Federal Trade Commission/Department of Justice ACO Working Group

Index of Questions and Answers Received in the PSA Share Calculation Electronic Mailbox Established Under the ACO Policy Statement

March 31, 2013

The Federal Trade Commission (FTC) and Department of Justice (DOJ) issued the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (the ACO Policy Statement) in October 2011 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. Under the ACO Policy Statement, an ACO may calculate its primary service area (PSA) shares to determine whether it falls within an antitrust safety zone for certain ACOs that are highly unlikely to raise significant competitive concerns. The ACO Policy Statement also describes certain conduct an ACO may want to avoid if it has high PSA shares or other indicia of market power.

In order to provide guidance in calculating PSA shares, the FTC and DOJ have established an electronic mailbox to allow ACOs to submit questions regarding their PSA share calculations. The questions submitted to the mailbox can be grouped into four subject categories: (1) data for calculating PSA shares, (2) calculating PSA shares, (3) the voluntary review process, and (4) miscellaneous. The questions received in the mailbox are listed in abbreviated form by subject category in the index below, along with corresponding links to the full questions and answers provided by the FTC/DOJ ACO Working Group.[1] This index will be updated periodically to include any additional questions received in the mailbox.

I. Data for Calculating PSA Shares

1. In what file format will the Medicare claims data be provided?

2. What is the date of the claims data CMS has made publicly available for calculating an ACO's PSA shares under the ACO Policy Statement?

3. Is it possible to obtain Medicare data for services that are more narrowly defined than the available data?

4, 5, 6, 7, and 8. When will 2011 claims data be available to calculate PSA shares? [Note: These five questions relate to a similar issue. Therefore, only one question is included here].

[1] The ACO Working Group has (1) edited the questions and answers, where appropriate, for clarity and to exclude any confidential information, and (2) omitted questions related to issues under the proposed ACO Policy Statement that are no longer relevant under the final Policy Statement. Nothing in these questions and answers is intended to modify the ACO Policy Statement, and to the extent any discrepancies arise, the ACO Policy Statement governs.

9. Is there a notification list to which I can subscribe for changes in status regarding the availability of updated data on the CMS website for calculating PSA shares?

10. Are there any plans to provide the "numerators" for calculating PSA shares for an ACO?

11. What is the process for calculating PSA shares and how do we request the data?

12. Could you refer me to the contact person at CMS that may be able to explain how to utilize beneficiary zip codes from the claims and what data source was used?

13. The CMS webpage with data files for calculating PSA shares refers to the Policy Statement for obtaining detailed instructions on using this data. What is the Policy Statement?

14. Has the data on the CMS website in the download file, "Medicare Data to Calculate Your Primary Service Areas," been wage adjusted?

II. Calculating PSA Shares

1. Do the physician fee-for-service claims in the CMS data set include physician extenders' (i.e. nurse practitioner, physician assistant) services?

2. Where a single hospital system partners with multiple IPAs to create separate ACOs, does the ACO have to include services provided by the IPAs in the other ACOs – e.g., for ACO 1, services provided by IPA 2 and IPA 3 – in calculating its PSA shares?

3. Does an ACO participant that does not appear to fit within the categories of physician specialty, major diagnostic categories for inpatient facilities or outpatient categories have to calculate its PSA shares?

4. In calculating PSA shares, should an ACO use counties based on facility location or patient residence?

5. Is the PSA definition (not the market share calculation) relative to the "participant" or the "common service"?

6. How do we determine which postal zip codes to use in defining PSAs?

7. Should we define the service area for Medicare patients only or all patients in calculating PSA shares?

8. Can someone direct me to where it describes how to calculate PSA shares for a hospital?

9. Who will calculate an ACO's PSA shares?

10. Please provide us with PSA calculation instructions.

11. Please send me information on how to calculate an ACO's shares within relevant PSAs along with any illustrative examples and relevant information.

