

Medicare Shared Savings Program: Accountable Care Organizations Final Rule Summary

Background

The Patient Protection and Affordable Care Act (PPACA), enacted on March 23rd, 2010, includes provisions to improve quality and lower the costs of care to Medicare patients. Among these provisions, termed the “Shared Savings Program”, are concepts to implement a large scale, value-based purchasing program whereby providers are rewarded for high quality, efficient clinical care. The Centers for Medicare and Medicaid Services (CMS) intend to implement the Shared Savings Program through the use of Accountable Care Organizations (ACOs).

On October 20, 2011, CMS published its final rule for the Medicare Shared Savings Program: Accountable Care Organizations. Like the proposed rule, the central theme of the final rule is a focus on a “three-part aim” which is: 1) better care for individuals; 2) better health for populations; and 3) lower growth in expenditures. The rule outlines in detail how CMS plans to implement the Shared Savings Program through the use of ACOs.

The final rule states that the intent of the program is to “promote accountability for a population of Medicare beneficiaries, improve the coordination of fee-for-service (FFS) items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incent higher value care”. In order to share in savings, ACOs must both meet the quality performance standards and generate shareable savings.

CMS made significant modifications to the proposed rule in order to “reduce burden and cost for participating ACOs”. These modifications include:

1. Greater flexibility in eligibility to participate in the program
2. Multiple start dates in 2012
3. Establishment of a longer agreement period for those starting in 2012
4. Greater flexibility in the governance and legal structure of an ACO
5. Simpler and more streamlined quality performance standards
6. Adjustments to the financial model to increase financial incentives to participate
7. Increased sharing caps
8. No down-side risk and first-dollar sharing in Track 1
9. Removal of the 25% withhold of shared savings
10. Greater flexibility in timing for the evaluation of sharing savings
11. Greater flexibility in antitrust review
12. Greater flexibility in timing of repayment of losses
13. Additional options for participation of FQHCs and RHCs

Provisions of the Final Rule

Sufficient Number of Primary Care Providers and Beneficiaries (Page 21)

In response to concerns that the 5,000 beneficiary requirement would be a deterrent to small and rural practices, CMS expanded the assignment methodology to allow more beneficiaries to be assigned to those ACOs that might have initially been “too close” to the threshold, increasing the ability for smaller ACOs to participate. CMS also reiterated that unlike a managed care network, patients assigned to an ACO may receive care from providers both inside and outside the ACO.

Identification of Providers in ACOs (Page 25)

CMS explained in the proposed rule that there are two data sources that could be used to identify the specific providers of services and suppliers participating in ACOs—specifically, their-- (1) National Provider Identifier (NPI); and (2) TIN. The TIN may be an employer identification number (EIN) or social security number (SSN). CMS proposed to identify an ACO operationally as a collection of Medicare enrolled TINs. More specifically, an ACO will be identified operationally as a set of one or more TINs currently practicing as a "group practice arrangement" or in a "network" such as where "hospitals are employing ACO professionals" or where there are "partnerships or joint ventures of hospitals and ACO professionals" as stated under section 1899(b) (1) (A) through (E) of the Act. For example, a single group practice that participates in the Shared Savings Program would be identified by its TIN. A network of independent practices that forms an ACO would be identified by the set of TINs of the practices constituting the ACO. CMS finalized the proposal to require that organizations applying to be an ACO provide their ACO participant TINs and NPIs on the application. In addition, it is the ACO's responsibility to maintain and update the list.

CMS also finalized the proposal that each ACO participant TIN is required to commit to an agreement and each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one ACO for purposes of the Shared Savings Program. However, CMS clarified and emphasized that individual provider NPIs are not exclusive to one ACO, only the ACO participant TINs under which providers bill for services that are included in the assignment of beneficiaries. For example, exclusivity of an ACO participant leaves individual NPIs free to participate in multiple ACOs if they bill under several different TINs. Similarly, an individual NPI can move from one ACO to another during the agreement period, provided that he or she has not been billing under an individual TIN. A member of a group practice that is an ACO participant, where billing is conducted on the basis of the group's TIN, may move during the performance year from one group practice to another, or into solo practice, even if doing so involves moving from one ACO to another.

