Issue Brief

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KEY POINTS

- This final rule contains provisions relating to Medicare payments to providers of services and suppliers participating in accountable care organizations under the Medicare Shared Savings Program.
- Providers of services and suppliers can continue to receive traditional Medicare fee-for-service payments under Parts A and B, and still be eligible for additional payments, if they meet specified quality and savings requirements.

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CMS Releases Final ACO Rules

The Centers for Medicare & Medicaid Services has issued final rules that will implement Section 3022 of the Affordable Care Act. This final rule contains provisions relating to Medicare payments to providers of services and suppliers participating in accountable care organizations under the Medicare Shared Savings Program. Under these provisions, providers of services and suppliers can continue to receive traditional Medicare fee-for-service payments under Parts A and B, and still be eligible for additional payments, if they meet specified quality and savings requirements.

The 696-page rule was placed on public display Oct. 20. It is scheduled for publication in the Nov. 2 *Federal Register*. A copy is currently available at http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf.

Briefly, CMS stipulates the following concepts and requirements.

PROVIDERS ELIGIBLE TO PARTICIPATE

Under the final rule, "a group of providers and suppliers of services agree to work together with the goal that patients get the right care at the right time in the right setting." The final rule requires that each group of providers be held accountable for at least 5,000 beneficiaries annually for a period of three years. Each group must include health care providers and Medicare beneficiaries on its governing board.

CMS states all Medicare providers can participate in an ACO to coordinate care, but only certain types of providers are able to sponsor one. Sponsors include physicians in group practice arrangements, networks of individual practitioners and hospitals that are partnering with or employ eligible physicians, nurse practitioners, physician assistants and specialists. To help providers serving rural and other underserved areas, the final rule, unlike the proposed rule, allows rural health clinics and federally qualified health centers to work together to coordinate care for patients.

MEASURING QUALITY IMPROVEMENT

The rule will link the amount of shared savings an ACO may receive, and in certain instances shared losses it may be accountable for, to its performance on quality standards on patient experience, care coordination and patient safety, preventive health and at-risk populations. CMS notes these standards will be measured in a way that accounts for providers who treat patients with more complex conditions.

To earn shared savings for the first performance year, providers must fully and accurately report across four domains of quality. Providers will begin to share in savings based on how they perform in the second and third performance years.

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SHARING SAVINGS AND SHARING LOSSES

CMS is implementing two models: a one-sided shared savings model in which providers only share in savings and a two-sided shared savings and losses model, in which providers also share in losses if growth in costs go up. The proposed rule had required ACOs in the one-sided shared savings model to share losses in the third year of the agreement period. In response to comments, CMS has modified the proposal, and the final rule allows ACOs to participate under the one-sided shared savings-only model for the entire length of their first agreement period. ACOs may share up to 50 percent of the savings under the one-sided model and up to 60 percent of the savings under the two-sided model, depending on their quality performance.

CMS will develop a target level of spending for each ACO to determine its financial performance. Because health care spending for any group of patients normally varies from year to year, CMS also will establish a minimum savings and minimum loss rate that would account for these variations. Both shared savings and shared losses will be calculated on the total savings or losses, not just the amount by which the savings or losses exceed the minimum savings or loss rate. In addition, the amount of shared savings would depend on how well the team of providers performs on the quality measures specified in the rule.

The following CMS chart highlights some of the key differences between the proposed and final rules.

Proposed Rule Versus Final Rule for ACOs in the Medicare Shared Savings Program

Topic	Proposed Rule	Modifications in Final Rule
Transition to risk in Track 1	ACOs could choose from two tracks, each entailing a 3-year agreement. Track 1 would comprise 2 years of one-sided shared savings with a mandatory transition in year 3 to performance-based risk under a two-sided model of shared savings and losses. Track 2 would comprise 3 years all under the two-sided model.	Remove two-sided risk from Track 1. Two tracks would still be offered for ACOs at different levels of readiness, with one providing higher sharing rates for ACOs willing to also share in losses.
Prospective versus retrospective	Retrospective assignment based on utilization of primary care services, with prospective identification of a benchmark population.	A preliminary prospective-assignment method with beneficiaries identified quarterly; final reconciliation after each performance year based on patients served by the ACO.
Proposed measures to assess quality	65 measures in 5 domains, including patient experience of care, utilization claims–based measures, and measures assessing process and outcomes. Pay for full and accurate reporting first year, pay for performance in subsequent years. Alignment of proposed measures with existing quality programs and private-sector initiatives	33 measures in 4 domains. (Note: Claims-based measures not finalized to be used for ACO-monitoring purposes) Longer phase-in measures over course of agreement: first year, pay for reporting; second year and third year, pay for reporting and performance. Finalize as proposed.
Sharing savings	One-sided risk model: sharing beginning at savings of 2 percent, with some exceptions for small, physician-only, and rural ACOs. Two-Sided Risk Model: sharing from first dollar.	Share on first dollar for all ACOs in both models once minimum savings rate has been achieved. *continued*

MISSOURI HOSPITAL ASSOCIATION

Proposed Rule Versus Final Rule for ACOs in the Medicare Shared Savings Program		
Topic	**Proposed Rule**	**Modifications in Final Rule**
Sharing beneficiary ID claims data	Claims data shared only for patients seen by ACO primary care physician during performance year; beneficiaries given opportunity to decline at the point of care.	The ACO may contact beneficiaries from provided quarterly lists to notify them of data sharing and opportunity to decline.
Eligible entities	The four groups specified by the Affordable Care Act, as well as critical access hospitals paid through Method II, are eligible to form an ACO. ACOs can be established with broad collaboration beyond these providers.	In addition to groups included in the proposed rule, Federally Qualified Health Centers and Rural Health Clinics are also eligible to both form and participate in an ACO. In order for beneficiaries to be assigned on the basis of utilization of primary care services, these organizations must provide a list of practitioners who directly render primary care services in their facilities.
Start date	Agreement for 3 years with uniform annual start date; performance years based on calendar years.	Program established by Jan.1, 2012; first round of applications are due in early 2012. First ACO agreements start 4/1/2012 and 7/1/2012. ACOs will have agreements with a first performance "year" of 18 or 21 months. ACOs starting 4/1/2012 and 7/1/2012 have option for an interim payment if they report CY 2012 quality measures. ACO must report quality measures for CY 2013 to qualify for first-performance-year shared savings.
Aggregate reports and preliminary prospective list	Reports will be provided at the beginning of each performance year and include: name, date of birth, sex, and health insurance claim number.	Additional reports will be provided quarterly.
Electronic health record Use	Aligning ACO requirements with EHR requirements, 50 percent of primary care physicians must be defined as meaningful users by start of second performance year.	No longer a condition of participation. Retained EHR as quality measure but weighted higher than any other measure for quality-scoring purposes.
Assignment process	One-step assignment process: beneficiaries assigned on the basis of a plurality of allowed charges for primary care services rendered by primary care physicians (internal medicine, general practice, family practice, and geriatric medicine).	Two-step assignment process: Step 1: for beneficiaries who have received at least one primary care service from a physician, use plurality of allowed charges for primary care services rendered by primary care physicians. Step 2: for beneficiaries who have not received any primary care services from a primary care physician, use plurality of allowed charges for primary care services rendered by any other ACO professional.
Marketing guidelines	All marketing materials must be approved by CMS.	"File and use" 5 days after submission and after certifying compliance with marketing guidelines; CMS to provide approved language.

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In addition to this final rule, the following related documents also were released.

- A joint CMS and U.S. Department of Health and Human Services' Office of Inspector General interim final rule with comment period addresses waivers of certain fraud and abuse laws in connection with the Shared Savings Program at www.ofr.gov/inspection.aspx.
- An antitrust policy statement is posted at www.ftc.gov/opp/aco/ and www.justice.gov/atr/public/health_care/aco.html.
- An Internal Revenue Service fact sheet for tax-exempt organizations participating in the Medicare Shared Savings Program through accountable care (FS-2001-11) is posted at www.irs.gov.

