophistication to inform the Agencies of potentially anticompetitive conduct. One could safely count on organizations that believe they have been injured by ACOs acting in an anticompetitive manner to bring to the attention of Agencies any hint of an unlawful exercise of market power on the part of ACOs, just as they do now. The Agencies too have plentiful experience investigating and bringing cases in the health care context, so there is little reason to think they would encounter particular difficulty identifying violations of the antitrust laws by ACOs.³²

³¹ See *e.g.*, Statement of Joel I. Klein, Assistant Attorney General, Antitrust Division, U.S. Department of Justice, “Hearing on Antitrust Issues in Agricultural Business, Senate Committee on Agriculture” (Jul. 27, 1999). (“We are law enforcers, not regulators. We do not have the power to restructure any industry, any market, or any company, or stop any practice, except to prevent or cure specific violations of the antitrust laws that we can prove in court. Our authority rests ultimately on our ability to bring enforcement actions. And when we bring an action, the court decides whether the antitrust laws are being violated in the particular instance, and whether the remedy we are seeking fits the violation.”).

³² As noted above, CMS has stated that this regulatory approach is important because it avoids disrupting the Shared Savings Program by immunizing all approved ACOs from antitrust challenge during the three-year approval period. See CMS Proposed Rule, 76 Fed. Reg. 19630. Of course, that both assumes that enough ACOs will be found to be anticompetitive to actually disrupt the program and also ignores the fact that there already exist a whole host of reasons an ACO could be removed from the program, *including* mandatory antitrust re-review in the event of a “significant” change in ACO composition, 76 Fed. Reg. 19626. Indeed, the ACA itself recognizes that an agreement can be terminated before the end of the three-year period. ACA § 1899(d)(4).

The proper balance between regulation and enforcement must not be sacrificed for the sake of predictability in review of ACOs. Though most providers want some level of predictability, they do not want it to the exclusion of all other considerations. **Accordingly, the AHA proposes that CMS remove the requirement that ACOs obtain a letter of approval from the Agencies in order to be approved and that the Agencies in turn make the review process voluntary.** Under a voluntary regime, those ACO applicants who value predictability can submit to a review while those that believe their ACO will not have competitive problems can choose not to. We also suggest that the voluntary review take a much more streamlined approach. As discussed below, the framework for the mandatory review is exceedingly burdensome. The Agencies should be able to provide guidance in 90 days to those who seek more certainty based on a simplified set of information.³³

IV. The Proposed Statement Falls Short of Its Own Stated Goals

While the AHA believes, for the reasons given above, that the Proposed Statement, as incorporated into the CMS Proposed Rule, is inappropriate and lacking in statutory authority, we also offer comments on the substance of the Proposed Statement. The Proposed Statement enunciates a number of worthy goals, including a “streamlined analysis”; a desire to “achieve for many consumers the benefits Congress intended”; and an intent to “clarify the antitrust analysis” of ACOs. While the AHA – and indeed most parties with any interest in ACOs – supports these goals, the Proposed Statement falls far short of meeting, and in fact undermines, each goal in a variety of ways.

A. Agencies’ Antitrust Analysis is Not Streamlined

While the term “streamlined,” and other similar language, appears throughout the Proposed Statement and reflects the Agencies’ attempt to create an abbreviated form of antitrust review for ACOs, the process as designed will in fact be extremely burdensome and costly for ACO applicants.

First, the deceptively simple, three-step process of calculating the PSA shares of an ACO’s common services³⁴ conceals a tremendous amount of work that must be completed simply to determine whether or not an ACO is subject to mandatory review. While the AHA looks forward to the publication of CMS data as promised in the Proposed Statement, sorting through all the data to determine the share for each common service will be extremely time-consuming and expensive, even assuming the data from CMS are clean and accurate.

The Proposed Statement envisions a tidy world in which two hospitals are the only members of an ACO and offer 10 services, each with only two in common. In reality, an ACO could include not only multiple hospitals, but also a number of outpatient facilities and several

³³ A list of providers, the services they provide, and where they operate; and a list of payers with which they contract, in addition to the CMS application, should suffice.