Eligible Entities and Beneficiary Assignment (Page 38)

The statute defines the following groups of providers of services and suppliers as eligible to participate as an ACO:

- ACO professionals (i.e. physicians, physicians assistants, nurse practitioners, or clinical nurse specialists) in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Other groups of Medicare providers as determined by the Secretary

The proposed rule discussed the fact that the statute provides the Secretary with the flexibility to limit or expand the list of eligible participants. In the final rule, CMS indicates that they received many comments regarding beneficiary assignment and the establishment of benchmarks for ACOs that include Federally Qualified Health Centers (FQHCs) and/or Rural Health Clinics (RHCs). In response to the comments, CMS made modifications to the proposed assignment process to recognize the different payment methodologies and claims data that are used by FQHCs and RHCs as compared to the payment methodologies and claims data that are available for physician offices/clinics that are paid under the physician fee schedule. As a result, FQHCs and RHCs will be eligible to form ACOs and may also be ACO participants in ACOs formed by other entities.

In addition to the above, any Medicare enrolled entities not specified above can participate in the Shared Savings Program as ACO participants by joining an ACO containing one or more of the organizations eligible to form an ACO.

Legal Structure (Page 48)

The statute requires an ACO to “have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to participating providers of services and suppliers” and to have a “mechanism for shared governance”. In order to meet this requirement, CMS proposed that an ACO be “an organization that is recognized and authorized to conduct its business under applicable State law” and that it must have a tax identification number (TIN). The ACO itself is not required to be enrolled in the Medicare program, however, the participating ACO professionals are required to be enrolled in Medicare.

Any existing legal entity that meets the above requirement is eligible, however, “if an existing entity, such as a hospital employing ACO professionals would like to include as ACO participants other providers of services and suppliers who are not already part of its existing legal structure, a separate entity would have to be established in order to provide all ACO participants a mechanism for shared governance and decision making”. CMS decided to finalize this proposal despite receiving many opposing comments, stating that

they believe the requirement is “essential to protect against fraud and abuse and ensure that the ACO is accountable for its responsibilities under the Shared Savings Program by enabling (CMS) to audit and assess ACO performance”. In response to comments received, CMS clarified that entities organized pursuant to Federal and tribal law will also be allowed to participate in the Shared Savings Program, as long as the entity is able to meet the participation requirements as outlined in the final rule.

Distribution of Savings (Page 54)

CMS proposed that shared savings be paid directly to the ACO as identified by its TIN. Despite many comments suggesting that CMS provide guidance on distribution of savings within an ACO, CMS does not believe it has the authority to specify how shared savings are distributed among ACO participants; however, CMS will require that the ACO indicate in its application how it plans to use the shared savings “to meet the goals of the program”. Specifically, “ACOs would have to indicate how potential shared savings would be used to promote accountability for their Medicare population and the coordination of their care as well as how they might be invested in infrastructure and redesigned care processes for high quality and efficient health care service delivery”. This requirement is intended to “both guard against improper financial incentives as well as ensure appropriate beneficiary protections”.

It was not mentioned in the final rule that specialists be paid at a rate of 0.05% of shared savings. However, specialists are still allowed to participate in more than one ACO.

Governance (Page 55)

CMS proposed that an ACO must “establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO”. This governing body may be “a board of directors, board of managers, or any other governing body that provides a mechanism for shared governance and decision-making for all ACO participants”. CMS proposed that if the ACO is, for example, a hospital with an existing governing body, the ACO would not need to form a new governing body provided the existing body is able to meet all of the criteria of an ACO governing body.

The proposed rule indicated that the governing body must also include representation of the beneficiaries served by the ACO. In response to comments received, CMS finalized this requirement with an option (discussed later) to allow for flexibility for those ACOs that seek innovative ways to involve beneficiaries in ACO governance.