III. Voluntary Review

1. After a newly formed ACO requests voluntary expedited review under the procedures in the ACO Policy Statement, how long will it take for the reviewing agency to contact me before the 90 day review commences?

2. What happens at the end of the voluntary expedited review?

3. Is the ACO granted a waiver from further antitrust challenges or granted safety zone treatment following a voluntary review?

IV. Miscellaneous

1. When and where will the applications to participate in the new ACO program be made available?

2. Is an ACO a collaboration among non-competitors where the participants are a hospital system and an IPA whose physician members own facilities, such as surgical centers and imaging centers, that compete with services provided by the hospital system?

3. In light of the fact that the final ACO Policy Statement does not require mandatory antitrust review, can you offer any guidance for an entity that will be over the 50% threshold in terms of PSA shares?

4. How can small business medical provider offices that are proprietor organizations effectively work together consistent with the antitrust and Stark Laws?

5. Is there a document available that outlines service area and number of assigned lives for each ACO?

Federal Trade Commission/Department of Justice ACO Working Group

Questions and Answers Relating to Data Used to Calculate Primary Service Area Shares Under the ACO Policy Statement

Under the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (the ACO Policy Statement), ACOs may send questions regarding primary service area (PSA) share calculations to an electronic mailbox. The Federal Trade Commission/Department of Justice ACO Working Group received and answered the questions below related to obtaining and using Medicare and other data for calculating PSA shares.

1. In what file format will the Medicare claims data be provided?

A: If you are referring to the Medicare claims data to use for calculating PSA shares under the ACO Policy Statement, CMS has posted a file with the data at https://www.cms.gov/sharedsavingsprogram/35_Calculations.asp#TopOfPage.

CMS has made this data publicly available for an ACO that elects to calculate its PSA shares under the ACO Policy Statement. A newly formed ACO that has chosen to seek voluntary expedited antitrust review must provide the information set forth in the ACO Policy Statement, including any PSA share calculations the ACO may have performed or, alternatively, other data that show the current competitive significance of the ACO. An ACO also may calculate PSA shares if it wants to determine whether it falls within the safety zone under the ACO Policy Statement. The ACO Policy Statement is available at http://www.ftc.gov/opp/aco/index.shtml.

Please contact CMS if you have questions regarding the file format for any other data you are expecting to receive from CMS.

2. What is the date of the claims data CMS has made publicly available for calculating an ACO's PSA shares under the ACO Policy Statement?

A: You asked us to confirm the date of the claims data CMS has made publicly available for calculating an ACO's PSA shares under the ACO Policy Statement. The files contain claims data for 2010. The date in the file name may reflect when the 2010 data was pulled for the file.

3. Is it possible to obtain Medicare data for services that are more narrowly defined than the available data?

A: You have asked about obtaining Medicare data for more narrowly defined services. For purposes of calculating PSA shares under the ACO Policy Statement, ACOs should use the physician specialty codes, outpatient categories, and data CMS currently has made available on its website. CMS has informed us that it does not have the resources

necessary to generate more detailed or narrowly defined data for calculating PSA shares. CMS also suggested that you may want to contact The Research Data Assistance Center (1-888-9RESDAC or www.resdac.org) for further information.

As explained in the Policy Statement, PSA shares are useful as a screening device. Alternative data and information also may be useful in evaluating the likely competitive significance of an ACO. The Agencies recognize that an ACO may have reliable evidence other than PSA shares from which one may reasonably conclude that the ACO is unlikely to raise competitive concerns. A newly formed ACO that has chosen to seek voluntary expedited antitrust review must provide either the PSA share calculations the ACO may have performed or other data that show the current competitive significance of the ACO or ACO participants. In addition, the ACO may submit any other documents and information that it believes may be helpful in assessing the ACO's likely impact on competition. The documents or information may include anything that may establish a clearer picture of competitive realities in the market, including evidence that the ACO is not likely to have market power in the relevant market.

4, 5, 6, 7, and 8. When will 2011 claims data be available to calculate PSA shares? [Note: These five questions relate to a similar issue. Therefore, only one question is included here].