³⁴ 1. Identify each service provided by at least two independent ACO participants; 2. Identify the PSA for each common service for each participant; and 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 services.

independent physician groups, each of which could offer far more than 10 services. Indeed, there are 25 major diagnostic categories (MDCs), 55 Medicare Specialty Codes (MSCs) and 31 outpatient treatment categories, each of which could be a potential common service for an ACO requiring the ACO to sift through mountains of data to attempt to calculate PSA shares. Even assuming availability of data for calculations, evaluation of a single overlap would take several hours of calculation and verification. **The AHA estimates a minimum cost of \$1,500 per overlap for calculations where data is readily available, with costs substantially higher if data must be compiled across entities from disparate sources. An ACO could potentially spend several hundred thousand dollars on this analysis alone.**

Moreover, for all but the largest and most sophisticated physicians' offices, merely ascertaining the physicians' PSAs from zip codes and then matching that to billing codes will prove a virtually insurmountable task. Many small offices have no electronic records and would have to pay a consultant (or their billing service) to compile the information or do it manually themselves.

Further, the CMS data will not take into account specialties, like obstetrics and pediatrics, which are infrequently used by Medicare beneficiaries and thus would not be kept in any sort of centralized manner. Thus, to even identify all the physicians in a PSA offering such services, let alone to calculate a given ACO's PSA share, would be extremely burdensome, if not impossible.

We also note that the 75 percent PSA mandated by the Proposed Statement is inconsistent with existing case law. While the Proposed Statement does not purport to be defining relevant markets, it is using PSAs as proxies for markets. But antitrust case law defines markets based on where consumers can turn for services offered, not simply on where providers get their patients.³⁵ Moreover, in a number of hospital merger cases, the courts considered 90 percent service areas as one starting point for geographic market definition.³⁶ Ironically, perhaps in response to its failure to persuade the courts to define narrow geographic markets in hospital merger cases, the FTC has now rejected the "Elzinga-Hogarty" approach (which uses hospital service areas) to finding a geographic market based on patient flow data.³⁷ The Proposed Statement appears to reflect the Agencies' desire to have it both ways, arguing in some contexts that patient flow is not a good tool for defining markets, while proposing the exact same type of data as a proxy for a relevant market in the ACO context. Similarly, on the product market side, the Proposed Statement seems to reject the cluster market approach it has embraced in the

³⁵ See *Bathke v. Casey's General Stores, Inc.*, 64 F.3d 340, 346 (8th Cir. 1995).

³⁶ See *California v. Sutter Health Sys.*, 84 F. Supp. 2d 1057, 1069 (N.D. Cal.) *aff'd* 217 F.3d 846 (9th Cir. 2000); *FTC v. Freeman Hosp.*, 911 F. Supp. 1213, 1218 (W.D. Mo.) *aff'd* 69 F.3d 708 (8th Cir. 1995); *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 977 (N.D. Iowa 1995) *vacated as moot* 107 F.3d 632 (8th Cir. 1997).

³⁷ Professor Elzinga himself testified that that the Elzinga-Hogarty "test was not an appropriate method to define geographic markets in the hospital sector." *In re Evanston Northwestern Healthcare Corp.*, 2007 FTC LEXIS 210, *206 (F.T.C. Aug. 6, 2007).

hospital merger context³⁸ in favor of a far more granular product market focused on specific service lines.

B. Frontloaded Review is Costly and Burdensome

Compounding the burdensome calculation exercises, the Proposed Statement's "guilty until proven innocent" approach frontloads the review process to an unnecessary degree. From purely a cost perspective, ACO participants will be required to spend significant money and resources up front with no certainty that it will better their chances of becoming an ACO and for reasons wholly unrelated to whether or not they will be able to achieve benefits for Medicare beneficiaries. Indeed, the up-front burden is imposed on all ACO applicants, even those that ultimately clear the PSA screens, because there is no way to know in advance whether a particular ACO might trigger mandatory review in one or more service lines.

In addition, if an ACO is required to undergo the mandatory review, the Proposed Statement requests a multitude of documents and data, with virtually no crossover with the sizeable amount of information already required to be submitted to CMS as part of the ACO application – and that is not including the expenditure of resources required to respond to requests for additional information and engaging with the Agencies.³⁹ Then, the Proposed Statement requires a full-blown antitrust analysis by those ACOs that cross into the mandatory review threshold in order to be prepared to explain to the Agencies why the 50 percent trigger does not mean that an ACO is anticompetitive, even though at that point in the review there will still not have been any allegation of wrongdoing.