COMMENTS

Since CMS issued its proposed ACO rule in April, many questions have been raised about the viability of the program as proposed. CMS said that it has "made significant modifications to reduce burden and cost for participating ACOs. These modifications include: (1) greater flexibility in eligibility to participate in the Shared Savings 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 percent withhold of shared savings; (10) greater flexibility in timing for the evaluation of sharing savings (claims run-out reduced to three months); (11) greater flexibility in antitrust review; and (12) greater flexibility in timing for repayment of losses; and (13) additional options for participation of FQHCs and RHCs."

CMS estimates the following ACO savings to the program.

Net Federal Savings	CY 2012	CY 2013	CY 2014	CY 2015	CYs (2012-215)
10th Percentile	-$30 Million	-$20 Million	$10 Million	$0 Million	$0 Million
Median	$20 Million	$90 Million	$160 Million	$190 Million	$470 Million
90th Percentile	$70 Million	$210 Million	$320 Million	$370 Million	$940 Million
ACO Bonus Payments					
10th Percentile	$60 Million	$180 Million	$280 Million	$360 Million	$890 Million
Median	$100 Million	$280 Million	$410 Million	$520 Million	$1,310 Million
90th Percentile	$170 Million	$420 Million	$600 Million	$740 Million	$1,900 Million
Costs	The estimated start-up investment costs for participating ACOs range from $29 million to $157 million, with annual ongoing costs ranging from $63 million to $342 million, for the anticipated range of 50 to 270 participating ACOs. With the mean participation of ACOs, the estimated aggregate average start-up investment and four year operating costs is $451 million.				
Benefits	Improved healthcare delivery and quality of care and better communication to beneficiaries through patient centered-care.				

Because the display copy layout and a table of contents by page number of this rule will change when published, the following discussion follows the order of the rule.

continued

Perhaps the most important component in understanding the final rule's overall requirements is to focus on the regulation provisions themselves.

This is a well-written document, and CMS provides a "final decision" paragraph at the end of each section. Such paragraphs are incorporated in the material that follows.

BACKGROUND AND INTRODUCTION

CMS said the intent of the Shared Savings Program is to promote accountability for a population of Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care.

CMS clearly states that "it is important to note that the Shared Savings Program is not a managed care program. Medicare FFS beneficiaries retain all rights and benefits under traditional Medicare. Medicare FFS beneficiaries retain the right to see any physician of their choosing, and they do not enroll in the Shared Savings Program."

DEFINITIONS

In regulation §425.20, CMS makes the following definitions.

Accountable care organization means a legal entity that is recognized and authorized under applicable state, federal or tribal law, is identified by a taxpayer identification number, and is formed by one or more ACO participant(s) that is(are) defined at §425.102(a) and also may include any other ACO participants described at §425.102(b).

ACO participant means an individual or group of ACO provider(s)/supplier(s) that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants that is required under §425.204(c)(5).

ACO professional means an ACO provider/supplier who is either of the following.

- A physician legally authorized to practice medicine and surgery by the state in which he/she performs such function or action.
- A practitioner who is one of the following.
  - (i) A physician assistant (as defined at §410.74(a)(2)).
  - (ii) A nurse practitioner (as defined at §410.75(b)).
  - (iii) A clinical nurse specialist (as defined at §410.76(b)).

ACO provider/supplier means an individual or entity that:

- is a provider (as defined at §400.202) or a supplier (as defined at §400.202)
- is enrolled in Medicare
- bills for items and services it furnishes to Medicare FFS beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations
- is included on the list of ACO providers/suppliers that is required under §425.204(c)(5).

ELIGIBILITY AND GOVERNANCE

1. General Requirements

a. Accountability for Beneficiaries

Section 1899(b)(2)(A) of the act requires participating ACOs to "be willing to become accountable for the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to it." To satisfy this requirement, CMS proposed that an

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ACO executive who has the authority to bind the ACO must certify to the best of his or her knowledge, information and belief that the ACO participants are willing to become accountable for and to report to CMS on the quality, cost and overall care of the Medicare FFS beneficiaries assigned to the ACO. CMS further proposed that this certification would be included as part of the ACO's application and participation agreement.

Final Decision: CMS is finalizing its policy on certification of accountability for beneficiaries as proposed without change (§425.100 and 425.204).

b. Agreement Requirement

Section 1899(b)(2)(B) of the act requires participating ACOs to "enter into an agreement with the secretary to participate in the program for not less than a three-year period …."

Final Decision: CMS is finalizing this proposal on agreements as described under §425.208 and §425.210. Further, as described in §425.200, the ACO's agreement period will be for not less than three years, consistent with statute, although some agreement periods may be longer than three years.

c. Sufficient Number of Primary Care Providers and Beneficiaries

Section 1899(b)(2)(D) of the act requires participating ACOs to "include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO …" and that at a minimum, "the ACO shall have at least 5,000 such beneficiaries assigned to it …"

Final Decision: CMS is finalizing its proposals without change (§425.110).

d. Identification and Required Reporting on Participating ACO Professionals

Final Decision: CMS is finalizing its proposals on operational definition of an ACO as a collection of Medicare-enrolled TINs, the obligation of the ACO to identify its ACO participant TINs and national provider identifier on the application, the obligation of the ACO to update the list, and the required exclusivity of ACO participants upon whom assignment is based without change under sections 425.20, 425.204(5), 425.302(d) and 425.306, respectively. CMS clarifies that ACO participants upon which beneficiary assignment is not dependent are not required to be exclusive to a single Medicare Shared Savings Program ACO. This final exclusivity policy extends to the ACO participant TINs of FQHCs, RHCs and ACO participants that include NP, PAs and specialists upon which beneficiary assignment will be dependent.

2. Eligible Participants

Section 1899(b) of the act establishes eligibility requirements for ACOs participating in the Shared Savings Program. Section 1899(b)(1) of the act allows several designated groups of providers of services and suppliers to participate as an ACO under this program, "as determined appropriate by the secretary," and under the condition that they have "established a mechanism for shared governance."

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

- ACO professionals 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

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- other groups of providers of services and suppliers as the secretary determines appropriate

Final Decision: CMS is finalizing its proposals for identifying groups of providers of services and suppliers that may join to form an ACO under §425.102. Specifically, the entities identified in section 1899(b)(1)(A) through (D) of the act will be able to form ACOs, provided they meet all other eligibility requirements. In addition, critical access hospitals billing under method II, FQHCs and RHCs also may form independent ACOs if they meet the eligibility requirements specified in this final rule. In addition, any Medicare enrolled entities not specified in the statutory definition of eligible entities in section 1899(b)(1)(A)-(D) of the act 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.

3. Legal Structure and Governance

Section 1899(b)(2)(C) of the act 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."

a. Legal Entity

CMS continues to support its proposal that each ACO certify that it is recognized as a legal entity under state law and authorized by the state to conduct its business.

Final Decision: CMS is finalizing its proposal that an ACO must be a legal entity for purposes of all program functions identified in this final rule. CMS also is finalizing commenters' suggestion that ACOs licensed under federal or tribal law are eligible to participate in the Shared Savings Program. In addition, an ACO formed among multiple ACO participants must provide evidence in its application that it is a legal entity separate from any of its ACO participants. (§425.104)

b. Distribution of Shared Savings

CMS will make any shared savings payments directly to the ACO as identified by its TIN. As explained in the proposed rule, the statute does not specify how shared savings must be distributed, only that the ACO be a legal entity so that the ACO can accept and distribute shared savings.

Final Decision: CMS is finalizing its proposals under §425.204(d) without change.

c. Governance

Section 1899(b)(1) of the act requires that an ACO have a "mechanism for shared governance" and section 1899(b)(2)(F) of the act requires that an "ACO shall have in place a leadership and management structure that includes clinical and administrative systems."

CMS will not finalize its proposal that each ACO participant have proportionate control of the ACO governing body.

Final Decision: In sum, CMS is finalizing the requirement that an ACO must maintain an identifiable governing body with authority to execute the functions of the ACO as defined in this final rule, including but not limited to the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinating care.

The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities. The governing body must have a transparent governing process.