In response to comments received, CMS revised its proposals to provide ACOs greater flexibility in the composition of their governing bodies. Specifically, CMS did not finalize its proposal that each Medicare-enrolled ACO participant TIN, or its representative, be on the ACO’s governing body. Instead, CMS will require an ACO to provide “meaningful participation” in the composition and control of the ACO’s governing body for ACO participants or their designated representatives. In addition,

CMS did not finalize the proposal that each ACO participant have “proportionate control” of the ACO governing body.

In addition, CMS clarified that the governing body’s responsibilities include providing oversight and strategic direction, holding management accountable for meeting the goals of the ACO, which include the three-part aim. CMS believes that because of these broad responsibilities, the governing body is ultimately responsible for the success or failure of the ACO and that it will facilitate accomplishing the ACO’s mission. CMS also stated that the governing body also must have a transparent governing process to ensure that they are able to monitor and audit the ACO as appropriate. The ACO must have a conflicts of interest policy for the governing body.

Additionally, the proposed rule stated that in order to be eligible to receive shared savings, the ACO participants must have at least 75 percent control of the ACO’s governing body and “each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body”. The goal of this proposal was to ensure “that ACOs remain provider-driven, but also leaves room for both non-providers and small provider groups to participate in the program”. CMS finalized this proposal.

An ACO that seeks to compose its governing body in such a way that it does not meet either the requirement regarding 75% ACO participant control or the requirement regarding beneficiary representation on the governing body would be able to describe in its application how the proposed structure of its governing body would involve ACO participants in innovative ways in ACO governance and provide a meaningful opportunity for beneficiaries to participate in the governance of the ACO.

Leadership and Management Structure (Page 75)

CMS proposed that ACOs leadership and management structure meets certain criteria, including, but not limited to:

- The ACO’s operations would be managed by an executive, officer, manager, or general partner, whose appointment and removal are under the control of the organization’s governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.
 - Final rule: Finalized provision.
- Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present in that State.
 - Final rule: In response to comments received, CMS is finalizing the proposed requirement that an ACO have a senior-level medical director who is a board-certified physician, however, they are modifying the original proposal to eliminate the full-time requirement. Instead, CMS will require that clinical management and oversight be managed by a

senior-level medical director who is one of the ACO's physicians. CMS also clarified that an "on site" physician is one who is present at any clinic, office, or other location participating in the ACO.

- ACO participants and ACO providers/suppliers would have meaningful commitment to the ACO's clinical integration program to ensure its likely success.
 - Final rule: In response to comments received in opposition to this requirement, CMS states, "We do not see how an ACO could achieve its mission if its providers and suppliers do not agree to comply with and implement the ACO's required processes. Such a commitment is necessary, although insufficient in and of itself, to ensure that an ACO achieves the three-part aim.
- The ACO would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program.
 - Final rule: In response to comments that this requirement would be onerous in rural areas, CMS decided to eliminate this requirement. Instead, as part of its application, an ACO will be required to describe how it will establish and maintain an ongoing quality assurance and improvement program, led by an appropriately qualified health care professional.

As part of the application process, an ACO would need to submit documentation that all of the criteria are met.

In an effort to allow flexibility, CMS proposed that ACOs with "innovative leadership and management structures" have an opportunity in the application process to explain how their existing structure would achieve the same goals. CMS received positive feedback on this proposal and as such, finalized it.

Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, Coordination of Care, and Demonstrating Patient-centeredness (Page 91)

CMS proposed that the ACO must document in its application, its plans to: 1) promote evidence-based medicine; 2) promote beneficiary engagement; 3) report internally on quality and cost metrics; and 4) coordinate care. CMS finalized this proposal.

Specifically, with regard to evidence-based medicine, CMS proposed that "the ACO would describe the evidence-based guidelines it intends to establish, implement, and periodically update". The final rule states that CMS is finalizing this proposal and that "these guidelines must cover diagnoses with significant potential for the ACO to achieve quality improvements, taking into account the circumstances of individual beneficiaries."