C. Burdensome and Costly Calculations Likely Will Subject Many ACOs to Mandatory Review

Our analysis has shown that there are many parts of the country in which an ACO would trigger mandatory review based on exceeding the 50 percent threshold.⁴⁰ We retained the economic consulting firm Compass Lexecon to analyze: (1) nationwide data, focusing on Metropolitan Statistical Areas (MSAs) with three or four hospital systems, (2) data from a large western state and a medium-sized eastern state, focusing on areas with three or four hospital systems, and (3) data from a single medical center in the northeast. All of these analyses confirmed that in the overwhelming majority of these areas, hospitals that sought to partner with any other hospital likely would exceed the 50 percent review threshold in one or more MDCs, and potentially could exceed threshold in MSCs and/or outpatient treatment categories, as well,

³⁸ See *Sutter Health*, 84 F. Supp. 2d. at 1067; *Freeman Hospital*, 911 F. Supp. at 1226-27; *Mercy Health*, 902 F. Supp. at 976.

³⁹ For example, Item 4 in the list of documents to be provided requires the submission of "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." Read in conjunction with the requirement that the ACO "represent in writing that it has . . . provided all responsive material," 76 Fed. Reg. 21890, n. 34, the quantity of documents required to be produced can be quite large.

⁴⁰ We would be pleased to discuss our analysis in more detail with the Agencies at their convenience.

and thus be faced with costs of potentially several hundred thousand dollars in order to defend their ACO application before one of the Agencies.

Nationwide, we compiled data on population, admissions, bed count and the number of independent hospitals by MSA. While this data did not allow us to perform the precise analysis required by the Proposed Statement, the analysis is sufficiently similar to be highly predictive. We focused on MSAs with three or four hospitals: There are 162 such MSAs. **In every MSA, an ACO that included the largest hospital and any other hospital would likely exceed the 50 percent threshold, and therefore be subject to mandatory review.**

To further test our assumption, we obtained data from a large western state that did permit us to perform the calculations required in the Proposed Statement using Medicare data. Among the findings from this analysis was that the required calculations take a great deal of time and effort, particularly the verification of contiguous zip codes, which involves a degree of manual processing. **Again, we found that virtually any ACO in this western state that includes the largest hospital system in an MSA would be subject to mandatory review if it included any other hospital.**⁴¹ In many cases, an ACO formed with the second and third largest systems would be subject to mandatory review,⁴² even though other hospitals would remain available to form competing ACOs.

We also conducted a similar analysis in a medium-sized eastern state, and the results were the same. In at least a dozen MSAs, an ACO involving the largest hospital and one other would require mandatory review based on shares of over 50 percent in multiple PSAs for each hospital.

Finally, we analyzed data from a large medical center in the northeast that would appear to be a likely ACO candidate. Using the calculations prescribed in the Proposed Statement, the medical center has a share of over 50 percent in a number of MDCs; accordingly, adding only one more hospital would very likely bring the ACO into the mandatory review process.

D. 90-Day Expedited Review Is Not Realistic

While the above discussion demonstrates the many instances in which the Proposed Statement falls short of its goal to create a streamlined process, there is one instance in which the Proposed Statement does manage to streamline the process, albeit in a wholly unrealistic manner: the Proposed Statement requires the Agencies to complete their entire review in 90 days. It is hard to fathom that a review that truly attempts to assess the likelihood that an ACO would exercise market power could actually be completed in 90 days, especially given the volume of information required to be submitted. Further, the failure to adhere to the set time frame brings no consequences – as discussed above, ACOs may have no recourse for adverse decisions, so they certainly have no recourse if the Agencies take 91 or 901 days to complete their analyses.

⁴¹ These included the largest cities which most would conclude involve competitively structured markets.

⁴² We also note that even those potential ACOs not subject to mandatory review would in most cases not be in the safety zone.

Moreover, the Proposed Statement is silent on whether the time in which the Agencies decide which one will handle the review is included in the 90-day time period; given the Agencies' checkered history of cooperation, that may not be an insignificant period of time. If the 90-day period is tolled until the Agencies make their decision, then the promise of a 90-day review is somewhat illusory; if it is included, then the Agencies are actually promising to complete the review in perhaps 75 or 80 days, which is even more unrealistic.⁴³

Finally, some aspects of the Proposed Statement create unnecessary complication: asking providers to supply share information based on the Medicare data adds an unnecessary middleman to an already complicated process. It would be preferable and more efficient for the Agencies to get this information directly from CMS, relieving some of the burden on applicants. Not only would this reduce some of the work that providers have to do, but it also would streamline the process for the Agencies: rather than going back and forth with ACOs about their share calculations, the Agencies will have a complete understanding of the data since they would be getting it directly from the source.