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The governing body members shall have a fiduciary duty to the ACO and must act consistently with that fiduciary duty. The ACO must have a conflicts of interest policy for the governing body. The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives. (§425.106)

d. Composition of the Governing Body

CMS proposed that to be eligible for participation in the Shared Savings Program, the ACO participants must have at least 75 percent control of the ACO's governing body.

Final Decision: In summary, CMS will finalize its proposals that at least 75 percent control of the ACO's governing body must be held by the ACO's participants. The governing body of the ACO must be separate and unique to the ACO in the cases where the ACO comprises multiple, otherwise independent entities that are not under common control (for example, several independent physician group practices). However, the members of the governing body may serve in a similar or complementary manner for a participant in the ACO.

Each ACO should provide for beneficiary representation on its governing body. In cases in which the composition of an ACO's governing body does not meet the 75 percent ACO participant control threshold or include the required beneficiary governing body representation, the ACO must describe why it seeks to differ from the established requirements and how the ACO will involve ACO participants in innovative ways in ACO governance and/or provide for meaningful participation in ACO governance by Medicare beneficiaries. (§425.106)

4. Leadership and Management Structure

Section 1899(b)(2)(F) of the act requires an eligible ACO to "have in place a leadership and management structure that includes clinical and administrative systems."

Final Decision: CMS will finalize the requirement that the ACO's operations 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.

In addition, clinical management and oversight must be managed by a senior-level medical director who is one of the ACO's physicians, who is physically present on a regular basis in an established ACO location and a board-certified physician who is licensed in one of the states in which the ACO operates.

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. ACO participants and ACO providers/suppliers must demonstrate a meaningful commitment to the mission of the ACO. A meaningful commitment can be shown when ACO participants and ACO providers/suppliers agree to comply with and implement the ACO's processes required by section 1899(b)(2)(G) of the act and are held accountable for meeting the ACO's performance standards for each required process.

As part of their applications, ACOs must submit certain documentation on their leadership and management structures,

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including clinical and administrative systems, to ensure that the ACO meets the eligibility requirements.

CMS is finalizing the following document requests to effectuate leadership and management structure requirements.

- ACO documents (for example, participation agreements, employment contracts and operating policies) sufficient to describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO.
- Supporting materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders. In addition, upon request, the ACO also may be required to provide copies of documents effectuating the ACO's formation and operation, including charters, bylaws, articles of incorporation, and partnership, joint venture, management or asset purchase agreements.
- CMS will finalize its proposal to allow ACO applicants to describe innovative leadership and management structures that do not meet the final rule's leadership and management requirements. (§425.108, §425.112, and §425.204)

5. Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, Coordination of Care and Demonstrating Patient-centeredness

a. Processes to Promote Evidence-based Medicine

Section 1899(b)(2)(G) of the act requires an ACO to "define processes to promote evidence-based medicine …" CMS explained in the proposed rule that evidence-based medicine can be generally defined as the application of the best available evidence gained from the scientific method to clinical decision-making. CMS proposed that as part of the application, the ACO would describe the evidence-based guidelines it intends to establish, implement and periodically update.

Final Decision: To be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement and periodically update its processes to promote evidence-based medicine. These guidelines must cover diagnoses with significant potential for the ACO to achieve quality improvements, taking into account the circumstances of individual beneficiaries. (§425.112)

b. Processes to Promote Patient Engagement

Section 1899(b)(2)(G) of the act also requires an ACO to "define processes to promote … patient engagement." CMS described in the proposed rule that the term "patient engagement" is the active participation of patients and their families in the process of making medical decisions.

CMS proposed that ACOs will be required to use the Consumer Assessment of Health Providers and Systems survey.

Final Decision: To be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement and periodically update processes to promote patient engagement. In its application, an ACO must describe how it intends to address all of the following areas: (a) evaluating the health needs of the ACO's assigned population; (b) communicating clinical knowledge/evidence-based medicine to beneficiaries; (c) beneficiary engagement and shared decisionmaking and (d) written

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standards for beneficiary access and communication, and a process in place for beneficiaries to access their medical record. (§425.112)

c. Processes to Report on Quality and Cost Measures

Section 1899(b)(2)(G) of the act requires an ACO to "define processes to … report on quality and cost measures."

Final Decision: CMS will finalize its proposal that to be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement and periodically update its processes and infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics to enable the ACO to monitor, provide feedback, and evaluate ACO participant and ACO provider/supplier performance and to use these results to improve care and service over time. (§425.112)

d. Processes to Promote Coordination of Care

Section 1899(b)(2)(G) of the act requires an ACO to "define processes to … coordinate care, such as through the use of telehealth, remote patient monitoring and other such enabling technologies."

Final Decision: CMS will finalize its proposal requiring ACOs to define their care coordination processes across and among primary care physicians, specialists, and acute and post-acute providers. The ACO also must define its methods to manage care throughout an episode of care and during its transitions. The ACO must submit a description of its individualized care program as part of its application, along with a sample care plan, and explain how this program is used to promote improved outcomes for, at a minimum, their high-risk and multiple chronic condition patients. The ACO also should describe additional target populations that would benefit from individualized care plans. In addition, CMS will finalize its proposal that ACOs describe how they will partner with community stakeholders as part of their application. ACOs that have stakeholder organizations serving on their governing body will be deemed to have satisfied this requirement. (§425.112)

6. Overlap with other CMS Shared Savings Initiatives

a. Duplication in Participation in Medicare Shared Savings Programs

The statute includes a provision that precludes duplication in participation in initiatives involving shared savings. Section 1899 of the act states that providers of services or suppliers that participate in certain programs are not eligible to participate in the Shared Savings Program.

Section 1899(b)(4) of the act states these exclusions are "(A) A model tested or expanded under section 1115A [the Innovation Center] that involves shared savings under this title or any other program or demonstration project that involves such shared savings; (B) The independence at home medical practice pilot program under section 1866E."

Final Decision: CMS has identified several current initiatives in which ACO participants receive shared savings such that they would be prohibited from participation in the Shared Savings Program: independence at home, the Medicare Health Care Quality Indiana Health Information Exchange and North Carolina Community Care Network demonstrations, multi-payer advanced primary care initiative arrangements involving shared savings, PGP transition demonstration, the Care Management for High-Cost Beneficiaries Demonstrations, and the Pioneer ACO Model through the Innovation Center. CMS said that there may be other demonstrations or programs that will be

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implemented or expanded as a result of the ACA, and it will update the list of duplicative shared savings efforts periodically to inform prospective Shared Savings Program participants and as part of the application.

An ACO application that contains TINs that are already participating in another Medicare program or demonstration involving shared savings will be rejected.

b. Transition of the Physician Group Practice (PGP) Demonstration Sites into the Shared Savings Program

The PGP demonstration, authorized under section 1866A of the act, serves as a model for many aspects of the Shared Savings Program. The ACA provided authority for the secretary to extend the PGP demonstration. On Aug. 8, 2011, CMS announced the PGP transition demonstration will follow many of the same parameters from the original PGP demonstration, with some modifications. The modifications include shifting spending benchmarks to the national rather than regional level, aligning beneficiaries first with primary care physicians and then specialists, and implementing a patient experience of care survey. All 10 PGP demonstration participants have agreed to participate in the PGP transition demonstration.

Thus, the PGP sites will not be permitted to participate concurrently in the Shared Savings Program.

c. Overlap with the Center for Medicare & Medicaid Innovation (Innovation Center) Shared Savings Models

Final Decision: CMS is finalizing its proposal to exclude Pioneer ACO model participants from participation in the Shared Savings Program. In addition, because the Pioneer ACO model may begin before the Shared Savings Program and will assign beneficiaries prospectively, CMS will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both. (§425.114)

ESTABLISHING THE AGREEMENT WITH THE SECRETARY

1. Options for Start Date of the Performance Year

CMS states it will start accepting applications from prospective ACOs shortly after Jan. 1, 2012. For information on the application process, CMS refers readers to its "Notice of Intent" that will appear shortly after publication of this final rule at https://www.cms.gov/sharedsavingsprogram/.