A: We are currently working with CMS on the availability of 2011 data to calculate PSA shares and will let you know as soon as we have more information.

Under the FTC/DOJ Antitrust Enforcement Policy Statement Regarding ACOs Participating in the Shared Savings Program (Policy Statement), PSA share calculations are useful as a screening device. Alternative data and information also may be useful in evaluating the likely competitive significance of an ACO. Neither the Policy Statement nor the CMS regulations require an ACO to calculate its PSA shares. An ACO may want to calculate its PSA shares to determine whether it falls within the safety zone under the Policy Statement. Also, an ACO that determines it has high PSA shares or other possible indicia of market power may wish to avoid the conduct set forth in the Policy Statement. A newly formed ACO that has chosen to seek voluntary expedited 90 day antitrust review must provide the information set forth in the Policy Statement, including any PSA share calculations the ACO may have performed or, alternatively, other data that show the current competitive significance of the ACO.

9. Is there a notification list to which I can subscribe for changes in status regarding the availability of updated data on the CMS website for calculating PSA shares?

A: Although there isn't a notification list, we have your contact information and will be back in touch with you when we have an update from CMS on the availability of the data.

10. Are there any plans to provide the "numerators" for calculating PSA shares for an ACO?

A: You have asked about availability of data to use for the "numerator" to calculate an ACO's Primary Service Area ("PSA") shares. Under the ACO Policy Statement, an ACO seeking expedited voluntary review must provide information sufficient to show either PSA share calculations the ACO may have performed or other data that show the current competitive significance of the ACO or its participants. An ACO calculating its PSA shares will need to provide its own data for the "numerator." CMS has provided the necessary data for the "denominator" on its website.

11. What is the process for calculating PSA shares and how do we request the data?

A: You have asked about the process for calculating an ACO applicant's PSA shares under the ACO Policy Statement. Neither the Policy Statement nor the CMS ACO regulations require an ACO to calculate PSA shares. However, an ACO may want to calculate its PSA shares to determine whether it falls within the safety zone under the ACO Policy Statement. Also, an ACO that determines it has high PSA shares or other possible indicia of market power may wish to avoid the conduct set forth in the Policy Statement. A newly formed ACO that has chosen to seek voluntary expedited 90 day antitrust review must provide the information set forth in the ACO Policy Statement, including any PSA share calculations the ACO may have performed or, alternatively, other data that show the current competitive significance of the ACO. The ACO Policy Statement is available at http://www.justice.gov/atr/public/health_care/aco.html and http://www.ftc.gov/opp/aco/index.shtml.

The Appendix to the ACO Policy Statement explains how to calculate PSA shares for an ACO that elects to do so. CMS has made publicly available the necessary data to calculate the "denominator" on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Calculations.html. An ACO calculating its PSA shares will need to provide its own data for the "numerator."

12. Could you refer me to the contact person at CMS that may be able to explain how to utilize beneficiary zip codes from the claims and what data source was used?

A: CMS contacts are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Regional_Contacts.html.

13. The CMS webpage with data files for calculating PSA shares refers to the Policy Statement for obtaining detailed instructions on using this data. What is the Policy Statement?

A: The "Policy Statement" referred to is the final *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program*, which can be found at

http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf and http://www.justice.gov/atr/public/health_care/276458.pdf. The Appendix to the ACO Policy Statement contains detailed instructions on how to calculate PSA shares.

14. Has the data on the CMS website in the download file, "Medicare Data to Calculate Your Primary Service Areas," been wage adjusted?

A: To reflect local market conditions, Medicare's base payment rates are adjusted by a local wage index. The data provided for calculating PSA shares are actual payment amounts that reflect this adjustment. If you are asking about the data being wage adjusted in some other way, could you please clarify your question?