E. Preapplication to Agencies is Burdensome and Unnecessary

Another area that creates unnecessary problems for ACOs is the requirement that an ACO applicant submit its entire application to the Agencies 90 days before it submits its CMS application. According to this rule, if an ACO has assembled its submissions for both antitrust and CMS review at the same time – a perfectly reasonable course of action – it nonetheless must hold back its CMS application for 90 days after submitting its antitrust review materials. Thus, the supposedly streamlined antitrust review has the potential to slow down the CMS review process by three months, undermining the urgency with which the *Affordable Care Act* is attempting to address rising health care costs. There is no reason why the Agencies' review cannot be conducted during the time that CMS is also reviewing the application.

V. To Achieve the Benefits Congress Intended

In the Introduction to the Proposed Statement, the Agencies recognize that they must “maximize and foster opportunities for ACO innovation” in order to “achieve for many consumers the benefits Congress intended.”⁴⁴ Congress created the Medicare Shared Savings Program to incentivize providers to create ACOs that lower cost and improve treatment, but the Proposed Statement throws up numerous roadblocks that will chill the formation of ACOs.

Despite the protestations of various DOJ and FTC staff members who have commented on the Agencies' desire to make the Proposed Statement as unobtrusive as possible, it is now

⁴³ In the past, the agency advisory opinion process has taken up to 645 days, at a cost to the requester of nearly \$100,000. David Balto, *Making Health Reform Work: Accountable Care Organizations and Competition*, Center for American Progress, February 28, 2011, http://www.americanprogress.org/issues/2011/02/aco_competition.html.

⁴⁴ 76 Fed. Reg. 21895.

clear that many providers that may have initially been interested in forming ACOs have backed off in the face of the Proposed Statement and the incredible burden of compliance it creates. Fewer ACO candidates will mean fewer parties working to innovate with cost-saving and quality measures, likely thwarting the intention of Congress. Instead of a robust population of ACOs focused on innovation and quality control, we may be left with a few small, fully-integrated organizations that are best-suited to survive antitrust review rather than to deliver the best health care at the lowest cost. Under the proposed regime, the more comprehensive an ACO in terms of care offered, the greater the burden – the Proposed Statement penalizes those that are most likely to fulfill the goals that Congress had in mind when it passed the *Affordable Care Act*.

More specifically, there are a number of filters in the Proposed Statement that are not narrowly tailored enough to achieve their intended purpose; while they are designed to function as screens to weed *out* ACOs that pose no threat, they will actually end up sweeping *in* large numbers of ACO applicants, many of whom likely present no anticompetitive concerns. As a result, they will discourage many ACOs from even applying to the Shared Savings Program.

A. 50 percent Mandatory Review Threshold is Too Low and Overly Broad

For example, the Mandatory Review threshold of 50 percent is too low. As detailed above, there are many places in which the combined PSA share of an ACO would exceed 50 percent in at least one specialty. And this low threshold, coupled with the strict rule that a PSA share in excess of 50 percent in even a single common service requires mandatory antitrust review, could create a host of unintended consequences. For example, an ACO could have a combined PSA share of greater than 50 percent in only non-Medicare services; thus, an ACO could end up getting disqualified from the Medicare program based on a high share in pediatric services.

Similarly, the decision to make MDCs synonymous with services fails to recognize that some MDCs are made up of as many as 80 Diagnostic Related Groups (DRGs), meaning that an ACO could appear to have a high common share in a particular MDC, even though the shares in any given DRG do not cross the threshold.⁴⁵ Presumably, the Agencies' response to these hypothetical situations will be that these are circumstances in which the reviewing agency will use its discretion to conclude that there is not a competitive problem with a particular ACO. While that may be true, it provides little comfort, as potential ACO applicants will likely opt not to expend the resources to get to the decision point in the face of such uncertainty.

B. Rural Exception is Too Narrow

The Rural Exception also appears too narrow. From the wording, the exception applies only to a single physician per specialty per county, not a single physician group. This would suggest an odd imperative to split up physician groups to benefit from the exception.