Final Decision: As specified in §425.200, for the first year of the Shared Savings Program (CY 2012), ACOs will be afforded the flexibility to submit to begin participation in the program on April 1 (resulting in an agreement period of three performance years, with the first performance year of the agreement consisting of 21 months) or July 1 (resulting in an agreement period of three years, with the first performance year of the agreement consisting of 18 months).

During all calendar years of the agreement period, including the partial year associated with both the April 1, 2012, and July 1, 2012 start dates, the eligible providers participating in an ACO that meet the quality performance standard but do not generate shareable savings will qualify for a physician quality reporting system incentive payment. (§425.504)

2. Timing and Process for Evaluating Shared Savings

CMS notes the statute is silent with respect to when the shared savings determination should be made.

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Final Decision: CMS says that with its review of the public comments received on the proposed policy, it is finalizing a policy, under §425.602, §425.604, and §425.606, of using three-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.

3. New Program Standards Established During the Agreement Period

Final Decision: Under §425.212, CMS will finalize its proposal that ACOs be held responsible for all regulatory changes in policy, with the exception of eligibility requirements concerning the structure and governance of ACOs, calculation of sharing rate and beneficiary assignment. CMS will modify its proposal to allow ACOs the flexibility to voluntarily terminate their agreement in those instances where regulatory standards are established during the agreement period that the ACO believes will affect the ability of the ACO to continue to participate in the Shared Savings Program.

4. Managing Significant Changes to the ACO during the Agreement Period

Final Decision: Under §425.214, CMS is modifying its proposal 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 these additions/subtractions of ACO participants or providers/suppliers. In addition, in the event of "significant changes," which is defined as an event that occurs resulting in an ACO being unable to meet the eligibility or program requirements of the Shared Savings Program, the ACO must also notify CMS within 30 days. Such changes may necessitate, for example, adjustments to the ACO's benchmark but allow the ACO to continue participating in the Shared Savings Program. Such changes also may cause the ACO to no longer meet eligibility. For example, losing a large primary care practice could cause the ACO assignment to fall below 5,000 and result in termination of the agreement.

5. Coordination with Other Agencies

The antitrust agencies are releasing concurrently with this final rule a final antitrust policy statement in response to the comments. Nothing in this final rule shall be construed to modify, impair or supersede the applicability of any of the federal antitrust laws.

COORDINATING THE SHARED SAVINGS PROGRAM APPLICATION WITH THE ANTITRUST AGENCIES

CMS proposed to require that certain ACOs be subject to mandatory review by the antitrust agencies before it would approve their participation in the Shared Savings Program.

CMS is not finalizing its proposal. Rather, CMS will accept such an ACO into the Shared Savings Program regardless of whether it voluntarily obtains a letter from the antitrust agencies and regardless of the contents of any letter it may have voluntarily obtained from the antitrust agencies, assuming that the ACO meets the other eligibility requirements set forth in this final rule.

PROVISION OF AGGREGATE AND BENEFICIARY IDENTIFIABLE DATA

1. Data Sharing

To participate in the Shared Savings Program, Section 1899(b)(2)(G) of the act states an "ACO shall define processes to … report on quality and

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cost measures, and coordinate care …" Section 1899 of the act does not address what data, if any, CMS should make available to ACOs on their assigned beneficiary populations to support them in evaluating the performance of ACO participants and ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health.

2. Sharing Aggregate Data

Final Decision: CMS will finalize without change its proposals related to sharing of aggregate data (see part 425 subpart H in regulatory text of this final rule).

3. Identification of Historically Assigned Beneficiaries

CMS proposed to disclose the name, date of birth, sex and health insurance claim number of the preliminary prospective assigned beneficiary population.

Final Decision: CMS is finalizing its proposal to provide the ACO with a list of beneficiary names, dates of birth, sex and HICN derived from the beneficiaries whose data were used to generate the preliminary prospective aggregate reports (Subsection H). CMS is modifying its 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.

4. Sharing Beneficiary Identifiable Claims Data

CMS is finalizing its proposal to share data with the ACO once the beneficiary has been notified and has not declined to have their data shared.

5. Giving Beneficiaries the Opportunity to Decline Data Sharing

Final Decision: CMS will finalize its proposal in §425.704 to allow ACOs to request beneficiary identifiable data on a monthly basis. In addition, CMS is modifying this proposal in §425.708 to allow the ACO the option of contacting beneficiaries from the list of preliminarily prospectively assigned beneficiaries 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. The ACO would be responsible for repeating the notification and opportunity to decline sharing information during the next face-to-face encounter with the beneficiary to ensure transparency, beneficiary engagement, and meaningful choice.

ASSIGNMENT OF MEDICARE FFS BENEFICIARIES

Section 1899(c) of the act requires the secretary to "determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services."

Final Decision: CMS is finalizing its proposed policies concerning the eligibility of Medicare FFS beneficiaries for assignment to an ACO. Specifically, as required by the statute and consistent with the definition of Medicare fee-for service beneficiary in §425.20, under §425.400(a) only individuals enrolled in the original Medicare FFS program under parts A and B, and not enrolled in an MA plan under Part C, an eligible organization under section 1876 of the

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act, or a PACE program under section 1894 of the act, can be assigned to an ACO.

1. Definition of Primary Care Services

Final Decision: CMS is finalizing its proposal to define "primary care services" in §425.20 as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439) as primary care services. CMS will establish a cross-walk for these codes to certain revenue center codes used by FQHCs (prior to Jan. 1, 2011) and RHCs so that their services can be included in the ACO assignment process.

a. Consideration of Physician Specialties in the Assignment Process
Final Decision: Under §425.402, after identifying all patients who had a primary care service with a physician who is an ACO provider/supplier in an ACO, CMS 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 final policy allows consideration of all physician specialties in the assignment process. CMS describes this step-wise approach in greater detail in the final rule.

b. Consideration of Services Furnished by Nonphysician Practitioners in the Assignment Process
Final Decision: Under §425.402 of this final regulation, CMS is adopting a two step-wise process for beneficiary assignment. The final step-wise assignment process takes into account two decisions; (1) the decision to base assignment on the primary care services of specialist physicians in the second step of the assignment process; and (2) the decision to take into account the plurality of all primary care services provided by ACO professionals in determining which ACO is truly responsible for a beneficiary's primary care in the second step of the assignment process.

2. Prospective Versus Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings

Section 1899(d)(1) of the act provides that an ACO may be eligible to share savings with the Medicare program if the ACO meets quality performance standards established by the secretary and meets the requirements for realizing savings for its assigned beneficiaries against the benchmark established by the secretary under section 1899(d)(1)(B) of the act.

Final Decision: Under §425.400, CMS is revising its proposed policy to provide for prospective assignment of beneficiaries to ACOs in a preliminary manner at the beginning of a performance year based on most recent data available. Assignment will be updated quarterly based on the most recent 12 months of data. Final assignment is determined after the end of each performance year based on data from that year.
CMS also is finalizing its proposal that beneficiary assignment to an ACO is for purposes of determining the population of Medicare FFS beneficiaries for whose care the ACO is accountable, and for determining whether an ACO has achieved savings, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

continued

No exclusions or restrictions based on health conditions or similar factors will be applied in the assignment of Medicare FFS beneficiaries. CMS also is finalizing its proposal to determine assignment to an ACO based on a statistical determination of a beneficiary's utilization of primary care services, rather than on a process of enrollment or "voluntary selection" by beneficiaries. The specific methodology (the "step-wise" approach) is described in §425.402. In that methodology, CMS also is finalizing its proposal to assign beneficiaries to no more than one ACO.

3. Majority Versus Plurality Rule for Beneficiary Assignment

Section 1899(c) of the act requires that Medicare FFS beneficiaries be assigned to "an ACO based on their utilization of primary care services" furnished by an ACO professional who is a physician, but it does not prescribe the methodology for such assignment, nor criteria on the level of primary care services utilization that should serve as the basis for such assignment.

Final Decision: In §425.402, CMS is finalizing its proposal to adopt a plurality of primary care services, defined in terms of allowed charges, as the basis for assignment. However, CMS is modifying the way in which it will calculate that plurality to apply it in the two-step assignment process.