Patient-Centeredness Criteria (Page 92)

CMS proposed the following criteria to ensure that the ACO meets the statutory requirement of “patient-centeredness”:

- A beneficiary experience of care survey in place and a description in the ACO application how the ACO will use the results to improve care over time.
- Patient involvement in ACO governance.
- A process for evaluating the health needs of the ACO’s assigned population, including consideration of diversity in their patient populations, and a plan to address the needs of their population.
- Systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs.
- A mechanism in place for the coordination of care (for example, via use of enabling technologies or care coordinators).
- A process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.
- Written standards in place for beneficiary access and communication and a process in place for beneficiaries to access their medical records.
- Internal processes in place for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time.

CMS also stated in the proposed rule that for patient engagement, measures may include “the use of decision support tools and shared decision making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions”.

CMS points out that many of the other requirements overlap with the above criteria for patient-centeredness, which should reduce the burden of the ACO in meeting these eligibility requirements. CMS finalized these proposals.

Process to Report on Quality and Cost Measures (Page 102)

CMS proposed that ACOs may use several different processes for reporting on quality and cost measures including, but not limited to, developing a population health data management capability, or implementing practice and physician level data capabilities with point-of-service (POS) reminder systems to drive improvement in quality and cost outcomes. CMS finalized this proposal.

Processes to Promote Coordination of Care (Page 103)

CMS proposed to prohibit the ACO from developing any policies that would restrict a patient’s freedom to seek care from providers and suppliers outside the ACO. CMS also proposed that the process to promote coordination of care should include the ACOs having systems in place to identify high-risk individuals and processes to develop

individualized care plans for targeted patient populations. This plan would be voluntary for the beneficiary. CMS finalized these proposals.

Overlap with other CMS Shared Savings Initiatives (Page 107)

The statute includes a provision that precludes duplication in participation in initiatives involving shared savings. CMS states in the final rule that an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program under one ACO participant TIN and another shared savings program under a different non-ACO participant TIN if the patient population is unique to each program. Applications for participation in the Shared Savings Program will be reviewed carefully to assess for overlapping TINs.

CMS also states in the final rule that as the Innovation Center gains experience with different ACO payment models, proven methods can be used to enhance and improve the Shared Savings Program over time.

Options for Start Date of the Performance Year (Page 126)

CMS states in the final rule that they will start accepting applications from prospective ACOs shortly after January 1, 2012. A Notice of Intent will be published “shortly after publication of this final rule”. They will provide for two application periods for the first year of the Shared Savings Program whereby applications will be accepted for an April 1, 2012 or July 1, 2012 start date. All ACOs that start in 2012 will have agreement periods that terminate at the end of 2015. Under this final rule, ACOs will begin receiving data immediately upon entry to the program. After completing its first performance year, the ACO will be evaluated on its performance on the ACO quality metrics and a shared savings payment will be calculated. All ACOs will be eligible to receive the PQRS incentive payments for each calendar year in which they fully and completely report the Group Practice Reporting Operation (GPRO) measures, regardless of their start date.

Timing and Process for Evaluating Shared Savings (Page 132)

Based upon review of the public comments received, CMS is finalizing the proposal of using 3-months of claims run-out data, with the application of an appropriate completion percentage, to calculate the benchmark and per capita expenditures for the performance year.

New Program Standards Established During the Agreement Period (Page 135)

CMS finalized their proposal that ACOs be held responsible for all regulatory changes in policy, with the exception of: eligibility requirements concerning structure and governance of ACOs, calculation of sharing rate, and beneficiary assignment. However, CMS is modifying the proposal to allow ACOs the flexibility to voluntarily terminate their agreement in those instances where regulatory standards are established during the

agreement period which the ACO believes will impact the ability of the ACO to continue to participate in the Shared Savings Program.