⁴⁵ For example, cardiac surgery is in the same MDC as lower level cardiology services (MDC 5, which includes about 50 surgical DRGs and over 30 medical DRGs). This could cause a two-hospital ACO to cross the 50 percent threshold simply because one hospital receives significant revenues from its cardiac surgery program, even though the second hospital does not offer cardiac surgery.

Presumably, the Agencies did not intend to require a three-person physician group in a rural country to be ineligible for the Rural Exception, so the Proposed Statement should be corrected to allow the exception to apply to single physician *groups* per specialty per county. And the Agencies should not be concerned that expanding the Rural Exception to include physician groups will provide a greater opportunity for anticompetitive behavior, since physician groups, just as individual physicians and hospitals looking to make use of the Rural Exception, will have to contract with the ACO on a non-exclusive basis.

C. Basing Calculations on Medicare Fee for Service Data is Highly Problematic

Using Medicare fee-for-service payment data as the basis for calculating PSA shares also presents problems, as it may overstate or understate shares of commercial patients and/or overall shares, resulting in procompetitive ACOs getting disqualified based on incorrect data. For example, physicians who choose not to see Medicare patients, or who see few Medicare patients, are not in the CMS data the Agencies propose that ACOs use for calculating PSA shares, so the shares of those physicians will be understated. In addition, services provided to Medicare patients on other than a fee-for-service basis are not in the CMS data. In many areas of the country, Medicare Advantage plans are significant; physicians who provide services to Medicare Advantage patients also will be undercounted. This problem will be particularly apparent in states with a significant presence of managed care entities that do not provide services to Medicare beneficiaries on a fee-for-service basis. When assessing the likelihood that an ACO will exercise market power, the Agencies will have to take these providers into account.

D. Review Standards Are More Stringent Than the 1996 Statements

In addition, the review process as articulated applies regardless of the type of payment negotiated with payers, *e.g.*, fee-for-service or capitated, and regardless of whether there are joint fee negotiations, *e.g.*, an ACO with a few independent specialists that would use a messenger model where those specialists have their own contracts. This stands in contrast to the 1996 Health Care Statements in which these arrangements affected the treatment physician networks received from the Agencies. Thus, while ACOs were created to foster clinical integration, the standards developed in the Proposed Statement are, in some ways, less forgiving than the prior regime created by the 1996 Health Care Statements.

E. Conduct to Avoid is Overbroad and Could Penalize Procompetitive Activity

In most of the prior examples, in identifying certain conduct to avoid for ACOs wanting to minimize the chances of an antitrust challenge, the Agencies have drawn their lines at too high a level of generality. Similarly, anti-steering provisions and exclusivity, in certain forms at least, would actually promote the goals of ACOs, and discouraging them categorically serves little purpose. By lumping all anti-steering provisions into a frowned-upon category, the Agencies are depriving ACOs of one method by which they can encourage coordinated care; in fact, requiring ACOs to allow payers to steer patients to other providers would seem to actively disrupt any sort of coordination that the ACO might be expected to achieve.

As written, the Proposed Statement would seem to prohibit even the most unquestionably procompetitive behavior, such as offering health plans a better price in return for not steering patients outside the ACO. Furthermore, any concerns about anti-steering provisions would seem largely moot as long as providers do not agree to contract only through the ACO, because nothing would stop payers that believe the ACO to be too expensive from contracting separately with ACO providers or with providers not affiliated with an ACO.

Even the concept of exclusive contracting is more complicated than the Proposed Statement suggests: exclusivity in the sense of a payer not being allowed to contract with a provider other than through an ACO may be anticompetitive – if the provider has a large market share. However, the notion of a provider agreeing to contract with only one ACO while still remaining free to contract directly with health plans does not immediately appear problematic and could even promote the goals of ACOs with respect to coordination of care.

More broadly, the Proposed Statement misses the point that the purpose of the Shared Savings Program is to encourage clinical integration to increase the cost effectiveness and quality of care. It further seems to miss the point that the role of antitrust review is to ensure that there is sufficient competition in a given area, not to ensure that there are at least two competing ACOs in any given area. In some places, a single ACO may be the best hope of achieving the increase in quality that Congress intended. And, as long as providers in the ACO are available to contract independently with health plans in the area, competition will still thrive.