QUALITY AND OTHER REPORTING REQUIREMENTS

1. Introduction

In this section of the final rule, CMS discusses measures to assess the quality of care furnished by an ACO; requirements for data submission by ACOs; quality performance standards; the incorporation of reporting requirements under section 1848 of the act for the Physician Quality Reporting System; and aligning ACO quality measures with other laws and regulations.

2. Measures to Assess the Quality of Care Furnished by an ACO

a. General

CMS proposed the use of 65 measures to establish quality performance standards that ACOs must meet to be eligible for shared savings for the first performance period. CMS has modified its proposed domain structure by combining the care coordination and patient safety domains. In addition, CMS is moving certain proposed claims-based measures, such as inpatient safety measures and ambulatory care sensitive condition (ACSC) admissions measures, to its monitoring program.

CMS is finalizing the Consumer Assessment of Healthcare Providers and Systems modules listed in Table 1, below, for quality performance purposes. CMS is not finalizing the "Helpful, Courteous, Respectful Office Staff" module proposed for quality performance measurement and reporting or scoring purposes but notes that this module is still a core part of the CAHPS survey to be collected for informational purposes only.

Final Decision: In summary, CMS has modified the quality reporting by reducing the measure set to 33 measures total, or 23 scored measures when accounting for the patient experience survey modules scored as one measure and the all or nothing diabetes and CAD measures scored as one measure each.

CMS also will fund the administration of an annual 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

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vendor to administer the survey and report results using standardized procedures.

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, below.

Of the 33 measures being finalized, seven are collected via patient survey, three are calculated via claims, one is calculated from Electronic Health Records Incentive Program data, and 22 are collected via the group practice reporting option web interface.

Table 1: Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

	Domain	Measure Title	NQF Measure #/ Measure Steward	Method of Data Submission	Pay for Performance Phase In R = Reporting P=Performance		
					Year 1	Year 2	Year 3
AIM: Better Care for Individuals							
1	Patient/Caregiver Experience	CAHPS: Getting Timely Care, Appointments and Information	NQF #5, AHRQ	Survey	R	P	P
2	Patient/Caregiver Experience	CAHPS: How Well Your Doctors Communicate	NQF #5 AHRQ	Survey	R	P	P
3	Patient/Caregiver Experience	CAHPS: Patients' Rating of Doctor	NQF #5 AHRQ	Survey	R	P	P
4	Patient/Caregiver Experience	CAHPS: Access to Specialists	NQF #5 AHRQ	Survey	R	P	P
5	Patient/Caregiver Experience	CAHPS: Health Promotion and Education	NQF #5 AHRQ	Survey	R	P	P
6	Patient/Caregiver Experience	CAHPS: Shared Decision Making	NQF #5 AHRQ	Survey	R	P	P
7	Patient/Caregiver Experience	CAHPS: Health Status/ Functional Status	NQF #6 AHRQ	Survey	R	R	R
8	Care Coordination/ Patient Safety	Risk-Standardized, All Condition Readmission*	NQF #TBD CMS	Claims	R	R	P
9	Care Coordination/ Patient Safety	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease (AHRQ Prevention Quality Indicator (PQI) #5)	NQF #275 AHRQ	Claims	R	P	P
10	Care Coordination/ Patient Safety	Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8)	NQF #277 AHRQ	Claims	R	P	P
11	Care Coordination/ Patient Safety	Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment	CMS	EHR Incentive Program Reporting	R	P	P
12	Care Coordination/ Patient Safety	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility	NQF #97 AMA-PCPI/NCQA	GPRO Web Interface	R	P	P

MISSOURI HOSPITAL ASSOCIATION

continued

	Table 1: Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings						
	Domain	Measure Title	NQF Measure #/ Measure Steward	Method of Data Submission	Pay for Performance Phase In R = Reporting P=Performance		
					Year 1	Year 2	Year 3
13	Care Coordination/ Patient Safety	Falls: Screening for Fall Risk	NQF #101 NCQA	GPRO Web Interface	R	P	P
AIM: Better Health for Populations							
14	Preventive Health	Influenza Immunization	NQF #41 AMA-PCPI	GPRO Web Interface	R	P	P
15	Preventive Health	Pneumococcal Vaccination	NQF #43 NCQA	GPRO Web Interface	R	P	P
16	Preventive Health	Adult Weight Screening and Follow-up	NQF #421 CMS	GPRO Web Interface	R	P	P
17	Preventive Health	Tobacco Use Assessment and Tobacco Cessation Intervention	NQF #28 AMA-PCPI	GPRO Web Interface	R	P	P
18	Preventive Health	Depression Screening	NQF #418 CMS	GPRO Web Interface	R	P	P
19	Preventive Health	Colorectal Cancer Screening	NQF #34 NCQA	GPRO Web Interface	R	R	P
20	Preventive Health	Mammography Screening	NQF #31 NCQA	GPRO Web Interface	R	R	P
21	Preventive Health	Proportion of Adults 18+ who had their Blood Pressure Measured within the preceding 2 years	CMS	GPRO Web Interface	R	R	P
22	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (<8 percent)	NQF #0729 MN Community Measurement	GPRO Web Interface	R	P	P
23	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (<100)	NQF #0729 MN Community Measurement	GPRO Web Interface	R	P	P
24	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Blood Pressure <140/90	NQF #0729 MN Community Measurement	GPRO Web Interface	R	P	P
25	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Tobacco Non Use	NQF #0729 MN Community Measurement	GPRO Web Interface	R	P	P
26	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): Aspirin Use	NQF #0729 MN Community Measurement	GPRO Web Interface	R	P	P
27	At Risk Population - Diabetes	Diabetes Mellitus: Hemoglobin A1c Poor Control (>9 percent)	NQF #59 NCQA	GPRO Web Interface	R	P	P
28	At Risk Population - Hypertension	Hypertension (HTN): Blood Pressure Control	NQF #18 NCQA	GPRO Web Interface	R	P	P
29	At Risk Population – Ischemic Vascular Disease	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/dl	NQF #75 NCQA	GPRO Web Interface	R	P	P
30	At Risk Population – Ischemic Vascular Disease	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic	NQF #68 NCQA	GPRO Web Interface	R	P	P

continued

Table 1: Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings							
					Pay for Performance Phase In R = Reporting P=Performance		
	Domain	Measure Title	NQF Measure #/ Measure Steward	Method of Data Submission	Year 1	Year 2	Year 3
31	At Risk Population - Heart Failure	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	NQF #83 AMA-PCPI	GPRO Web Interface	R	R	P
32	At Risk Population – Coronary Artery Disease	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Drug Therapy for Lowering LDL-Cholesterol	NQF #74 CMS (composite) / AMA-PCPI (individual component)	GPRO Web Interface	R	R	P
33	At Risk Population – Coronary Artery Disease	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)	NQF # 66 CMS (composite) / AMA-PCPI (individual component)	GPRO Web Interface	R	R	P

Table 2: ACO Agreement Period Pay for Performance Phase-In Summary			
	Performance Year 1	Performance Year 2	Performance Year 3
Pay for Performance	0	25	32
Pay for Reporting	33	8	1
Total	33	33	33

3. Requirements for Quality Measures Data Submission by ACOs

a. General

CMS proposed that during the year following the first performance period, each ACO would be required to report via the group practice reporting option (GPRO) Web interface the applicable proposed quality measures with respect to services furnished during the performance period.

b. GPRO Web Interface

CMS proposed using the same sampling method used in the 2011 PQRS GPRO I that would require that the random sample for measures reported via ACO GPRO must consist of at least 411 assigned beneficiaries per measure set/domain. If the pool of eligible, GPRO assigned beneficiaries is less than 411 for any measure set/domain, then CMS proposed to require the ACO to report on 100 percent, or all, of the assigned beneficiaries.

c. Certified EHR Technology

In the proposed rule, CMS included information on which of the proposed quality measures for the Shared Savings Program are currently included in the EHR Incentive Programs and stated its intent to continue to further align the measures between the two programs.

continued

Final Decision: CMS is finalizing its proposal to use surve-based measures, claims and administrative databased measures, and the GPRO Web interface as a means of ACO quality data reporting for certain measures, as listed in Table 1. For the ACO GPRO measures, CMS is finalizing its proposal to use the same sampling method used in the 2011 PQRS GPRO I. CMS also is finalizing its proposal to retain the right to validate the data ACOs enter into the GPRO Web interface via a data validation process based on the one used in phase I of the PGP demonstration.