Managing Significant Changes to the ACO during the Agreement Period (Page 139)

CMS is modifying the proposed rule so that ACO participants and ACO providers/suppliers may be added and subtracted over the course of the agreement period. ACOs must notify CMS of the change within 30 days of the additions/subtractions of ACO participants or providers/suppliers. Additionally, in the event of “significant changes”, which is defined as an event that occurs resulting in an ACO being unable to meet eligibility or program requirements, the ACO must also notify CMS within 30 days.

Coordinating the Shared Savings Program Application with the Antitrust Agencies (Page 147)

In response to comments received, CMS is modifying its proposal and instead adopting an approach that relies on three prongs to maintain competition among ACOs. First, the Antitrust Agencies will offer a voluntary expedited antitrust review to any newly formed ACO before it is approved to participate in the Program. Second, CMS will provide the Antitrust Agencies with aggregate claims data regarding allowable charges and fee-for-service payments, which will assist in calculating PSA shares for ACOs participating in the Shared Savings Program. Third, the Antitrust Agencies will rely on their existing enforcement processes for evaluating concerns raised about an ACO’s formation or conduct and filing antitrust complaints when appropriate. CMS emphasized that acceptance of an ACO into the Program represents no judgment about the ACO’s compliance with the antitrust laws or the ACO’s competitive impact in a commercial market.

Sharing Aggregate Data (Page 159)

CMS finalized its proposal to supply ACOs with aggregated (de-identified) data on beneficiary use of health care services. This data will be based on data for those beneficiaries historically assigned and included in the calculation of the ACO’s benchmark. These reports will include, when available, aggregated metrics on the beneficiary population and beneficiary utilization data at the start of the agreement period, based on the historical data used to calculate the benchmark.

CMS also finalized its proposal to provide the ACO with a list of beneficiary names, dates of birth, sex, and HICN derived from the beneficiaries whose data was used to generate the preliminary prospective aggregate reports. CMS is modifying their proposal to provide similar information in conjunction with each quarterly aggregated data report, based on the most recent 12 months of data, consistent with the time frame listed in the proposed rule.

Sharing Beneficiary Identifiable Claims Data (Page 168)

The final rule states that more complete beneficiary-identifiable information will be available to ACOs upon request, in compliance with applicable laws. This data will be limited to the available claims of beneficiaries who received a primary care service from a primary care physician participating in the ACO during the performance year, and who have been given the opportunity to decline to have their claims data shared with the ACO but have declined to do so. As a condition of receiving the data, the ACO would be required to submit a formal data request, either at the time of application or later in the agreement period, and explain how it intends to use these data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population.

Giving Beneficiaries the Opportunity to Decline Data Sharing (Page 178)

CMS modified its proposed rule in order to allow the ACO the option of contacting beneficiaries from the list of preliminarily prospectively assigned beneficiaries in order to notify them of the ACO's participation in the program and their intent to request beneficiary identifiable data. If, after a period of 30 days from the date the ACO provides such notification, neither the ACO nor CMS has received notification from the beneficiary to decline data sharing, the ACOs would be able to request beneficiary identifiable data.

Assignment of Medicare Fee-for-Service Beneficiaries (Page 185)

CMS identified the following elements that need to be considered when assigning Medicare beneficiaries to ACOs:

1. An operational definition of an ACO so that ACOs can be efficiently identified, distinguished, and associated with the beneficiaries for whom they are providing services;
2. A definition of primary care services for purposes of determining the appropriate assignment of beneficiaries;
3. A determination concerning whether to assign beneficiaries prospectively or retrospectively; and
4. A determination concerning the proportion of primary care services that is necessary for a beneficiary to receive from an ACO in order to be assigned to that ACO for purposes of the program.

CMS clarified that "assignment" does not mean that the patient may not choose to receive care from a provider outside the ACO.

Definition of Primary Care Services (Page 189)

CMS finalized their proposal to define "primary care services" as the set of services identified by the following HCPCS codes: 99201-99215, 99304-99340, 99341-99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439). In addition, CMS will also establish a cross-walk for these codes to certain revenue codes

used by FQHCs and RHCs so that their services can be included in the ACO assignment process (detailed on pages 217-218). CMS will require ACOs that include FQHCs/RHCs to provide, through an attestation, a list of their physician NPIs that provide direct patient primary care services, that is, the physicians that actually furnish primary care services in the FQHC or RHC.

