

# HEALTH REFORM IMPACT

## What you need to know NOW

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

### **ACOs Part II: Oasis or Mirage? The FTC and DOJ Proposed Statement on ACOs**

April 29, 2011

On March 31, 2011, simultaneously with the publication of the CMS Proposed Rule for the Medicare Shared Savings Program, the United States Department of Justice ("DOJ") and Federal Trade Commission ("FTC") released for public comment a joint "Proposed Statement of Antitrust Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (the "Proposed Statement"). Importantly, the Proposed Statement provides that the participants in a CMS-approved accountable care organization ("ACO") that jointly contract with third party payers outside the Medicare program will not be subject to *per se* liability for price-fixing under the antitrust laws. Instead, joint negotiations by qualifying ACOs will be subject to the more lenient "rule of reason" standard of review so long as the ACO provides essentially the same services in the commercial market and uses the same governance and leadership structure and the same clinical and administrative processes it uses to qualify for participation in the Shared Savings Program. ACOs remain eligible for "rule of reason" review so long as they remain participants in the Shared Savings Program.

This is an important development for independent providers that wish to jointly negotiate with payers. Generally, absent use of an arrangement such as an ACO, clinical integration, or the messenger model, an agreement among such providers to jointly negotiate contracts with payers is considered *per se* illegal price fixing – because once an agreement among the providers has been established, liability automatically attaches without consideration of claims of valid business reasons or pro-competitive benefits for the joint negotiations. On the other hand, if the "rule of reason" standard is applied, the Courts consider many factors and ultimately if the pro-competitive benefits outweigh the anticompetitive effects of the arrangement, there will not be antitrust liability.

The Proposed Statement, available on our website [here](#), sets forth the requirements that an ACO must meet in order to participate in the Shared Savings Program.<sup>1</sup> The Proposed Statement establishes a safety zone within which qualifying ACOs will not be subject to challenge by the antitrust agencies and also creates a mandatory review process for ACOs that are deemed to have the potential to harm competition. ACOs that fail this mandatory review will not be approved by CMS.

---

<sup>1</sup> See also Part I of our series on ACOs, "ACOs Part I: Assembly Instructions," [available here](#)

The Proposed Statement states that it is only applicable to collaborations among independent providers that were formed after March 23, 2010, that seek to become approved to participate in the Shared Savings Program. The Proposed Statement contemplates that many already-existing organizations will apply to become ACO participants in the Shared Savings Program. These entities, then, will not be subject to the mandatory review process. On the other hand, if the Proposed Statement is read literally, pre-existing entities may not be guaranteed freedom from enforcement actions even if they would otherwise fall within the safety zone.

### *Safety Zone*

Under the Proposed Statement, absent extraordinary circumstances, the antitrust agencies will not challenge an ACO that meets CMS' eligibility criteria to participate in the Shared Savings Program and has a 30% or less share of each service<sup>2</sup> provided by two or more independent ACO participants within the ACO's Primary Service Area.<sup>3</sup> The safety zone provides a limited exception, however, for the inclusion of certain providers with shares exceeding 30% in rural counties.

An ACO that includes a hospital or ambulatory surgery center is not eligible for the safety zone unless the hospital or ambulatory center participates on a non-exclusive basis, meaning that it must be allowed to contract individually with commercial payers and to affiliate with other ACOs. Additionally, the safety zone is available only if any "dominant provider"<sup>4</sup> included in the ACO participates on a non-exclusive basis. Moreover, an ACO that includes a "dominant provider" is eligible for the safety zone only if the ACO does not require any commercial payers to contract exclusively with the ACO and also does not restrict any commercial payer's ability to contract with other ACOs or provider networks.

Even if an ACO meets the requirements for the safety zone, it may later lose the protection of the safety zone if the ACO increases its Primary Service Area share over 30% through the inclusion of additional providers in the ACO. Thus, ACOs seeking to take advantage of the safety zone will have to continually evaluate the antitrust impact of any provider additions. ACOs will not fall out of the safety zone, however, if they gain Primary Service Area share simply by serving more patients through the same ACO participants.

### *Mandatory Review Process*

The Proposed Statement sets up a mandatory review process for ACO's that have a 50% or greater share in the Primary Service Area of any one service provided by two or more independent ACO participants. The Proposed Statement notes that this mandatory review process "provides a valuable indication of the potential for competitive harm from ACO's with high [Primary Service Area] shares."<sup>5</sup> During this mandatory review process, the agencies will consider any information or data provided by the ACO suggesting that the ACO's high shares do not reflect actual market power and will also consider any pro-competitive justifications offered by the ACO. Notably, ACOs falling under the 50% threshold that wish to have additional certainty regarding their antitrust exposure may voluntarily undergo the review process. ACOs that do not pass the review process will not be allowed to participate in the Shared Savings Program.