4. Quality Performance Standards

CMS believes that all four domains it is adopting are of considerable importance and, therefore, agree with the comments that supported weighting each domain equally and will finalize its proposal to do so. This means the four measure domains (patient/caregiver experience, care coordination/patient safety, preventive health and at-risk population) will be weighted at 25 percent each in calculating an ACO's overall quality performance score for purposes of determining its final sharing rate. In addition, CMS is finalizing the following disease categories within the at-risk population domain: diabetes, hypertension, ischemic vascular disease, heart failure and coronary artery disease.

CMS is finalizing its proposal to establish national benchmarks for quality measures using a national sample of Medicare FFS claims data, Medicare Advantage quality data or a flat percentage if FFS claims/MA quality data are not available. CMS believes national benchmarks are more appropriate than regional benchmarks, because Medicare FFS is a national program, and CMS would like to measure quality improvement and make comparisons over time between FFS and ACO populations on a national basis. CMS will use a flat national percent establishing the minimum at 30 percent and the maximum at 90 percent as indicated in Table 3 below. CMS will provide a longer phase in to pay-for-performance. All 33 measures used for scoring purposes will be pay-for-reporting in year one of the agreement. In year two, eight measures will continue to be pay-for-reporting, while 25 measures will be used for pay-for-performance. In year three (and four if applicable), 32 measures will be pay-for-performance, and one measure, the health status/functional status module, will be pay-for-reporting.

Final Decision: CMS recognizes that achieving the quality performance standard on 33 out of 33 measures may be difficult, especially in the early years. Accordingly, CMS has modified this final rule to require that ACOs achieve the quality performance standard on 70 percent of the measures in each domain. If an ACO fails to achieve the quality performance standard on at least 70 percent of the measures in each domain, CMS will place the ACO on a corrective action plan and re-evaluate the following year. If the ACO continues to underperform in the following year, the agreement would be terminated.

This approach also means that an ACO could fail one or more individual measures in each domain and still earn shared savings. ACOs must achieve the minimum attainment level on at least 70 percent of the measures in each domain to continue in the program.

It should also be noted that if an ACO fails to completely and accurately report the EHR measure, the ACO would miss the 70 percent cut-off for the care coordination domain because this measure is double-weighted for both scoring purposes and for purposes of determining poor performance.

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Table 3: Sliding Scale Measure Scoring Approach		
ACO Performance Level	Quality Points (all measures except EHR)	EHR Measure Quality Points
90+ percentile FFS/MA Rate or 90+ percent	2 points	4 points
80+ percentile FFS/MA Rate or 80+ percent	1.85 points	3.7 points
70+ percentile FFS/MA Rate or 70+ percent	1.7 points	3.4 points
60+ percentile FFS/MA Rate or 60+ percent	1.55 points	3.1 points
50+ percentile FFS/MA Rate or 50+ percent	1.4 points	2.8 points
40+ percentile FFS/MA Rate or 40+ percent	1.25 points	2.5 points
30+ percentile FFS/MA Rate or 30+ percent	1.10 point	2.2 points
<30 percentile FFS/MA Rate or <30 percent	No points	No points

Table 4: Total Points for Each Domain Within the Quality Performance Standard				
Domain	Total		Total	
	Individual Measures	Total Measures for Scoring Purposes	Potential Points Per Domain	Domain Weight
Patient/Caregiver Experience	7	1 measure with 6 survey module measures combined, plus 1 individual measure	4	25%
Care Coordination/ Patient Safety	6	6 measures, plus the EHR measure double-weighted (4 points)	14	25%
Preventative Health	8	8 measures	16	25%
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure	14	25%
Total	33	23	48	100%

As illustrated in Table 4 above, a maximum of two points per measure could be earned under both the one-sided and two-sided model based on the ACO's performance, except on the EHR measure, which is weighted double any other measure and would be worth four points.

The total potential for shared savings will be higher under the two-sided model (discussed below) because the maximum potential shareable savings based on quality performance is 60 percent of the savings generated, compared to 50 percent under the one-sided model. That is, 100 percent of the reporting of the quality measures in the first year of the Shared Savings Program will result in an ACO earning 50 or 60 percent of shareable savings, depending on whether the ACO is in the one-sided or two-sided model.

5. Incorporation of Other Reporting Requirements Related to the Physician Quality Reporting System (PQRS) and Electronic Health Records Technology under Section 1848 of the Act

continued

Final Decision: CMS is finalizing its proposal to incorporate PQRS reporting requirements and incentive payment under the Shared Savings Program. Specifically, CMS is finalizing the use of the GPRO Web interface, as proposed, as well as its proposal that eligible professionals who are ACO providers/suppliers constitute a group practice under their ACO participant TIN for purposes of qualifying for a PQRS incentive under the Shared Savings Program. Therefore, an ACO, on behalf of its EPs, is required to satisfactorily submit quality data on the GPRO quality measures in Table 1 of this final rule. Such EPs within an ACO may qualify for a PQRS incentive under the Shared Savings Program only as a group practice and not individuals. ACO participants and ACO providers/suppliers also may not seek to qualify for the PQRS incentive under traditional PQRS, outside of the Shared Savings Program. CMS also is finalizing the calendar year reporting period of Jan. 1 through Dec. 31 for purposes of the PQRS incentive under the Shared Savings Program.

CMS is not finalizing its proposal regarding an ACO's failure to report all required ACO quality measures. That is, if an ACO fails to meet the Shared Savings Program quality performance standard and is not eligible for shared savings, EPs in a group practice that is an ACO participant TIN may nevertheless earn the PQRS incentive under the Shared Savings Program, as long as the ACO satisfactorily reports, on behalf of its EPs, the ACO GPRO quality measures for the reporting period. Thus, ACO participant TINs in ACOs that meet the satisfactory reporting requirements will still be eligible for a PQRS incentive payment under the Shared Savings Program, even if the ACO does not generate shareable savings for the Shared Savings Program.

A complete list of PQRS EPs is available at www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf. In addition, similar to traditional PQRS, an EP cannot qualify for the PQRS incentive as both a group and as an individual under the same TIN.

CMS is not finalizing the proposal to require that at least 50 percent of an ACO's primary care physicians be determined to be "meaningful EHR users" as that term is defined in 42 CFR 495.4 by the start of the second performance year to continue participation in the Shared Savings Program. Instead, CMS will double weight the quality measure "Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment."

SHARED SAVINGS AND LOSSES

1. Authority For and Selection of Shared Savings/Losses Model

CMS proposed that ACOs participating in the Shared Savings Program would have an option between two tracks.

Track 1: Under Track 1, shared savings would be reconciled annually for the first two years of the three-year agreement using a one-sided shared savings approach, with ACOs not being responsible for any portion of the losses above the expenditure target. However, for the third year of the three-year agreement, CMS proposed to establish an alternative two-sided payment model with these ACOs subject to share in any losses as well as savings.

Track 2: More experienced ACOs that are ready to share in losses with greater opportunity for reward could elect to immediately enter the two-sided model. An ACO participating in Track 2 would be under the two-sided model for all three years of its agreement period.

Final Decision: As provided in §425.600, CMS will establish the Shared Savings Program on existing FFS

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payments, using both shared savings only (Track 1) and shared savings and losses models (Track 2). CMS is modifying its proposal for Track 1 so that it will be a shared savings only model for the duration of the ACO's first agreement period. CMS will make final its proposal that ACOs electing Track 2 will be under the two-sided model for the duration of their first agreement period. CMS also is finalizing its proposal to require all ACOs to participate in the two-sided model in agreement periods subsequent to the initial agreement period.

2. Shared Savings and Losses Determination

a. Overview of Shared Savings and Losses Determination

The following table provides an overview of CMS' final decisions on elements of the program's financial models.