CMS decided in the final rule that after identifying all patients that had a primary care service with a physician who is an ACO provider/supplier in an ACO, they will employ a “step-wise” approach as the basic assignment methodology. Under this approach, beneficiaries are first assigned to ACOs on the basis of utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians. This policy thus allows consideration of all physician specialties in the assignment process. The “step-wise” approach also considers primary care services furnished by other providers/suppliers of that ACO (including NPs, PAs, and CNSs).

Prospective vs. Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings (Page 222)

For each year of an agreement period each ACO will have an assigned population of beneficiaries. Eligibility for shared savings will be based on whether the requirements for receiving shared savings payments are met for this assigned population. CMS refers to each year for which such determinations must be made as a "performance year."

CMS modified their proposed policy in response to comments to adopt a preliminary prospective assignment methodology with final retrospective reconciliation. Under this model, CMS will create a list of beneficiaries likely to receive care from the ACO based on primary care utilization during the most recent periods for which adequate data are available, and provide a copy of this list to the ACO. During the performance year, CMS will update this list periodically on a rolling basis to allow the ACO to adjust to likely changes in its assigned population. At the end of each performance year, CMS will reconcile the list to reflect beneficiaries who actually meet the criteria for assignment to the ACO during the performance year. Determinations of shared savings or losses for the ACO will be based on this final, reconciled population.

Majority vs. Plurality Rule for Beneficiary Assignment (Page 244)

CMS finalized their proposal to adopt a “plurality” of primary care services, defined in terms of allowed charges, as the basis for assignment. However, they are modifying the way in which that plurality is calculated in order to apply it to the two-step assignment process described above. CMS states in the final rule that adoption of a majority standard, as suggested by many commenters, would result in the assignment of fewer beneficiaries to each ACO. Adopting a stricter majority standard would therefore not be conducive to assignment of enough beneficiaries to ACOs for the program to be viable or to make a contribution to improving quality and promoting more cost-effective care for

Medicare beneficiaries. In response to concerns regarding assignment of “snowbirds”, CMS stated that the methodology is essentially self-correcting for the effects of seasonal migrations and extensive travel, since it directly reflects where a beneficiary receives the plurality of his or her primary care services.

Quality and Other Reporting Requirements (page 256)

CMS proposed the use of 65 measures to establish quality performance standards that ACOs must meet and report in order to be eligible for shared savings for the first performance period.

In the final rule, CMS reduces the amount of measures that are required to be reported down to 33 to encourage participation, reduce reporting burden, and achieve more focused and meaningful improvements, particularly in the first agreement period. Of the 33 measures CMS is finalizing, 7 are collected via patient survey, 3 are calculated via claims, 1 is calculated from EHR Incentive Program data, and 22 are collected via the GPRO web interface. (See **Table 1** in Attachment 1 of this summary) CMS has modified this final rule to define the quality performance standard at the reporting level in the first year and based on performance in subsequent years. Rather than transition all measures from pay for reporting to pay for performance in the second performance year of the ACO agreement period as proposed, CMS will transition only a portion of the measures to pay for performance in the second performance year, and then all but one of the measures to pay for performance in the third performance year, as outlined in **Table 2** in Attachment 1.

CMS believes it is important to start with a combination of both process and outcomes measures, but may move to more outcomes-based measures and fewer process measures over time. CMS has modified their proposed domain structure in this final rule by combining the care coordination and patient safety domains to better align with other CMS value-based purchasing initiatives and the National Quality Strategy and to emphasize the importance of ambulatory patient safety and care coordination. In addition, CMS is moving certain proposed claims-based measures, such as inpatient safety measures and ambulatory care sensitive condition (ACSC) admissions measures, to their monitoring program to prevent ACOs from engaging in gamesmanship and manipulation of at-risk patients.