F. Convoluted Proposed Statement Does Not Sufficiently Clarify the Agencies' ACO Analysis

The Proposed Statement expresses an intent to “clarify the antitrust analysis of newly formed collaborations among independent providers that seek to become ACOs.”⁴⁶ But while the Proposed Statement possesses a veneer of clarity and predictability, the devil is, as always, in the details. In practice, the convoluted Proposed Statement raises more questions than it answers about how to create an ACO to avoid antitrust challenge.

The creation of three different thresholds that lead to three distinct pathways creates the appearance of detailed guidance, but a closer look reveals that there is little actual instruction about how an ACO can show it does not raise anticompetitive concerns. The Proposed Statement is mostly silent on what the Agencies will do to evaluate an ACO once it begins the review process and on what an ACO with over 50 percent PSA share in its common services can show to demonstrate it is not anticompetitive.

Granted, the Proposed Statement states that ACOs subject to mandatory review can “reduce the likelihood of antitrust concern by avoiding the five types of conduct described as conduct the avoidance of which can “significantly reduce the likelihood of an antitrust investigation” for ACOs with PSA shares between 30 and 50 percent, but there is no further guidance about how to distinguish among ACOs with high PSA shares to determine which may

⁴⁶ 76 Fed. Reg. 21895.

be anticompetitive and which may be competitively benign.⁴⁷ As such, the Agencies may in effect develop a presumption that all large ACOs are problematic, which, as discussed above, may undermine the very purpose of the Shared Savings program by harming those ACOs best positioned to deliver savings and quality care to Medicare.

G. Lack of Process for and Clarity of Re-Review for “Material Changes”

Another area lacking in clarity is that of re-review. Nowhere in the Proposed Statement is the process for re-review mentioned. However, the CMS Proposed Rule states that if at any time during the three-year agreement period, there occurs a “material” change in the participant and/or provider/supplier composition, the ACO must notify CMS within 30 days and recalculate its PSA shares for common services; if any PSA share is greater than 50 percent, there will be mandatory antitrust re-review of the ACO. Stemming from what appears to be a series of drafting errors in the CMS Proposed Rule, the precise circumstances requiring re-review are difficult to discern.

For example, Section 425.21(a)(1) of the CMS Proposed Rule states that “During the 3-year agreement, an ACO may remove, but not add, ACO participants . . . and it may remove or add ACO providers/suppliers.” Section 425.4 defines a participant as a provider or a supplier, indicating that an ACO both can and cannot add providers and suppliers during the three-year period. Similarly, also in section 425.21, this time in subsection (a)(2), the Rule requires that an ACO notify CMS within 30 days of any “significant change, as defined in paragraph (b) of that section. Paragraph (b) defines a significant change to mean, among other things, “a material change as defined in §425.14” of the Rule. Upon examining section 425.14, one finds that, in subsection (a)(4), a “material change” is defined as a “significant change (as defined in § 425.21(b)).”

Needless to say, these are rather circular definitions, and they do not provide much insight into the contours of the meaning of the terms significant or material, nor do they make clear whether a provider can be added during the three-year period. An ACO participant who is, for example, considering adding a new specialty, will need to know under what circumstances that might trigger re-review, and no such guidance is given in either the CMS Proposed Rule or the Proposed Statement.

There are other questions stemming from the re-review concept that the Proposed Statement does not answer. The exit of a market participant, such as due to closure of a facility or a physician’s decision to cease active practice in the area, could wildly alter the PSA share of an ACO through no fault of its own – would such a change prompt re-review in and of itself? Even if it did not, if an ACO happened to be required to undergo re-review for other reasons, and its PSA share turns out to have changed drastically as a result of market conditions, would that cause it to be terminated from the Shared Savings Program? Additionally, the timing of re-review after a significant change is unclear; while CMS requires notice within 30 days of the change, there is no mention of when (or if) information must be submitted to the Agencies for re-

⁴⁷ See discussion of anti-steering and exclusivity above.

review. Even worse, if an ACO is re-reviewed because of change in composition and fails, does that open it up to antitrust exposure in the time before that determination is made?

All in all, the Proposed Statement comes up short, not only of providers' expectations but of the Agencies' own enunciated goals. And yet, there exists a successful program of antitrust review coordinated with another agency from which the DOJ, FTC and CMS could draw to improve the processes detailed in the Proposed Statement.