Federal Trade Commission/Department of Justice ACO Working Group

Questions and Answers Relating to Calculating Primary Service Area Shares Under the ACO Policy Statement

Under the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (the ACO Policy Statement), ACOs may send questions regarding primary service area (PSA) share calculations to an electronic mailbox. The Federal Trade Commission/Department of Justice ACO Working Group has received and answered the PSA share calculation questions below.

1. Do the physician fee-for-service claims under primary care in the physician data set provided on the CMS website include physician extenders' (i.e. nurse practitioner, physician assistant) services?

A: You have asked whether the services of nurse practitioners, physician assistants, or other "physician extenders" are included in calculating an ACO's PSA shares. The services of these health care providers are only included in the calculation if their services are billed to Medicare under a National Provider Identifier ("NPI") of a physician. CMS has included in the publicly available data the fee-for-service allowed charges for the services of these providers only when they are billed under the NPI of a physician. However, the CMS data does not include the allowed charges for "physician extenders" who bill Medicare directly for their services.

2. Where a single hospital system partners with multiple IPAs to create separate ACOs, does the ACO have to include services provided by the IPAs in the other ACOs – e.g., for ACO 1, services provided by IPA 2 and IPA 3 – in calculating its PSA shares?

A: You have asked about calculating PSA shares in a case where a single hospital system partners with multiple IPAs to create separate ACOs. Specifically, you have posed a hypothetical in which a hospital system sets up three separate, legally distinct ACOs with three different IPAs – e.g., ACO 1, comprising Hospital 1 of the hospital system and IPA 1; ACO 2, comprising Hospital 2 of the hospital system and IPA 2; and ACO 3, comprising Hospital 3 of the hospital system and IPA 3. The hospital system owns a majority stake in each ACO. As we understand your question, you have asked whether, in identifying common services for an ACO and calculating that ACO's share of those common services, the ACO must include services provided by the IPAs in the other ACOs – e.g., for ACO 1, services provided by IPA 2 and IPA 3.

The short answer is yes. The ACO Policy Statement states that "[i]f an entity owned by an ACO participant provides services in a PSA, those services should be included in the share calculation regardless of whether the affiliated organization participates in the ACO." As such, any ACO owned by a participating hospital or hospital system should be included in identifying common services and in calculating shares of common services in the relevant PSAs (to the extent that ACO provides a common service in a relevant PSA).

We illustrate this answer with two examples that build on your hypothetical. First, assume that the ACOs operate in different areas. For example, ACO 1 serves patients in New York, ACO 2 serves patients in Chicago, and ACO 3 serves patients in Los Angeles. In identifying common services for ACO 1, you would include services provided by ACO 2, which includes IPA 2, and ACO 3, which includes IPA 3. But there would be no zip codes from which both ACOs draw patients, so the PSA shares calculated for IPA 1, for example, would not include charges from IPA 2 or IPA 3.

Second, assume that all of the ACOs operate in the same area. Again, in identifying common services for ACO 1, you would include services provided by ACO 2, which includes IPA 2, and ACO 3, which includes IPA 3. However, in this case, there are zip codes from which both ACOs draw patients, so the PSA shares calculated for IPA 1, for example, could include charges from IPA 2 or IPA 3. For example, if both IPA 1 and IPA 2 (but not Hospital 1) provide Service A, Service A is a common service. If both IPA 1 and IPA 2 provide Service A in either IPA's PSA, you should calculate that PSA share using both IPA 1's and IPA 2's charges in that PSA.

3. Does an ACO participant that does not appear to fit within the categories of physician specialty, major diagnostic categories for inpatient facilities or outpatient categories have to calculate its PSA shares?

A: You asked about calculating an ACO's PSA shares for services other than the three categories of services specified in the ACO Policy Statement: (1) physician specialties, (2) major diagnostic categories for inpatient facilities, and (3) outpatient categories for outpatient facilities. As you point out, the ACO Policy Statement does not apply to other types of providers although they may participate in ACOs. Services not included in these three categories are not used for purposes of calculating PSA shares under the ACO Policy Statement.