(Page 271) CMS will fund the survey and administration of an annual Consumer Assessment of Health Providers and Systems (CAHPS) patient experience of care survey for ACOs participating in the Shared Savings Program in 2012 and 2013. Starting in 2014, ACOs participating in the Shared Savings Program must select a survey vendor (from a list of CMS-certified vendors) and will pay that vendor to administer the survey and report results using standardized procedures developed by CMS. Since the patient/caregiver experience measures have been removed from the required set of

reporting measures, this is CMS' way to collect data on the patient experience consistently across all ACOs.

Electronic Health Records (Page 341)

CMS has dropped the requirement that 50% of its primary care providers have electronic health records (EHR) incorporated into their practices. CMS intends to further align both the Shared Savings Program and EHR incentive program through subsequent rulemaking. CMS anticipates that certified EHR technology (including EHR modules certified to calculate and submit clinical quality measures) would be an additional measure reporting mechanism used by ACOs under the Shared Savings Program in future program years.

Authority For and Selection of Shared Savings/Losses Model (Page 375)

CMS proposed to offer two models for an ACO to participate under. The one-sided lower risk model was offered for the ACOs to participate at no risk the first two years and begin to take on risk in the third year and share in the savings at a rate of 50%, given that all measure were reported and other requirements met. The second model was the higher risk two-sided model where ACOs take on risk for the full three year period and, if all requirements are met, are offered to earn a larger percentage of shared savings (60%). Both models require repayment of any losses.

In the final rule, CMS will establish the Shared Savings Program on existing fee-for-service (FFS) payments, using both shared savings only (Track 1) and shared savings and losses models (Track 2). While making final their proposal to offer ACOs a choice of two tracks, CMS is modifying their proposal for Track 1 so that it will be a shared savings only model (known as the one-sided model) at a rate of 50% for the duration of the ACO's first agreement period. CMS will make final their proposal that ACOs electing Track 2 will be under the two-sided model for the duration of their first agreement period sharing in the savings at a rate of 60%. CMS is also finalizing their proposal to require all ACOs to participate in the two-sided model in agreement periods subsequent to the initial agreement period. CMS is modifying their proposal to allow continued participation by ACOs electing to do so who experience a net loss during their first agreement period. Specifically, CMS is requiring ACOs, which experience a net loss in their initial agreement period and apply to participate in a subsequent agreement period, to identify in their application the cause(s) for the net loss and to specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. CMS has revised the payment period in which these losses must be repaid to 90 days, up from what was proposed initially as 30 days.

On page 481, CMS announces the elimination of the 2 percent net sharing rate. After receiving many comments on this issue, CMS believes sharing on a first dollar basis with

all ACOs will be important for encouraging participation and ensuring ACOs receive capital to invest in achieving the program's goals and achieve a return on investment. First dollar sharing, compared to alternatives that would share on a lower threshold amount, appears the most effective way to ensure ACOs receive needed capital. At this time, CMS considers other program protections – in particular the minimum savings rate –to be adequate to ensure shared savings result from ACO performance rather than random variation.

Also on page 497, CMS modifies its original proposal to provide that an ACO's shared loss rate will be subject to a cap of 60 percent consistent with the maximum rate for sharing savings.

On page 515, CMS announced that they are eliminating the 25 percent withhold and the related proposed provision concerning forfeiture of the 25 percent withhold in the event of early termination from the program. This is effective for both the one-sided and two-sided model. See **Table 5** in Attachment 1.

Impact of IME and DSH (Page 436)

CMS initially proposed that indirect medical education (IME) adjustments and disproportionate share hospital (DSH) adjustments be included in the benchmark and performance year expenditures for the determination of an ACO's eligibility for shared savings. CMS received many comments on how this inclusion would disincentivize academic centers from participating in the ACO programs. In the final rule, CMS decided to change the status of IME and DSH adjustments to be excluded from benchmark and performance year expenditure calculations. Similar exclusions were proposed and finalized for GME, PQRS, eRx and EHR incentive payments for professionals and hospitals. See **Table 5** in Attachment 1.