---

<sup>2</sup> Services are defined as: (1) for physicians, the physician's primary specialty as identified by its Medicare Specialty Code; (2) for inpatient facilities, its Major Diagnostic Category; and (3) for outpatient facilities, an "outpatient category," as defined by CMS. The antitrust agencies have requested public comment on the best data to determine shares for these types of services.

<sup>3</sup> A "Primary Service Area" is defined as "the lowest number of contiguous postal zip codes from which [the ACO participant] draws at least 75% of its [patients]."

<sup>4</sup> An ACO participant is considered a "dominant provider" if it possesses a 50% or greater share of any service.

<sup>5</sup> Proposed Statement at 8.

The mandatory review process described in the proposed statement is similar in many ways to the Hart-Scott-Rodino ("HSR") premerger notification program. Like HSR, the agencies contemplate an expedited review process – here, the agencies promise to complete the review within 90 days of receiving all information required to be submitted by the Proposed Statement. Like HSR, the review process will require a fairly extensive search for and submission of many documents to the agencies. Specifically, the Proposed Statement contemplates that the following documents will be submitted:

- The CMS Shared Savings Program application and all supporting documents;
- Documents or agreements relating to the ability of ACO participants to compete with the ACO;
- Documents or agreements relating to any incentives to encourage ACO participants to contract with CMS or commercial payers through the ACO;
- Documents discussing the ACO's business strategies or plans to compete;
- Documents showing the formation of any ACO or ACO participant that was formed in whole or in part after March 23, 2010; and
- Additional documents showing Primary Service Area share calculations, restrictions on sharing of certain price information between ACO participants, the points of contact for the five largest commercial payers for the ACO's services, and the identity of competing ACOs.

In addition to this document production requirement, the agencies reserve the right to request additional documents and information as they deem necessary to evaluate the ACO. Furthermore, the Proposed Statement imposes a record-keeping requirement on ACOs, which are expected to maintain the data on which they relied to calculate their shares of services in their Primary Service Area.

As with the safety zone, an ACO that was not initially required to undergo the mandatory review process may be required to undergo the review at a later time if the ACO gains Primary Service Area share due to the inclusion of additional providers. On the other hand, an ACO that gains share simply by serving more patients with the same participants will not be required to undergo review. Moreover, the Proposed Statement contemplates that an ACO that has already undergone and passed its review may have to undergo another review if "there is a significant change to the ACO's provider composition such that the ACO . . . is materially different than what was reviewed." The Proposed Statement does not address whether an ACO that already participates in the Shared Savings Program may continue to operate while awaiting this review.

#### *Additional Guidance*

The Proposed Statement concludes by offering guidance as to the types of activities that ACOs falling below the mandatory review threshold should not undertake in order to avoid antitrust liability. The agencies note that following these guidelines will "reduce significantly the likelihood of an antitrust investigation."<sup>6</sup> The specific activities that an ACO should avoid are:

- Preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers;
- Tying sales of the ACO's services to a commercial payer's purchase of services from providers outside the ACO;
- Contracting with other ACO physician specialists, hospitals, ASCs, or other providers (except primary care physicians) on an exclusive basis;
- Restricting a commercial payers' ability to offer its enrollees certain cost, quality, efficiency, and performance information; and
- Sharing competitively sensitive pricing or other data among the ACO participants that could be used to set prices for services provided outside the ACO.

---

<sup>6</sup> Proposed Statement at 11.

### *Looking Forward*

The FTC and DOJ have invited public comment on the Proposed Statement, including whether there are other data sources that could provide a better basis for determining Primary Service Area shares for certain services and the overall burden of the proposed mandatory review process. The period for public comment ends May 31, 2011.

It will be interesting to see whether the submission of public comment results in any changes to the Proposed Statement. Hopefully, the antitrust agencies will further clarify what constitutes a "significant change" in an ACO's provider composition that warrants an additional mandatory review. In addition, it would be helpful for the antitrust agencies to explain whether an ACO is still eligible to participate in the Shared Savings Program pending re-review by the agencies. The antitrust agencies may also explain whether ACOs formed before March 23, 2010 may take advantage of the safety zones and/or the Proposed Statement's voluntary review mechanisms.

This alert is the second in a series dedicated to ACOs. Future issues of *Health Reform IMPACT* will discuss the quality, fraud and abuse and data sharing issues contained in the proposed rules and commentary related to Section 3022 of the Patient Protection and Affordable Care Act regarding ACOs. If you have questions, please contact any of the attorneys in our Healthcare Practice Group or Antitrust Practice Group listed below.

Also, please [click here](#) to visit our special webpage on Health Reform IMPACT.