PSA shares are a useful screen for evaluating potential competitive effects. Neither the ACO Policy Statement nor the CMS ACO regulations require an ACO to calculate PSA shares. However, an ACO may want to calculate its PSA shares for the three categories of services to determine whether it falls within the safety zone and whether the dominant participant limitation applies to the ACO. An ACO that determines it has high PSA shares or other possible indicia of market power may wish to avoid the conduct set forth in the ACO Policy Statement. An ACO also may use other data and information to evaluate the likely competitive significance of an ACO and its participants, including participants that provide any services that are not included in the three categories of services specified in the ACO Policy Statement.

4. In calculating PSA shares, should an ACO use counties based on facility location or patient residence?

A: PSAs are collections of zip codes, not counties. Shares should be calculated based on the patients residing in the PSA and should reflect providers serving patients residing in

the PSA, even if the providers are located outside of the PSA. We hope that answers your question. If it does not or you have further questions, please let us know.

5. Is the PSA definition (not the market share calculation) relative to the "participant" or the "common service"?

A: You asked us how to define the PSA for an integrated multi-specialty physician group practice. An integrated multi-specialty physician group practice will have a single PSA based on the zip code data for all of the patients of the physicians in that group practice. An ACO that elects to calculate its PSA shares should first identify the PSA(s) for each participant in the ACO that provides any common service. Each independent physician solo practice, each fully integrated physician group practice, each inpatient facility, and each outpatient facility will have its own PSA. For example, a fully integrated multi-specialty physician group practice will have one PSA that is defined as the lowest number of postal zip codes from which the group practice draws at least 75 percent of its patients. Next, separately for each common service, calculate the ACO's PSA share in the PSA of each participant that provides that service if at least two participants provide that service to patients from that PSA.

6. How do we determine which postal zip codes to use in defining PSAs?

A: You have asked how to determine which postal zip codes to use in defining PSAs. The zip codes that make up an ACO participant's PSA are those that comprise the smallest number of zip codes that when considered collectively are the source of at least 75% of the participant's patients.

As a first step in calculating PSA shares, identify each service provided by at least two independent ACO participants (i.e., each common service). Next, identify a PSA for each participant in the ACO that provides any common service. For each participant, the PSA is defined as the smallest collection of zip codes from which that participant draws at least 75% of its patients. Once you have identified these PSA(s), you can then calculate, separately for each common service, the ACO's PSA share in the PSA of each participant that provides that service if at least two participants provide that service to patients from that PSA.

Instructions for calculating PSA shares, including how to define a common service, are set forth in the Appendix to the ACO Policy Statement, available at http://www.ftc.gov/opp/aco/index.shtml.

7. Should we define the service area for Medicare patients only or all patients in calculating PSA shares?

A: The PSA definition is based on the smallest number of zip codes from which an ACO participant draws at least 75 percent of all its patients (not limited to Medicare patients).

8. Can someone direct me to where it describes how to calculate PSA shares for a hospital?

A: The instructions for the PSA share calculations can be found in the Appendix to the ACO Policy Statement at http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf on page 67031. Please let me know if you have any other questions.

9. Who will calculate an ACO's PSA shares?

A: You have asked who will calculate an ACO's PSA shares. Under the ACO Policy Statement, an ACO might seek to calculate its own PSA shares to use in evaluating the competitive significance of the ACO. The ACO Policy Statement does not intend that the Antitrust Agencies or CMS will provide PSA shares to ACOs. An ACO may calculate its PSA shares if it wants to determine whether it falls within the safety zone under the ACO Policy Statement. An ACO that determines it has high PSA shares or other possible indicia of market power may wish to avoid the conduct set forth in the ACO Policy Statement. A newly formed ACO that has chosen to seek voluntary expedited antitrust review must provide the information set forth in the ACO Policy Statement, including any PSA share calculations the ACO may have performed, or, alternatively, other data that show the current competitive significance of the ACO.