Table: 5 Shared Savings Program Overview				
	One-Sided Model		Two-Sided Model	
Issue	**Proposed**	**Final**	**Proposed**	**Final**
Transition to Two-Sided Model	Transition in third year of first agreement period	First agreement period under one-sided model. Subsequent agreement periods under two-sided model	Not Applicable	Not Applicable
Benchmark	Option 1 reset at the start of each agreement period.	Finalizing proposal	Option 1 reset at the start of each agreement period.	Finalizing proposal.
Adjustments for health status and demographic changes	Benchmark expenditures adjusted based on CMS-HCC model.	Historical benchmark expenditures adjusted based on CMS-HCC model. Performance year: newly assigned beneficiaries adjusted using CMS-HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS-HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year.	Benchmark expenditures adjusted based on CMS-HCC model.	Historical benchmark expenditures adjusted based on CMS-HCC model. Performance year : newly assigned beneficiaries adjusted using CMS-HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS-HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year.
Adjustments for IME and DSH	Include IME and DSH payments	IME and DSH excluded from benchmark and performance expenditures	Include IME and DSH payments	IME and DSH excluded from benchmark and performance expenditures
Payments outside Part A and B claims excluded from benchmark and performance year expenditures;	Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals	Finalize proposal	Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals	Finalize proposal
Other adjustments	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments	Finalize proposal	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments	Finalize proposal

MISSOURI HOSPITAL ASSOCIATION

continued

Table: 5 Shared Savings Program Overview				
	One-Sided Model		Two-Sided Model	
Issue	**Proposed**	**Final**	**Proposed**	**Final**
Maximum Sharing Rate	Up to 52.5 percent based on the maximum quality score plus incentives for FQHC/RHC participation	Up to 50 percent based on the maximum quality score	Up to 65 percent based on the maximum quality score plus incentives for FQHC/RHC participation	Up to 60 percent based on the maximum quality score
Quality Sharing Rate	Up to 50 percent based on quality performance	Finalizing proposal	Up to 60 percent based on quality performance	Finalizing proposal
Participation Incentives	Up to 2.5 percentage points for inclusion of FQHCs and RHCs	No additional incentives	Up to 5 percentage points for inclusion of FQHCs and RHCs	No additional incentives
Minimum Savings Rate	2.0 percent to 3.9 percent depending on number of assigned beneficiaries	Finalizing proposal based on number of assigned beneficiaries	Flat 2 percent	Finalizing proposal: Flat 2 percent
Minimum Loss Rate	2.0 percent	Shared losses removed from Track 1	2.0 percent	Finalizing proposal
Performance Payment Limit	7.5 percent.	10 percent	10 percent	15 percent
Performance payment withhold	25 percent	No withhold	25 percent	No withhold
Shared Savings	Sharing above 2 percent threshold once MSR is exceeded	First dollar sharing once MSR is met or exceeded.	First dollar sharing once MSR is exceeded.	First dollar sharing once MSR is met or exceeded.
Shared Loss Rate	One minus final sharing rate	Shared losses removed from Track 1	One minus final sharing rate	One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate not to exceed 60 percent
Loss Sharing Limit	5 percent in first risk bearing year (year 3)	Shared losses removed from Track	Limit on the amount of losses to be shared phased-in over 3 years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the annual limit would not be shared.	Finalizing proposal

b. Establishing the Benchmark

CMS notes that section 1899(d)(1)(B)(ii) of the act specifies several requirements with regard to establishing an ACO's benchmark. These requirements are as follows.

- First, the law requires the secretary "to estimate a benchmark for each agreement period for each ACO using the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO."
- Second, the law requires that "[s]uch benchmark shall be adjusted for beneficiary characteristics and such other factors as the secretary determines appropriate."
- Third, the law requires that the benchmark be "updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the secretary."

MHA
MISSOURI HOSPITAL ASSOCIATION

continued

- Finally, the law requires that "[s]uch benchmark shall be reset at the start of each agreement period."

Final Decision: CMS is making final its proposed methodology under §425.602 for establishing an ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the three years prior to the start of an ACO's agreement period using the ACO participants' TINs identified at the start of the agreement period.

CMS will calculate benchmark expenditures by categorizing beneficiaries in the following cost categories in the order in which they appear: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/nondual eligible Medicare and Medicaid beneficiaries. This benchmarking methodology will apply to all ACOs, including those consisting of FQHCs and/or RHCs (either independently or in partnership with other eligible entities).

CMS also is making final its proposals to truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for each benchmark and performance year; weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent; and reset the benchmark at the start of each agreement period. Further, CMS will use a three-month run-out of claims data and a completion factor to calculate benchmark expenditures.

c. Adjusting the Benchmark and Actual Expenditures

(1) Adjusting Benchmark and Performance Year Average per Capita Expenditures for Beneficiary Characteristics

Section 1899(d)(1)(B)(i) of the act stipulates that an ACO is eligible for shared savings "only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics" is below the applicable benchmark.

Final Decision: CMS is making final its proposal under §425.602 to risk adjust an ACO's historical benchmark expenditures using the CMS Hierarchal Condition Category (CMS-HCC) model. CMS is modifying its proposal under §425.604 and §425.606 to make additional risk adjustments to performance year assigned beneficiaries instead of capping growth in risk adjustments during the term of the agreement at zero percent. For newly assigned beneficiaries, CMS will annually update an ACO's CMS-HCC prospective risk scores to take into account changes in severity and case mix for this population. CMS will use demographic factors to adjust for severity and case mix for the continuously assigned population relative to the historical benchmark. However, if the continuously assigned population shows a decline in its CMS-HCC prospective risk scores, CMS will lower the risk score for this population.

An ACO's updated benchmark will be restated in the appropriate performance year risk relative to the risk profile of the performance year assigned beneficiaries. Further, CMS will make adjustments for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/nondual eligible Medicare and Medicaid beneficiaries.

CMS also is making final its proposal to monitor and evaluate the issue of more complete and accurate coding for future rule making and to use an audit process

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to ensure the appropriateness of ACO coding practices and to adjust ACO risk scores.

(a) Impact of IME and DSH

Final Decision: CMS is modifying its proposal under §425.602, §425.604 and §425.606 so as to exclude IME and DSH payments from ACO benchmark and performance year expenditures.

(b) Geographic and Other Payment Adjustments

Final Decision: CMS is making final its proposal under §425.602, §425.604, and §425.606 to include all Parts A and B expenditures, with the exception of IME and DSH adjustments, in the calculation of the benchmark and performance year expenditures. However, CMS intends to evaluate this issue and may address it in future rulemaking.

(2) Trending Forward Prior Year's Experience to Obtain an Initial Benchmark

(a) Growth Rate as a Benchmark Trending Factor

In the proposed rule, CMS considered two options for trending forward the most recent three years of per beneficiary expenditures for Parts A and B services to estimate the benchmark for each ACO.

Final Decision: CMS is finalizing its proposal under §425.602 to trend forward the most recent three years of per-beneficiary expenditures using growth rates in per beneficiary expenditures for Parts A and B services. That is, CMS will trend BY1 and BY2 forward, based on a growth rate, to BY3 dollars. Further, to trend forward the benchmark, CMS will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/nondual eligible Medicare and Medicaid beneficiaries.

(b) National Growth Rate as a Benchmark Trending Factor

Final Decision: CMS is finalizing its proposal under §425.602 to use a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the most recent three years of per beneficiary expenditures for Parts A and B services to estimate the benchmark for each ACO. In doing so, CMS will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/nondual eligible.

d. Updating the Benchmark During the Agreement Period

Final Decision: CMS is finalizing its proposal under §425.602 to update the benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program using data from CMS' Office of the Actuary.

e. Determining Shared Savings

(1) Minimum Savings Rate

Section 1899(d)(1)(B)(i) of the act states that "an ACO shall be eligible to receive payment for shared savings …only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark …" CMS calls this percent the minimum savings rate.

(a) One-sided Model

For the one-sided model CMS proposed a sliding scale confidence interval (CI) based on the number of assigned beneficiaries, as shown in the following table.

