Small Entity Compliance Guide
Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

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The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, March 29, 1996, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides". Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act (RFA). The Medicare Shared Savings Program Accountable Care Organizations final rule is estimated to have a significant economic impact on a substantial number of small entities, although participation in the program is voluntary. The complete text of the final rule can be found on the CMS website by clicking on the link to CMS-1345-F at http://www.cms.gov/sharedsavingsprogram/30_Statutes_Regulations_Guidance.asp#TopOfPage.

Section 3022 of the Affordable Care Act contains provisions relating to Medicare payments to providers of services and suppliers participating in accountable care organizations (ACOs) under the Medicare Shared Savings Program (Shared Savings Program). Under these provisions, providers of services and suppliers can continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, and be eligible for additional payments if they meet specified quality and savings requirements. The Shared Savings Program is a key component of the Medicare delivery system reform initiatives that will be implemented under the Affordable Care Act and is a new three-part approach to the delivery of health care aimed at: (1) better care for individuals; (2) better health for populations; and (3) lower growth in Medicare Parts A and B expenditures. Studies have shown that better care often costs less, because coordinated care helps to ensure that the patient receives the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors.

For purposes of the RFA, approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the Physician Fee Schedule (PFS). Most physician practices, hospitals and other providers are small entities, either by nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.0 to $34.5 million in any 1 year; NAIC Sector- 62 series). States and individuals are not included in the definition of a small entity.

Although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a FFS basis, we acknowledge that the program can affect many small entities and have drafted the rules and regulations accordingly in order to minimize costs and burden on such entities as well as maximize their opportunity to participate. The Shared Savings Program is designed to encourage individual physicians and small physician practices to integrate with other such practices as well as larger entities to create ACOs. Small

entities will both be allowed and encouraged to participate in the Shared Savings Program, provided their ACO has a minimum of 5,000 assigned beneficiaries, thereby realizing economic benefits through the utilization of enhanced and efficient systems of care and care coordination. Examples of increased economic benefits as a result of participating in this program include shared savings from this program, as well as qualifying for financial incentives from other CMS programs, such as Physician Quality Reporting System, Electronic Health Record, and Electronic Prescribing (e-Rx) Incentive Payments. Therefore, a solo, small physician practice or other small entity may realize these economic benefits as a function of participating in this program and the utilization of enhanced clinical systems integration, which otherwise may not have been possible. Lastly, we recognize that potential advantageous key drivers for participating physician groups would include institutional affiliations that allow greater access to financial capital, access to and experience using EHR and other IT systems and experience with pay-for-performance programs.

The overall impact, as detailed in the regulatory impact analysis (RIA) of the Shared Savings Program final rule, estimates an aggregate median impact of $1.31 billion in bonus payments to participating ACOs in the Shared Savings Program for calendar years (CYs) 2012 through 2015. In addition, the estimated aggregate average start-up investment and ongoing annual operating costs are $451 million, based on the anticipated mean participation rate of ACOs in the Shared Savings Program for CYs 2012 through 2015. Therefore, the anticipated benefits should exceed the costs, thereby reflecting a positive significant impact for ACOs participating in the Shared Savings Program. Furthermore, the program's first agreement period has been expanded by up to 6 to 9 months, rewarding ACOs who enter the program early in 2012 with a longer agreement period under their initial benchmark, while also accommodating ACOs that might require an additional year (or partial year) of preparation. It is important to note that these estimates are based on, but not limited to, the structure, maturity, performance, and financial exposure of a participating ACO. As a result of risk and uncertainty, not all ACOs will achieve shared savings and some may incur a financial loss if the ACO chooses to participate under Track 2, due to the requirement to repay a share of actual expenditures in excess of their benchmark.

The detailed aggregate cost estimate associated with the start-up investment of ACOs participating in the Shared Savings Program is expected to range between $29 million to $157 million. The RIA assumes that approximately 50 to 270 ACOs will participate in the Shared Savings Program. Furthermore, the aggregate ongoing annual operating costs for the participating ACOs, during the agreement period, are estimated to range between $63 million to $342 million. Lastly, detailed analysis of the bonus payments includes the 10^{th} and 90^{th} percentiles of the estimate distribution to reflect a bonus payment to ACOs of $890 million and $1.9 billion, respectively.