H. Exemption for Preexisting ACOs is Unclear and Likely Unhelpful

The Proposed Statement announces that it applies only to those ACOs "formed after March 23, 2010," a symbolically obvious choice perhaps, as it represents the day of final passage of the ACA, but one that does not offer any clarity for potential ACOs; in fact, the March 31 date only adds to the confusion engendered by the Proposed Statement.

As a threshold matter, the Proposed Statement appears to be out of step with the CMS Proposed Rule § 425.5, which lays out the eligibility requirements that must be met in order for an ACO to participate in the Shared Savings program. Specifically, § 425.5(d)(2) requires antitrust review for all ACOs with a greater than 50 percent PSA share of any common services and even specifically excludes ACOs subject to the Rural Exception but does not mention the March 23, 2010 date. CMS and the Agencies must get on the same page regarding whether ACOs formed prior to March 23, 2010 are required to comply with § 425.5(d)(2) or whether this amounts to a drafting error.

Even if CMS and the Agencies clear up this discrepancy, confusion will persist. For example, the Proposed Statement does not define the meaning of the term "formation," which could mean any number of things, from the date articles of incorporation are filed, to the date on which the ACO signs its first contract with a payer, or to the date of the first transmission of electronic medical records between two ACO participants. Further, it is questionable whether an ACO's formation will have any bearing on the extent to which it might demonstrate anticompetitive behavior, suggesting that pegging mandatory review to formation might not only cause confusion but also might not accomplish any purpose. More fundamentally, without any definition, an ACO may be hard-pressed to determine whether it falls into the pre- or post-March 23, 2010 category and thus unable to initiate the CMS application process without first requesting clarification, and, in all likelihood, further bogging down what appears to be an already lengthy process.

Finally, the benefit of this exemption of pre-March 23 ACOs is debatable. Those ACO-like entities that are deemed to have been formed prior to March 31, 2010 will be injected back into a pre-ACA regime of uncertainty, without the benefit of automatic Rule of Reason treatment. This arbitrary cutoff could end up harming Medicare beneficiaries, as those ACOs who have the most experience at coordinating care may face too much uncertainty to risk even applying to the Shared Savings program.

VI. A Potential Model That Satisfies the Agencies' Goals: DOJ Bank Merger Competitive Review

To the extent that the Agencies wish to seek authority to review ACOs prospectively, the DOJ Bank Merger review process provides a better model than the Proposed Statement. This is because it is streamlined, provides clear guidance to the parties, and does not undermine procompetitive conduct. As such, the Agencies and CMS should look to this process as an example of how to conduct the antitrust review of ACOs without hijacking the entire undertaking.

Unlike antitrust review of ACOs, competitive review of bank mergers, in one way or another, is mandated by statute, either by the *Bank Merger Act*⁴⁸ (if a merger of banks) or by the *Bank Holding Company Act*⁴⁹ (if a merger of bank holding companies). In a contemplated merger of banks, the reviewing banking agency must request a report from DOJ prior to approving the merger.⁵⁰ DOJ then has 30 days to deliver its report to the banking agency.⁵¹ By contrast, in a merger of bank holding companies, there is not an explicit requirement that DOJ review the transaction before its completion; however, there is a tacit requirement, as copies of merger application and all associated information sent to banking agencies must be contemporaneously filed with the DOJ (and FTC).⁵² The DOJ is not obligated to file a report on the transaction with the banking agencies but, by custom, it tends to.

Like the DOJ, FTC and CMS in the context of ACOs, DOJ and the banking agencies collaborated on the review process to be conducted on bank mergers. The Bank Merger Competitive Review was jointly issued by DOJ and banking agencies in 1995. "To speed [the] competitive review and reduce regulatory burden on the banking industry" – similar goals to those articulated in the Proposed Statement – the agencies created a double-screen process whereby each agency can whittle down the number of mergers to only those that raise significant competitive concerns. The banking agencies go first, employing Screen A, which states that if the post-merger HHI⁵³ is less than 1800, and the change in HHI is less than 200 in relevant geographic market, the agency will determine that merger "clearly [will] not have significant adverse effects on competition."⁵⁴

⁴⁸ 12 U.S.C. § 1828(c)(4).

⁴⁹ *Id.* at § 1843.

⁵⁰ *Id.* at § 1828(c)(4)(A).

⁵¹ *Id.* at § 1828(c)(4)(B).

⁵² 15 U.S.C. § 18a(c)(8).