10. Please provide us with PSA calculation instructions.

A: The instructions for the PSA share calculations can be found in the Appendix to the ACO Policy Statement at http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf on page 67031. Please let me know if you have any other questions.

11. Please send me information on how to calculate an ACO's shares within relevant PSAs along with any illustrative examples and relevant information.

A: You asked how to calculate an ACO's PSA shares under the ACO Policy Statement. Neither the Policy Statement nor the CMS ACO regulations require an ACO to calculate PSA shares. However, an ACO may want to calculate its PSA shares to determine whether it falls within the safety zone under the ACO Policy Statement. Also, an ACO that determines it has high PSA shares or other possible indicia of market power may wish to avoid the conduct set forth in the ACO Policy Statement. A newly formed ACO that has chosen to seek voluntary expedited 90 day antitrust review must provide the information set forth in the ACO Policy Statement, including any PSA share calculations the ACO may have performed, or, alternatively, other data that show the current competitive significance of the ACO. The ACO Policy Statement is available at http://www.justice.gov/atr/public/health_care/aco.html and http://www.ftc.gov/opp/aco/index.shtml.

The Appendix to the ACO Policy Statement describes how to calculate PSA shares, identifies data sources available for these calculations, and provides examples of calculations. As described in more detail in the Appendix, there are three steps in calculating PSA shares. First, identify each service, as defined in the Appendix, provided by at least two independent ACO participants (i.e., each common service). Next, identify

the PSA(s) for each participant (e.g., physician group, inpatient facility, or outpatient facility) in the ACO that provides any common service. A PSA is defined as the lowest number of postal zip codes from which the participant draws at least 75 percent of its patients. Lastly, separately for each common service, calculate the ACO's PSA share in the PSA of each participant that provides that service if at least two participants provide that service to patients from that PSA. CMS has made publicly available the necessary data to calculate the "denominator" on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Calculations.html. An ACO calculating its PSA shares will need to provide its own data for the "numerator."

Federal Trade Commission/Department of Justice ACO Working Group

Questions and Answers Relating to Voluntary Review Under the ACO Policy Statement

Under the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (the ACO Policy Statement), ACOs may send questions regarding primary service area (PSA) share calculations to an electronic mailbox. Some questions submitted to the mailbox related to various issues in addition to PSA share calculations. The Federal Trade Commission/Department of Justice ACO Working Group received and answered the questions below related to the procedures for obtaining voluntary review under the ACO Policy Statement.

1. After a newly formed ACO requests voluntary expedited review under the ACO Policy Statement, how long will it take for the reviewing agency to contact me before the 90 day review commences?

> **A:** Upon receipt of a request for review, the Agencies will promptly determine and notify the applicant which Agency will be the reviewing Agency. While we are unable to provide precise timing, the Agencies are committed to providing notice expeditiously and will do so as soon as is reasonably practicable, likely within a week or so depending on the specific circumstances.

2. What happens at the end of the voluntary expedited review?

> **A:** Within 90 days of receiving all of the documents and information described in the ACO Policy Statement, the reviewing Agency will advise the ACO that the ACO's formation and operation, as described in the documents and information provided to the Agency, does not likely raise competitive concerns (or does not likely raise competitive concerns conditioned on an understanding that the ACO will take certain steps to remedy specific concerns), potentially raises competitive concerns, or likely raises competitive concerns. As is current practice, both the request letter and the reviewing Agency's response will be made public consistent with applicable Agency confidentiality provisions.

3. Is the ACO granted a waiver from further antitrust challenges or granted safety zone treatment following a voluntary review?

> **A:** Although a favorable staff review takes the position that any competitive concerns are unlikely based on the facts presented to the Agency, this conclusion does not constitute a "waiver" from future antitrust challenge or otherwise confer safety zone treatment. If the facts change significantly subsequent to the review, or the information the ACO submitted was not accurate, the conclusion regarding competitive concerns could change. The Agencies also reserve the right to conduct a full antitrust investigation and take any appropriate enforcement action if the ACO's operations result in anticompetitive effects or if doing so would be in the public interest.