In the Shared Savings Program final rule, we have revised many of the policies in the proposed rule, so as to allow for greater flexibility regarding the specific structure and requirements of an ACO. We believe these changes will substantially reduce the burden associated with the infrastructure start-up and ongoing annual operating costs for participating ACOs in the Shared Savings Program. These modifications include the following:

- Greater flexibility in eligibility to participate in the Shared Savings Program.
- Multiple start dates in 2012.

- Establishment of a longer agreement period for those starting in 2012.
- Greater flexibility in the governance and legal structure of an ACO.
- Simpler and more streamlined quality performance standards.
- Adjustments to the financial model to increase financial incentives to participate.+
- Increased sharing caps.
- No down-side risk and first-dollar sharing in Track 1.
- Removal of the 25 percent withhold of shared savings.
- Greater flexibility in timing for the evaluation of sharing savings (claims run-out reduced to 3 months).
- Greater flexibility in antitrust review.
- Greater flexibility in timing for repayment of losses.
- Additional options for participation of FQHCs and RHCs. Specific analyses regarding these significant final policy modifications are discussed in detail in section II. of the final rule.

The participating ACO will be eligible to receive a shared savings payment if: (1) the ACO meets quality performance standards described in the rule, and (2) the ACO has been determined to reduce per capita costs of the beneficiaries assigned to it at or below a certain threshold, referred to as the minimum savings rate (MSR), below the benchmark. Under the final rule, CMS will establish a MSR that is designed to account for normal variation based on the number of Medicare beneficiaries assigned to the ACO under Track 1 and a fixed MSR under Track 2. The benchmark will be based on the Parts A and B fee-for-service per capita expenditures for beneficiaries assigned in any of the three years immediately preceding the start of the agreement period, and will be risk adjusted. The benchmark will be updated each year by the projected absolute amount of growth in national per capita Parts A and B expenditures for fee-for-service beneficiaries. The benchmark will be reset at the beginning of each agreement with the ACO. Benchmark expenditures and performance year expenditures will be truncated to minimize variation from catastrophically large claims.

The statute states that a percent of the difference between the benchmark and the estimated per capita costs for a performance year will be shared between the ACO and CMS. The statute also requires the Secretary to establish a limit on the total amount of savings that can be shared with the ACO (referred to in the proposed rule as the "sharing limit").

CMS will implement both a one-sided model (sharing of savings only for the term of an ACO's first agreement) and a two-sided model (sharing of savings and losses for the term of an ACO's agreement). This approach combines the one-sided model described under section 1899(d) of the Act with a risk-based approach under the authority granted CMS under section 1899(i) of the Act. CMS believes this approach has the advantage of providing an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller

ACOs, to gain experience with population management before transitioning to a risk-based model, while also providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides a greater share of savings, but at the risk of repaying Medicare a portion of any losses.

CMS provides the following online material that present compliance information regarding the Shared Savings Program final rule. The material is frequently updated to reflect the latest changes in Medicare Shared Savings Program policy. For example, this includes Medicare data made available to applicants of the Medicare Shared Savings Program, thereby allowing them to calculate their share of services in each applicable primary service area to determine whether or not the ACO would benefit from an expedited review from the antitrust agencies before entering the Shared Savings Program. The data is organized into a physician file, inpatient facility file, and outpatient facility file. Each file contains an aggregate dollar amount, reflecting the total Medicare payments or allowed charges including deductibles and co-insurance, for each zip code and each service category. Other material provided includes information on how applicants may determine shared savings and losses, as well as up-to-date information on CMS teleconferences and events. The materials serve, in part, as a compilation of small entity guides that meet the letter and spirit of the Small Business Regulatory Enforcement Fairness Act (SBREFA) and are located online at www.cms.gov/sharedsavingsprogram.

CMS also conducts Open Door Forums (ODFs) to improve transparency in CMS's policies. These forums provide small entities with an opportunity to obtain information, as questions, and express their views to senior CMS officials on nearly all major regulatory issues, especially those that might affect providers in a new or burdensome way. To find information on the Shared Savings Program ODFs, visit http://www.cms.gov/sharedsavingsprogram/40_Events.asp.

CMS also communicates information to providers through the use of mailing lists, or listservs. A list of listservs available to Medicare fee-for-service providers is available at www.cms.gov/prospmedicarefeesvcpmtgen/downloads/Provider_Listservs.pdf.

The public is also informed about changes CMS is proposing or making in the programs that it administers through the Quarterly Provider Update. This is completed at the beginning of each quarter and reflected online at http://www.cms.hhs.gov/quarterlyproviderupdates/.