⁵³ The Herfindahl-Hirschman Index, or HHI, is the standard measure used by economists to evaluate market concentration.

⁵⁴ The HHI threshold currently used by DOJ could be somewhat different, reflecting the 2010 revisions to the Horizontal Merger Guidelines.

In addition to using Screen A, DOJ also will use a tighter screen, Screen B, that applies a more narrow geographic market and weighs thrifts deposits differently as a secondary tool if it concludes that “Screen A does not reflect fully the competitive effects of the transaction in all relevant markets, in particular lending to small and medium-sized business.” If under Screen B, the HHI is less than 1800 and the change is less than 200, the transaction will generally not be further analyzed by DOJ. In some rare circumstances, DOJ will conduct further analysis on a transaction that has passed both screens. This is most likely to occur when: (1) “the screens’ market area does not fit the transaction;” and (2) “specialized products are involved.”

If post-merger the HHI exceeds 1800/200 in either Screen A or B, the agencies suggest – but do not require – that further information be furnished by the parties to the transaction to aid in making clear the competitive landscape. The type of information sought includes:

- “evidence that the merging parties do not significantly compete with one another;”
- “evidence that rapid economic change has resulted in an outdated geographic market definition, and that an alternative market is more appropriate;”;
- “evidence that market shares are not an adequate indicator of the extent of competition in the market;” and
- “evidence concerning entry conditions; of likely entry within next two years; expectations about potential entry by institutions not now in the market.”

The screening guidelines provide insight into the coordination among the agencies to attempt to streamline investigations and balance different approaches. The screening guidelines state that the agencies will rely on deposits by branch office. These data are provided in the FDIC Summary of Deposits database. While the agencies use different weights, the data sources for screening are the same. In addition, DOJ advises that it makes use of commercial and industrial loan data to assess the extent to which an institution is engaged in commercial lending. Both agencies also make use of *Community Reinvestment Act* (CRA) data.⁵⁵ Finally, several of the Reserve Banks make available pre-defined geographic markets in which data are made available for shares.

This process employed by DOJ and the banking agencies provides a blueprint for how to alter the proposed approach to antitrust enforcement of ACOs. For example, mimicking the bank merger process would properly shift the data burden back onto the Agencies rather than on the applicant – the Agencies would do a lot of the number-crunching that the Proposed Statement expects applicants to do. Having the Agencies deal with the data would allow for more consistent calculations across different applicants, improving the process. Moreover, in the bank merger review process, DOJ and the bank agencies use the same information for screening

⁵⁵ The CRA data are reported by depository institutions and provide insight into small business lending activity by local and non-local financial institutions (commercial and industrial loans and commercial real estate loans) in local geographies.

purposes. Thus, antitrust review of a bank merger does not place an added burden on the parties seeking to merge, something that the Proposed Statement purports to desire. The CMS application by itself is already quite burdensome and adding on top of that the separate antitrust agency application, makes the burden even harder to justify. Adopting a process by which an applicant's antitrust review is incidental to the evaluation of its application does not undermine the goal of ensuring that ACOs are not flouting the antitrust laws, nor does it create an unmanageable regulatory burden on applicants.

The screening mechanism used by the DOJ and the banking agencies in the merger review process is both simpler to calculate and more familiar to antitrust attorneys. Additionally, the bank merger review process is characterized by interplay between the DOJ and the banking agencies during the review process; rather than DOJ simply delivering a letter to the relevant banking agency at the end of its review that explains its decision, DOJ staff – both attorneys and economists – regularly interfaces with its banking agency counterparts, making the process collaborative and building a strong working relationship between the agencies.

The Proposed Statement already creates a forum for such interaction in the form of the Working Group; of course, the Working Group has as its only members the DOJ and FTC. The Working Group should be altered to include CMS members to facilitate coordination between the agencies so that the antitrust reviewers learn how their process is affecting ACO applicants. The three agencies relevant to ACOs have already shown a strong willingness to cooperate during the lead up to the Proposed Statement and its aftermath, and they should formalize this willingness by including CMS in the Working Group.

VII. Conclusion

The Proposed Statement is a disappointing document. Despite all the efforts of the various agencies involved in its planning, the Proposed Statement falls short of accomplishing what it set out to – designing a review process that could rapidly identify those ACOs that might pose a threat to competition without unduly hampering the development of the Medicare Shared Savings Program.