#### Bass, Berry & Sims Healthcare Attorneys

**Philip F. Berg**  
(615) 742-7908  
[pberg@bassberry.com](mailto:pberg@bassberry.com)

**Krista T. Cooper**  
(615) 742-7734  
[kcooper@bassberry.com](mailto:kcooper@bassberry.com)

**Meredith Edwards**  
(615) 742-7823  
[medwards@bassberry.com](mailto:medwards@bassberry.com)

**Mary Beth Fortugno**  
(615) 742-7739  
[mfortugno@bassberry.com](mailto:mfortugno@bassberry.com)

**Valere Fulwider**  
(615) 742-7822  
[vfulwider@bassberry.com](mailto:vfulwider@bassberry.com)

**Lauren Gaffney**  
(615) 742-7824  
[lgaffney@bassberry.com](mailto:lgaffney@bassberry.com)

**Pooneh Ghiassi**  
(615) 742-7782  
[pghiassi@bassberry.com](mailto:pghiassi@bassberry.com)

**Anna Grizzle**  
(615) 742-7732  
[agrizzle@bassberry.com](mailto:agrizzle@bassberry.com)

**Elisa E. Harris**  
(615) 742-6553  
[eharris@bassberry.com](mailto:eharris@bassberry.com)

**Angela Humphreys**  
(615) 742-7852  
[ahumphreys@bassberry.com](mailto:ahumphreys@bassberry.com)

**J. James Jenkins, Jr.,  
Chair**  
(615) 742-6236  
[jjenkins@bassberry.com](mailto:jjenkins@bassberry.com)

**Seth A. Killingbeck**  
(615) 742-7707  
[skillingbeck@bassberry.com](mailto:skillingbeck@bassberry.com)

**Daniel R. Kuninsky**  
(615) 742-7837  
[dkuninsky@bassberry.com](mailto:dkuninsky@bassberry.com)

**Claire F. Miley**  
(615) 742-7847  
[cmiley@bassberry.com](mailto:cmiley@bassberry.com)

**T. Scott Noonan**  
(615) 742-6273  
[snoonan@bassberry.com](mailto:snoonan@bassberry.com)

**Shannon Pinkston**  
(615) 742-7727  
[spinkston@bassberry.com](mailto:spinkston@bassberry.com)

**Cynthia Y. Reisz**  
(615) 742-6283  
[creisz@bassberry.com](mailto:creisz@bassberry.com)

**Brian D. Roark**  
(615) 742-7753  
[broark@bassberry.com](mailto:broark@bassberry.com)

**Catherine J.B. Sloan**  
(615) 742-7789  
[csloan@bassberry.com](mailto:csloan@bassberry.com)

**Danielle M. Sloane**  
(615) 742-7763  
[dsloane@bassberry.com](mailto:dsloane@bassberry.com)

**Nesrin Garan Tift**  
(615) 742-7903  
[ntift@bassberry.com](mailto:ntift@bassberry.com)

**Leigh Walton**  
(615) 742-6201  
[lwalton@bassberry.com](mailto:lwalton@bassberry.com)

**Elizabeth S. Warren**  
(615) 742-7719  
[ewarren@bassberry.com](mailto:ewarren@bassberry.com)

**Douglas M. Wolford**  
(615) 742-7917  
[dwolford@bassberry.com](mailto:dwolford@bassberry.com)

**Bass, Berry & Sims Antitrust & Trade Practices Group**

**R. Dale Grimes, Chair**  
(615) 742-6244  
[dgrimes@bassberry.com](mailto:dgrimes@bassberry.com)

**Joshua R. Denton**  
(615) 742-7761  
[jdenton@bassberry.com](mailto:jdenton@bassberry.com)

**Charles G. Jarboe**  
(615) 742-7850  
[cjarboe@bassberry.com](mailto:cjarboe@bassberry.com)

**E. Steele Clayton, IV**  
**Assistant Chair**  
(615) 742-6205  
[sclayton@bassberry.com](mailto:sclayton@bassberry.com)

**David R. Esquivel**  
(615) 742-6285  
[desquivel@bassberry.com](mailto:desquivel@bassberry.com)

**Matthew J. Sinback**  
(615) 742-7910  
[msinback@bassberry.com](mailto:msinback@bassberry.com)

**Ross Booher**  
(615) 742-7764  
[rbooher@bassberry.com](mailto:rbooher@bassberry.com)

**Erin M. Everitt**  
(615) 742-7997  
[eeveritt@bassberry.com](mailto:eeveritt@bassberry.com)

**Lucas Ross Smith**  
(615) 742-6526  
[lsmith@bassberry.com](mailto:lsmith@bassberry.com)

*The materials contained herein have been abridged from the statutory sources and should not be construed or relied upon for legal advice. Readers are urged to consult legal counsel concerning particular situations and specific legal questions.*

*To ensure compliance with requirements imposed by the IRS, we inform you that this message is not intended to be used, and cannot be used, by the addressee or any other person for the purpose of avoiding penalties that may be imposed under the Internal Revenue Code.*