ACO Marketing Guidelines (Page 532)

CMS proposed that all ACO marketing materials, communications, and activities developed or revised that are related to the ACO and its participation in the Shared Savings Program, such as mailings, telephone calls or community events, that are used to educate, solicit, notify, or contact Medicare beneficiaries or providers/suppliers regarding the ACO and its participation in the Shared Savings Program, be approved by CMS before use to protect beneficiaries and to ensure that they are not confusing or misleading. CMS received many comments on how burdensome it would be to have all marketing materials approved by CMS before they could be used. In response to these comments, CMS will develop template language that is pre-approved and provided to the ACOs to be used in marketing materials. Also, the final rule allows ACOs to use marketing materials 5 days after filing them with CMS if the organization certifies that the marketing materials comply with all applicable marketing requirements. CMS has revised the regulation to specify that all marketing materials and activities must use template language when available, must comply with the prohibition regarding certain beneficiary inducements, must not be used in a discriminatory manner or for

discriminatory purposes, and must not be inaccurate or misleading. Materials will be provided in "plain" language that is easily comprehensible, clear, concise, well organized, and complies with requirements of the Plain Writing Act of 2010. Finally, if ACOs are found not in compliance with marketing guidelines, they will be subject to penalties that are also outlined in this final rule.

Compliance Plans (Page 552)

CMS has added a provision requiring compliance plans to be updated periodically to reflect changes in law, including new regulations regarding mandatory compliance plan requirements of the Affordable Care Act. . In addition, CMS provides that "probable" violations of law should be reported to law enforcement. Finally, CMS clarifies that although both legal counsel to the ACO and the compliance officer may have a legal education, legal counsel to the ACO and the compliance officer must be different individuals. ACOs may use their current compliance officer, who must report directly to the ACO's governing body, provided that the compliance officer is not legal counsel to the existing organization and meets the requirements of §425.300.

Regulatory Impact (Page 591)

As detailed in **Table 8** in Attachment 1, CMS estimates a total aggregate median impact of \$470 million in net Federal savings for calendar years (CY) 2012 through 2015 from the implementation of the Shared Savings Program. The 10th and 90th percentiles of the estimate distribution, for the same time period, yields a net savings of \$940 million and \$0 million, respectively. These estimated impacts represent the effect on Federal transfers. Median estimated Federal savings are somewhat less than the estimate published for the proposed rule (estimated \$510 million net savings through 2014) due in part to loosening of ACO financial provisions such as first-dollar (below benchmark) sharing. This, combined with the easing of a number of program requirements and burdens, expands CMS' expected range of participation. Furthermore, CMS estimates a total aggregate median impact of \$1.31 billion in bonus payments to participating ACOs in the Shared Savings Program for CYs 2012 through 2015.

The 10th and 90th percentiles of the estimate distribution, for the same time period, yield a bonus payment to ACOs of \$890 million and \$1.9 billion, respectively. CMS estimates the aggregate cost associated with the start-up investment of ACOs participating in the Shared Savings Program will range from \$29 million to \$157 million. 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. Furthermore, aggregate ongoing annual operating costs for the participating ACOs are estimated to range from \$63 million to \$342 million. Both start-up investment and ongoing annual operating cost ranges utilize an anticipated participation rate of 50 to 270 ACOs in the Shared Savings Program.

Lastly, when utilizing the anticipated mean participation rate of ACOs in the Shared Savings Program, this yields an estimated aggregate average start-up investment and ongoing annual operating costs of \$451 million for CYs 2012 through 2015. Therefore, as illustrated in **Table 8**, for CYs 2012 through 2015 the total median ACO bonus payments of \$1.31 billion coupled with the aggregate average start-up investment and ongoing annual operating cost of \$451 million, incurred at the mean participation rate of ACOs in the Shared Savings Program, result in an estimated benefit-cost ratio of 2.9.