Federal Trade Commission/Department of Justice ACO Working Group

Miscellaneous Questions and Answers Relating to ACOs and the ACO Policy Statement

Under the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (the ACO Policy Statement), ACOs may send questions regarding primary service area (PSA) share calculations to an electronic mailbox. Some questions received in the mailbox related to various issues in addition to PSA share calculations. The Federal Trade Commission/Department of Justice ACO Working Group received and answered the questions below related to ACOs and the ACO Policy Statement other than PSA share calculations.

1. When and where will the applications to participate in the new ACO program be made available?

> **A:** You have asked about the availability of applications to participate in the Medicare Shared Savings Program (SSP). The Centers for Medicare and Medicaid Services (CMS) provides information about the SSP on its website (http://www.cms.gov/sharedsavingsprogram). We suggest you consult the CMS website for questions relating to the program application.

2. Is an ACO a collaboration among non-competitors where the participants are a hospital system and an IPA whose physician members own facilities, such as surgical centers and imaging centers, that compete with services provided by the hospital system?

> **A:** You have indicated that an independent practice association ("IPA") and a hospital system want to form an ACO. You also state that some IPA physician practices own facilities, such as surgical centers and imaging centers, that compete with services provided by the hospital system. Based on the facts in your e-mail, it appears that the answer to your question—"Would this ACO be a collaboration between non-competitors?—is no. It appears that the IPA participating in the ACO comprises independent medical practices that are considered separate participants for purposes of the PSA calculation. It further appears that the independent practices compete with each other and/or with the hospital system to provide certain services and as such should calculate the relevant PSA shares. This response is solely based on the facts you presented in your e-mail. If these facts change, our conclusion may no longer be valid.

3. In light of the fact that the final ACO Policy Statement does not require mandatory antitrust review, can you offer any guidance for an entity that will be over the 50% threshold in terms of PSA shares?

> **A:** You have requested guidance for an ACO with a PSA share above 50%. The Centers for Medicare and Medicaid Services ("CMS") proposed to require certain ACO applicants with PSA shares over 50% to obtain mandatory antitrust review. However, the final CMS regulations do not establish a 50% share threshold or require any antitrust

review. Therefore, the 50% threshold is not applicable under the final ACO Policy Statement.

As explained in the ACO Policy Statement, PSA shares are useful as a screening device. Alternative data and information also may be useful in evaluating the likely competitive significance of an ACO. We recognize that an ACO may have reliable evidence other than PSA shares from which the ACO may reasonably conclude that the ACO is unlikely to raise competitive concerns. Nonetheless, there may be circumstances in which an ACO would raise competitive concerns. The ACO Policy Statement describes certain conduct that ACOs with high PSA shares or other possible indicia of market power may wish to avoid, as well as conduct all ACOs should avoid. In addition, any newly formed ACO that desires further guidance can seek expedited 90 day review from the antitrust agencies.

4. How can small business medical provider offices that are proprietor organizations effectively work together consistent with the antitrust and Stark Laws?

A: Your question asks about application of the antitrust and Stark laws to your participation in an ACO. The ACO Policy Statement provides antitrust guidance to assist ACOs in determining whether they are likely to present competitive concerns. A copy of the ACO Policy Statement is available at http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf and http://www.justice.gov/atr/public/health_care/279568.pdf.

If you have specific questions relating to antitrust after reviewing the ACO Policy Statement, please let us know. For Stark and other issues not related to antitrust, we suggest you contact CMS at ACO@cms.hhs.gov.

5. Is there a document available that outlines service area and number of assigned lives for each Medicare Savings ACO?

A: You have asked about the service areas and number of assigned lives for ACOs approved to participate in the Shared Savings Program. CMS has posted lists of the ACOs with their service areas on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/News.html . We do not have any information regarding the number of assigned lives. You may want to contact CMS directly for the availability of that information. CMS contacts are available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Regional_Contacts.html.