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Table 6: Proposed Minimum Savings Rate by Number of Assigned Beneficiaries (One-Sided Model)		
Number of Beneficiaries	MSR (low end of assigned beneficiaries)	MSR (high end of assigned beneficiaries)
5,000 - 5,999	3.9 percent	3.6 percent
6,000 - 6,999	3.6 percent	3.4 percent
7,000 - 7,999	3.4 percent	3.2 percent
8,000 - 8,999	3.2 percent	3.1 percent
9,000 - 9,999	3.1 percent	3.0 percent
10,000 - 14,999	3.0 percent	2.7 percent
15,000 - 19,999	2.7 percent	2.5 percent
20,000 - 49,999	2.5 percent	2.2 percent
50,000 - 59,999	2.2 percent	2.0 percent
60,000+	2.0 percent	

Final Decision: CMS is finalizing its proposal under §425.604 to use a sliding scale, based on the size of the ACO's assigned population, to establish the MSR for ACOs participating under the one-sided model. (see above)

(b) Two-sided Model
CMS proposed to adopt a fixed 2 percent MSR for organizations operating under the two-sided model, in place of the variable minimum savings rate for organizations operating under the one-sided model.

Final Decision: CMS is finalizing its proposal under §425.606 to apply a flat 2 percent MSR to all ACOs participating under the two-sided model.

(2) Quality Performance Sharing Rate
Final Decision: CMS is finalizing its proposal under §425.604 and §425.606 that ACOs under the one-sided model can earn up to 50 percent of total savings based on quality performance, and ACOs under the two-sided model can earn up to 60 percent of total savings based on quality performance.

(3) Additional Shared Savings Payments
Final Decisions: The final rule will not contain a sliding scale-based increase in the shared savings rate, up to 2.5 additional percentage points under the one-sided model and up to 5 additional percentage points under the two-sided model, for ACOs that include an FQHC or RHC as an ACO participant.

The final rule will not contain additional financial incentives, beyond those established for quality performance, for the care of dual eligible beneficiaries or other factors related to the composition of the ACO or its activities, nor will the final rule include a preference for ACOs participating in similar arrangements with other payers.

(4) Net Sharing Rate
Final Decision: CMS is revising its proposal under §425.604 to allow for sharing on first dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR. CMS is finalizing its proposal under §425.606 similarly allowing sharing

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on a first dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.

(5) Performance Payment Limits
Final Decision: CMS is revising its proposal under §425.604 and §425.606 to raise the payment limit from 7.5 percent to 10 percent of an ACO's updated benchmark for ACOs under the one-sided model and to raise the payment limit from 10 percent to 15 percent of an ACO's updated benchmark for ACOs that elect the two-sided model.

f. Calculating Sharing in Losses
Final Decision: The shared losses methodology under §425.606 will mirror the shared savings methodology, comprised of a formula for calculating shared losses based on the final sharing rate, use of a MLR to protect against losses resulting from random variation and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay.

(1) Minimum Loss Rate
Final Decision: CMS is finalizing its proposal under §425.606 to apply a MLR for the two-sided model. To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must exceed its updated benchmark costs for the year by at least 2 percent. Once losses meet or exceed the MLR, an ACO would be responsible for paying the percentage of excess expenditures, on a first dollar basis, up to the proposed annual limit on shared losses.

(2) Shared Loss Rate
Final Decision: As proposed, under §425.606, the shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark will be determined based on the inverse of its final sharing rate based on quality performance (that is, 1 minus the shared savings rate). However, CMS is modifying 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.

g. Limits on Shared Losses
Final Decision: CMS is finalizing its proposal under §425.606 that the amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark: 5 percent in the first performance year of participation in a two-sided model under the Shared Savings Program, 7.5 percent in the second performance year, and 10 percent in the third performance year. Further, because CMS has eliminated the requirement for ACOs under the one-sided model to accept risk in their third performance year, CMS is not finalizing the proposed provision regarding the limits on shared losses for ACOs transitioning from the one-sided to two-sided model.

h. Ensuring ACO Repayment of Shared Losses
Final Decision: CMS is retaining its proposed policies under §425.204 concerning the repayment mechanism to ensure ACO repayment of shared losses. CMS will allow ACOs flexibility to specify their preferred method for repaying potential losses and how that would apply to ACO participants and ACO providers/suppliers.
During the application process and annually, each ACO under the two-sided model will be required to demonstrate that is has established a repayment mechanism. One-sided model ACOs requesting interim payment must make a similar demonstration at the time of application. CMS will determine the adequacy of an ACO's repayment mechanism prior to the start of each year.

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CMS also is finalizing its proposal that the repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of total per capita Medicare Parts A and B FFS expenditures for assigned beneficiaries, based either on expenditures for the most recent performance year or expenditures used to establish the benchmark. To the extent that an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, CMS will not carry forward unpaid losses into subsequent performance years and agreement periods.

i. Timing of Repayment

Final Decision: CMS is revising its proposed policies under §425.606(h) concerning timing of repayment of losses. If an ACO incurs shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

j. Withholding Performance Payments

Final Decision: CMS is revising its proposal to eliminate 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.

k. Determining First Year Performance for ACOs beginning April 1 or July 1, 2012

(1) Interim Payment Calculation

In the interim payment calculation, CMS will determine shared savings and losses based on the ACO's first 12 months of program participation.

(2) First Year Reconciliation

Final Decision: CMS is adopting a policy under §425.608 that will enable ACOs with start dates of April 1 and July 1, 2012, to opt for an interim payment calculation, to determine shared savings and losses, at the end of their first 12 months of program participation. Unless stated otherwise, the same methodology for determining shared savings and losses that applies under §§425.604 and 425.606 will apply to this interim payment calculation. For ACOs with start dates of April 1 or July 1, 2012, reconciliation for the first performance year will occur after the completion of the ACO's first performance year, defined as 21 months for April 1 starters and 18 months for July 1 starters. ACOs must indicate in their application whether they are requesting an interim payment calculation. ACOs that opt for interim payment during their first performance year must demonstrate as part of their application that they have an adequate repayment mechanism in place, consistent with the requirements for two-sided model ACOs in this final rule. ACOs that generate shared losses under the interim payment calculation must repay such losses within 90 days of notification of losses. Further, any monies determined to be owed by an ACO after first year reconciliation, whether as a result of additional shared losses or an overpayment of shared savings, must be repaid to CMS, in full, within 90 days of receipt of notification.

H. Additional Program Requirements and Beneficiary Protections

Final Decision: CMS is finalizing its proposal to require ACO participants to post signs in their facilities indicating their associated ACO provider's/supplier's participation in the Shared Savings Program and to make available standardized written notices developed by CMS to Medicare FFS beneficiaries whom they serve. All standardized written information provided by CMS will be in compliance with the Plain Writing Act of 2010. CMS is clarifying that the standardized written notices must be furnished in settings in which FFS beneficiaries are receiving primary care services.

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ACO MARKETING GUIDELINES

Final Decision: CMS is finalizing the definition of marketing materials and activities without substantive change at §425.20 of this final rule. This final rule allows ACOs to use marketing materials five days after filing them with CMS if the organization certifies that the marketing materials comply with all applicable marketing requirements.

PROGRAM MONITORING

Final Decision: CMS will finalize without substantive change the proposal to use the many methods at its disposal to monitor ACO performance and ensure program integrity, including but not limited to, undertaking an audit if CMS determines it is necessary.

COMPLIANCE PLANS

Final Decision: CMS is finalizing its proposed compliance plan requirements with minor modifications, as outlined in §425.300. Like the proposal, the final rule allows an ACO to coordinate and streamline compliance efforts with those of its ACO participants and ACO providers/suppliers. 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.

PROHIBITION ON CERTAIN REQUIRED REFERRALS AND COST SHIFTING

Final Decision: CMS is finalizing the requirement to prohibit ACOs, their ACO participants, their ACO providers/suppliers, from conditioning participation in the ACO on referrals of federal health care program business to the ACO, its ACO participants or its ACO providers/suppliers for services they know or should know are being provided to beneficiaries who are not assigned to the ACO.

CMS is modifying the final rule to prohibit limiting or restricting referrals of patients to ACO participants or ACO providers/suppliers within the same ACO, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the patient expresses a preference for a different provider, practitioner or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the judgment of the referring party.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting