Robert Wood Johnson Foundation

April 2011

# *Overview: Medicare Shared Savings Program for Accountable Care Organizations*

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## Introduction

On April 7, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule[1] implementing §3022 of the Patient Protection and Affordable Care Act (ACA), the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations (ACOs). Section 3022 adds a new §1899 establishing the MSSP.[2] CMS' proposed rule was accompanied by several additional policy documents:

- a policy issuance from CMS and the Office of the Inspector General (OIG) regarding waivers of certain civil money penalty provisions of law, the Federal anti-kickback statute, and provisions of the physician self-referral law (Stark Law) in the case of physicians and physician practices participating in ACOs in the MSSP for ACOs; [3]
- a "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program," issued jointly by the Department of Justice and the Federal Trade Commission, which oversee the enforcement of antitrust laws in the U.S.;[4] and
- a notice from the Internal Revenue Service seeking comment on the application of Internal Revenue Code §501(c)(3) (relating to tax exempt organizations) to nonprofit health care entities participating in ACOs.[5]

The proposed rule also contains a series of estimates that help shed light on Administration thinking regarding the potential impact of the program. Over the 2012-2014 time period, CMS median estimates place net savings of $510 million.[6] CMS notes the great uncertainties inherent in this estimate given the high degree of variability in terms of provider response to the

[1] 76 Fed. Reg. 19528 (April 7, 2011)
[2] Patient Protection and Affordable Care Act, Pub. L. No. 111-48 (2010); Health Care and Education Reconciliation Act, Pub. L. No. 111-52 (2010), adding new § 1899 to the Social Security Act (42 U.S.C. 1899).
[3] 76 Fed. Reg. 19655 (April 7, 2011)
[4] http://www.ftc.gov/opa/2011/03/aco.shtm (Accessed April 11, 2011)
[5] http://www.irs.gov/pub/irs-drop/n-11-20.pdf (Accessed April 11, 2011)
[6] 76 Fed. Reg. 19634

MSSP/ACO program (which is optional), how participating ACOs elect to structure themselves (shared savings only in the first 2 years, or acceptance of risk of loss from the beginning), whether Medicare beneficiaries elect to align themselves with an ACO participant, and other important factors. CMS estimates that between 1.5 and 4 million beneficiaries will make an ACO alignment choice.[7] Using the results of the Medicare PGP demonstrations to inform its calculations, the agency also estimates start-up and first-year costs of slightly more than $1.75 million, an ACO participation figure of between 75 and 150 ACOs, and aggregate start-up/initial operational costs of between $131.6 and $263.2 million.[8]

**Overall Observations**

The structure of the rule and the accompanying policy issuances suggest an emerging overall picture of how ACOs will develop over time and their role in the health care system.

- The proposed rule is designed to create an extremely high set of hurdles to the establishment and operation of ACOs, thereby assuring that ACO formation will roll out slowly over time, as reflected in agency estimates. Because ACOs are a relatively new concept that has generated much attention from both federal regulators and the antitrust enforcement agencies, it is perhaps not surprising that the proposed rule is designed in ways both direct and indirect to limit market entry, perhaps so that the agencies can test the waters. The fact that market entry may be so limited may account for the decision on the part of the antitrust enforcement agencies to take a relatively broad (i.e., permissive) stance toward the establishment of ACOs.
- Because of CMS' narrow approach to interpreting patient "assignment" for purposes of shared savings under the law, the proposed rule can be expected to have minimal impact in medically underserved communities, both urban and rural. This is because the proposed rule recognizes the assignment of only those patients under the care of physicians. This is true despite the fact that under the rule, ACO participants can include federally qualified health centers (FQHCs), rural health clinics (RHCs), and numerous types of health professionals such as nurse practitioners, physician assistants, and advanced clinical practice nurses. While these entities and professionals may participate, patients under their care will not count for shared savings assignment purposes, thereby diminishing the incentives of ACOs to include a diverse array of primary health care practices. The result is especially serious for RHCs and FQHCs, which together care for millions of medically underserved Medicare beneficiaries but are paid on an all-inclusive encounter basis, thereby precluding identification of precisely which procedures are furnished by physician members of care teams.[9]

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[7] 76 Fed. Reg. 19635

[8] 76 Fed. Reg. 19639

[9] For a longer discussion of patient assignment and FQHCs, see Sara Rosenbaum and Peter Shin, *Medicare's Accountable Care Organization Regulations: How Will Medicare Beneficiaries who Reside in Medically Underserved Communities Fare?* (George Washington University School of Public Health and Health Services, Geiger Gibson/RCHN Foundation Research Collaborative (2011)

- The proposed rule would require a major and ongoing investment of capital and a high level of commitment by ACO primary care physicians to the use of electronic health records (EHRs); the model therefore may work best for very mature markets in which large groups of physicians function as part of an integrated delivery system. Even here, however, at least some experts view the proposed shared savings arrangements as unrealistic given the initial investments that are required. Ironically, moreover, in markets in which such systems have been operational for a lengthy period of time, the potential for significant shared savings may be limited, and thus, the appetite for participation may be low, particularly because the federal government will recover a significant portion of any realized savings and because ACOs will be expected to share in the risk of loss.
- The proposed rule (as well as the Proposed Statement of Antitrust Enforcement) contemplates growth in ACO activities across all health care markets. It remains to be seen whether these markets will retain CMS' narrow approach to who may participate as ACOs, which patients will count for shared savings purposes, and structural, risk-sharing, and operational requirements. This question is particularly critical in the Medicaid market, where physician participation is low and health care practice teams are essential.
- The ACO rules represent a significant shift in HHS policy regarding the sharing of individual and aggregate-level beneficiary claims data to participating organizations, making considerable data available to ACOs in exchange for considerable provision of data back to CMS.

**Key Elements of the Proposed Rule**

1. Defining an ACO

Although the CMS rule specifies the structure of an ACO that wishes to participate in the MSSP, state Medicaid and CHIP programs, as well as insurers and health benefit plans, may elect to adopt different definitions. That is, the definition is not preemptive but instead applies only to the MSSP. The proposed CMS definition of an ACO is a:

> legal entity that is recognized and authorized under applicable state law, as identified by a Taxpayer Identification Number (TIN) and comprised of an eligible group of ACO participants that work together to manage and coordinate care for Medicare fee-for-service beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision-making process.[10]

Thus, ACOs are corporate creatures of state law; ACOs that meet the proposed conditions of participation may be part of the MSSP.

[10] 42 C.F.R. §425.4

2. Who can participate in an MSSP ACO, and who can form an MSSP ACO?

Under the rule, an ACO is comprised of "participants." CMS has elected to define who may be an ACO "participant" relatively broadly to include all providers and suppliers under Parts A and B (as defined in 42 C.F.R. §400.202), and ACO "professionals" who in turn are defined as physicians, nurse practitioners, physician assistants, and clinical nurse specialists.[11] The definition of who can participate in an ACO is thus expansive.

*However*, only certain ACO participants are eligible to *form* an ACO for MSSP participation purposes.[12] Participants that can form an ACO for purposes of MSSP program participation are: (1) ACO professionals working in a group practice; (2) networks of individual practices of ACO professionals; (3) partnerships and joint ventures between hospitals and ACO professionals; (4) hospitals employing ACO professionals; and (5) providers and suppliers that are not ACO professionals but that are recognized under the Medicare Act. FQHCs and RHCs are explicitly excluded from the groups that can *form* an ACO for MSSP purposes, for reasons of patient assignment policy, discussed below.[13] How this exclusion can be expected to also affect ACO formation by hospitals (such as Denver Health) that operate their outpatient programs through affiliated RHCs or FQHCs, since, in such a situation, primary care would be furnished by entities whose patients do not count for shared savings purposes.

3. MSSP eligibility conditions for ACOs

ACOs must meet a series of eligibility conditions:[14]

- *TIN*. The ACO must report the taxpayer identification/national provider identifiers (TINs/NPIs) for all participants
- *Commitment to accountability*. Every participant on whom beneficiary assignment is dependent must commit to a 3-year participation agreement and must be exclusive to one ACO.[15] Commitment means being accountable for quality, cost, and overall care, and must make information on quality, cost, and overall care available to the public as specified by CMS.[16]
- *Antitrust clearance*. ACOs falling within the Statements of Antitrust Enforcement pre-clearance requirements (discussed below) must request an expedited review from the

[11] Id
[12] 42 C.F.R. §425.5(b)
[13] 76 Fed. Reg. 19528
[14] 42 C.F.R. §425.5
[15] Participants on whom beneficiary assignment is not dependent must also make a 3-year commitment but the ACO must not require that their participation be exclusive. 42 C.F.R. §425.5(c)
[16] The rule is silent on consequences for participants, on whom beneficiary assignment is dependent, who break their 3-year commitments. Federal regulation 425.14(a)(4), however, permits CMS to terminate ACOs that do not meet eligibility requirements. Because participant commitment agreements are an eligibility requirement, early termination by participants could conceivably be grounds for ACO termination, regardless of whether early termination by individual participants reduces the ACO's assigned beneficiary population below the level required under the rule (i.e., at least 5000 beneficiaries).

agencies and must include a letter from the agencies indicating that they do not challenge or intend to challenge the proposed ACO.

- *Binding and certified agreements*. Upon being notified of eligibility to participate, the ACO CEO must sign a binding 3-year commitment agreement and certify information for accuracy and completeness. Violation of its certification can result in termination.
- *Marketing and communications:* The ACO must submit marketing materials to CMS before use, and must notify beneficiaries about its existence and participants. Certain communication materials must be pre-approved.
- *Election of "Track."* The ACO may elect to participate as either a Track 1 (the "one sided" model of shared savings, with risk of loss only during year 3) or Track 2 ACO (the "two-sided" model with shared risk of savings and loss throughout the 3-year agreement period). Beyond the initial time period, all agreements will be two-sided, with shared risk of savings and loss. Both models are subject to a 25% payment withhold to "help ensure repayment of any losses to the Medicare program."[17]
- *Legal structure*. The ACO must have a legal structure that can receive and distribute shared savings, and be recognized as a legal entity in the state in which it is incorporated. (Nothing in the rule prohibits an ACO from being incorporated in more than one state, thereby allowing the ACO to cross state boundaries,) Existing Medicare entities such as hospitals or group practices may also be able to serve as the legal ACO structure if they can satisfy all applicable ACO requirements. However, where multiple independent and competing entities are involved, the governing body must be a separate entity.
- *Governance*. The governing body must include both participants (at least 75% control) as well as at least one beneficiary representative. The governing body must have full governing powers in the areas of administrative, fiduciary, and clinical operations. [18]
- *Leadership and management*. Similarly, the ACO must have a leadership and management structure that demonstrates that clinical and administrative functions have been aligned with those of the MSSP in the form of action-oriented quality assurance, evidence based medical practice, and compliance and enforcement tools "including . . . expulsion from the ACO" if not met.[19] Extensive criteria evidencing clinical and administrative management are set forth in the rules. The key is that the evidence must show a:

> meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include, for example, a meaningful financial investment in the ACO or a

[17] 42 C.F.R. §425.5(c)(6)

[18] This governance requirement is also critical to the Statements of Antitrust Enforcement Policy, because it is evidence of the degree of clinical integration required by the enforcement agencies to demonstrate that the ACO is more than just a confederation of competitors. Separate questions arise with respect to governance structures where one or more ACO participants is a nonprofit entity. The IRS guidance and request for information is designed to address these issues and preliminarily indicate that participation is lawful if properly structured.

[19] 42 C.F.R. §425.5(c)(9)(vi) Again, this reflects both the requirements of the MSSP as well as antitrust considerations, which require that the entity function as a truly integrated entity rather than as a loose confederation of competitors.

> meaningful human investment (for example time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the participant and provider/supplier to make the clinical integration program succeed.[20]

- *Compliance plan*. The ACO must have an "effective" compliance plan. The elements should mirror the compliance plan guidance published by OIG for other types of providers, including designation of a compliance officer, mechanisms to identify and report suspected problems, and training/education for employees and contractors.
- *Distribution of savings*. The ACO must describe in its application how it plans to use shared savings, including the criteria for shared distribution, how the plan will achieve MSSP goals, and how the proposed plan will achieve the "general aims of better care for individuals, better health for populations, and lower growth in expenditures."[21]
- *Written request for shared savings*. An ACO must make a written request for shared savings, accompanied by full certifications, with government access to the underlying data.
- *Sufficient numbers of primary care providers and beneficiaries*. CMS will deem the ACO to have a sufficient number of primary care physicians and beneficiaries "if the number of beneficiaries historically assigned to the ACO participants using the assignment methodology is 5,000 or more.
- *Reporting on ACO professionals*. The ACO must provide certain information annually on participants.
- *Processes and patient-centeredness*. The ACO must, in its MSSP application, provide CMS with documentation of its plans to: (1) promote evidence based medicine; (2) promote beneficiary engagement;[22] (3) internally report quality and cost metrics; and (4) coordinate care. Nine separate patient-centeredness criteria are identified in the proposed rule.[23]

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[20] 42 C.F.R. §425.5(c)(9)(iv)

[21] 42 C.F.R. §425.5(c)(11)(i)-(iii)

[22] The Preamble (19547) defines patient engagement as "the active participation of patients and their families in the process of making medical decisions. Patient engagement in decision-making requires consideration of not only the best scientific evidence concerning medical treatment, but also the opportunity for patients and families to assess prospective treatment approaches in the light of their own values and convictions. Measure for promoting patient engagement may include but are not limited to 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."

[23] 425.5(c)(15). The criteria must be promoted by the governing body and integrated into practice by leadership and management working with the ACO's health care teams The 9 criteria are: (i) use of a patient experience of care survey; (ii) patient involvement in ACO governance; (iii) a process for evaluating health needs among the assigned population; (iv) a system for identifying high risk individuals and evaluating their needs, developing individualized care plans, and integrating community resources; (v) a care coordination mechanism; (vi) a process for communicating clinical and evidence based information in a way that is understandable; (vii) a process for patient engagement; (viii) written standards for beneficiary access and communications; and (ix) clinical service performance measurement over time.

ACOs must notify beneficiaries of their status and participation and offer them an opportunity to leave the practice. Thus, the basic beneficiary protection is framed as an "opt-out" provision.

4. Assigning Medicare fee-for-service beneficiaries to ACOs

The entire system of performance and payment has its base in the assignment of patients to ACOs. Assignment turns on:

> utilization of primary care services provided under this title [i.e., Medicare-covered services] by a primary care physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined.[24]

Thus, while participants can be a broad range of clinical health care professionals as well as health care entities such as FQHCs, RHCs, or nurse-managed clinics, patients *cannot be assigned to an ACO unless they have used primary care services by a primary care physician who is a member of the ACO*. This limitation on assignment means that Medicare patients served by FQHCs and RHCs are excluded from the assigned patient group because these providers are paid on a bundled basis and lack the procedure codes to identify which patients received Medicare covered procedures from staff physicians as opposed to NPs and PAs. Essentially, this excludes nearly 3 million Medicare beneficiaries in urban and rural medically underserved communities. Also excluded would be patients within a team care group practice whose receipt of care is from a NP or PA, as well as patients who receive primary care from a specialist. Primary care physicians are limited to physicians practicing in the areas of internal medicine, family practice, general practice, or geriatric practice. [25]

The assignment methodology is retrospective, thereby potentially limiting the extent to which ACOs are incentivized to improve their care from the initial phase of operations.[26] The methodology contains several steps.[27]

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[24] 42 C.F.R. 425.6(a)

[25] CMS bases this narrow reading of assignment on the statute, which provides that assignment shall be based on utilization of primary care services under Medicare "provided" by a primary care physician. The statute does not say *provided directly* but has been interpreted this way.

[26] For an excellent commentary on this limitation, see Steve Lieberman's *Health Affairs* blog http://healthaffairs.org/blog/2011/04/06/proposed-cms-regulation-kills-acos-softly/#more-10131 (Accessed April 16, 2011). Lieberman notes that the rule "imposes unfavorable economics, unrealistic requirements, high uncertainty, and significant risks for ACOs" because high start-up costs will require years of recoupment, a factor not taken into account in the proposed rule. In addition to presenting important estimates of actual start-up costs in relation to the shared savings formula, Lieberman writes that "[r]etrospective attribution undermines setting explicit performance targets, which require knowing in advance the patients and targets assigned to an ACO. Retrospective attribution can also lead to selection bias. Assigning patients after the close of the year does little to provide the tools needed to change provider behavior and culture. In contrast, providing timely, detailed claims data on assigned patients facilitates performance improvement."

[27] 42 C.F.R. §425.6(b). See generally, Preamble pp. 19562-19567.

- Step 1: CMS identifies, for each ACO, all primary care physicians who were an ACO physician during the performance year.
- Step 2: CMS determines at the end of the performance year the beneficiaries who received services designated as primary care during the performance year.[28]
- Step 3: CMS determines the total allowed charges for the designated primary care services[29] received from any provider or supplier during the performance year.
- Step 4: CMS will "add together the allowed charges for the primary care services provided by the primary care physicians in each ACO."
- Step 5: CMS assigns a beneficiary to an ACO if the beneficiary has received "a plurality[30] of his or her primary care services, as determined by the sum of the allowed charges for those services, from ACO-participating primary care physicians.

Note however that while assignment is retrospective for purposes of shared savings, data sharing is prospective. That is, during the "benchmark" period of performance, providers will have both aggregated population data and beneficiary claims data about the patients "they will likely be responsible for" even though for shared savings purposes they will not know until the end of the year which patients have been assigned to them.[31]

5. What is the structure of the shared savings program?

The shared savings program is complex and appears to experts to limit the extent to which ACOs can recoup their considerable initial investment.[32]

*Setting the benchmark*

[28] HCPCS Codes 99201-99215, 99304-99340, and 99341-99350, G)402, G0438, and G0439. 42 C.F.R. §425.4
[29] See note 20, supra
[30] CMS notes in the Preamble that it rejects a "majority" rule in favor of a "plurality" rule based on its experience under the PGP demonstration, in which use of a plurality rule resulted in the assignment of between 78 and 88 percent of all patients seen for primary care. CMS seeks comments on whether to use the plurality or majority rule as well as whether there should be a minimum threshold of visits before the plurality rule will be deemed satisfied.
[31] Preamble. 19566.

[32] In his *Health Affairs* blog on ACOs and the MSSP, Steve Lieberman raises doubts about economic viability: :Even highly successful ACOs are likely to need years before recouping start-up and operating expenses under the proposed regulation. Under the CMS 2-sided shared savings model, ACOs can share in bonuses if they save money but are liable for spending in excess of budget. Under the CMS 1-sided model, ACOs can share in bonuses without liability for losses in the first two years, after which they must adopt the 2-sided model. Barring special circumstances, financial risks greatly outweigh potential rewards from accepting 2-sided versus bonus only (1-sided) shared savings. New entities, and especially primary care oriented physician entities, will face prohibitive obstacles in qualifying as ACOs. Saving 5 percent in the first year of ACO operation would strike most observers as an outstanding success. Yet, a simple financial analysis incorporating CMS rules and assumptions highlights that annual savings may have to approach 7 percent to simply break-even on operating and start-up costs, before paying bonuses. http://healthaffairs.org/blog/2011/04/06/proposed-cms-regulation-kills-acos-softly/#more-10131 (Accessed April 16, 2011)

The first step is establishing a benchmark, which in turn will determine whether the ACO has achieved Medicare savings for assigned beneficiaries. The benchmark methodology is retrospective.

- Using the ACO's claims records, CMS computes per capita Medicare A and B expenditures for the 3 most recent available years for each assigned beneficiary. The most catastrophically high expenditures are "truncated" at the 99th percentile.[33] This amount is used to "estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics, including health status, using HCC adjustments."[34]
- The benchmark is then annually updated during each year of the agreement, based on annual national per capita Medicare expenditures for Parts A and B. The result is "risk adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the 3 years used to establish the benchmark."[35] The most recent benchmark year is weighted most heavily in order to assure that the benchmark reflects "more accurately the latest expenditures and health status of the ACO's assigned beneficiary populations."[36] In updating these amounts, CMS does not take into account expenditure increases or decreases under other value-based purchasing initiatives or HITECH, including PQRI, e-prescribing, or HITECH incentives.[37]

*Determining shared savings*. The formulas vary depending on whether the ACO is operating under the one-sided (shared savings with shared risk phased in) or two-sided (shared savings and shared risk) model.

*One-sided model*

In order to qualify for shared savings, the ACO using a 1-sided model must exceed its minimum savings rate, meet the minimum quality performance standards established by the rules, and maintain its MSSP eligibility standard.[38]

For each ACO operating under the 1-sided model, CMS determines whether the "estimated per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is below the applicable benchmark. . ."[39] CMS computes a "minimum savings rate" (MSR) based on the number of assigned beneficiaries. The MSR ranges from low to high, and the rate percentage declines as the number of assigned beneficiaries grows. Thus an ASO with 60,000+ assigned beneficiaries have an MSR of 2.0%, while a small ACO with fewer than 6,000 assigned beneficiaries has a MSR (at the low

[33] 42 C.F.R. §425.7(b)(1)
[34] 42 C.F.R. §425.7(a) and (b)
[35] 42 C.F.R. §425.7(b)(4)
[36] Id.
[37] 42 C.F.R. §425.7(b)(7)
[38] 42 C.F.R. §425.7(c)(3)
[39] 42 C.F.R. §425.7(c)

end of assigned beneficiaries) of 3.9% and an MSR at the high end of assigned beneficiaries of 3.6%.

An ACO operating under the one-sided model that exceeds its "minimum savings rate" is eligible to share savings net 2 percent of its benchmark. ACOs with fewer than 10,000 assigned beneficiaries in the most recent year for which CMS has complete claims data are exempt from the 2 percent net savings threshold adjustment if any one of certain criteria is met: (1) all ACO participants are physicians or physician groups; (2) 75% of the ACO's assigned beneficiaries resides in a county outside an MSA in the most recent year for which CMS has complete claims data; (3) 50% or more of the ACO's assigned beneficiaries in the most recent year for which there are complete claims data are assigned using the special assignment method available for critical access hospitals; and (4) at least 50% of the assigned beneficiaries had at least one encounter with a participating FQHC or RHC in the most recent year for which there are data.[40]

The final sharing rate in the one-sided model is calculated by adding the ACO's "earned quality performance sharing rate" (which can raise the shared savings payment by up to 50%, with an additional shared savings of up to 2.5 percentage points "if the ACO includes a rural health clinic or federally qualified health center within its structure."[41] Again, however, the FQHC/RHC incentive is tied to actual use of the entities by registered patients, and as a result, the potential to realize the incentive is unclear. ACO shared savings in the 1-sided model are capped at 7.5% of the benchmark.[42]

*Two sided model*

In the 2-sided model, as with the 1-sided model, both expenditure targets and quality performance count.[43] CMS similarly determines whether the estimated average per capita expenditures under the ACO, adjusted for beneficiary characteristics, are above or below the benchmark. To be eligible for savings or exposed to losses, the ACO's expenditures for the performance year must be above or below the benchmark by the minimum loss or savings rate, respectively.[44] The minimum savings rate and loss rate are both set at 2 percent of benchmark.[45]

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[40] This bonus is a mystery. Registered Medicare FQHC and RHC patients cannot be assigned to an ACO because, according to CMS, the procedure code data needed to link their care to a specific physician (as opposed to the bundled payment to the care team) are lacking (Preamble 19538). Therefore it is completely unclear what "assigned" patients CMS is referring to. The agency might mean patients assigned to other ACO physicians, but why they would make visits to participating FQHCs or RHCs is not clear, since presumably they are receiving their primary care from their physicians. They might conceivably receive case management or other patient support services from an FQHC or RHC, but the extent to which patients under the care of private physicians travel to either of these clinical providers for supplemental care is unknown.

[41] One RHC or FQHC inclusion immediately appears to bolster the final shared savings rate. However, the added incentive is only triggered, as noted, if at least 50 assigned beneficiaries (which cannot be FQHC or RHC patients, since they cannot be assigned) visits an FQHC or RHC. Thus, it is unclear that inclusion of either entity would result in any incentive. 42 C.F.R. §425.7(c)(7)

[42] 42 C.F.R. §425.7(c)(8)

[43] 42 C.F.R. §425.7(d)(3)

[44] 42 C.F.R. §425.7(d)

[45] 42 C.F.R. §425.7(d)(2)

The FQHC/RHC incentive is raised to 5.0 percentage points as well, but realization of this incentive hinges on use of the clinical entity by assigned patients.[46] The 2-sided ACO performance payment limit is capped at 10%, with limits placed on the magnitude of losses.[47]

The following table, prepared by Manatt Phelps and Phillips, LLP, adapted from the Federal Register Preamble[48] and reproduced here, offers a summary illustration of the shared savings formula:

| Design Element | One-Sided Model | Two-Sided Model |
|---|---|---|
| Maximum sharing rate | 52.5% | 65% |
| Quality scoring | 50.0% | 60.0% |
| FQHC/RHC participation incentives | 2.5% | 5% |
| Minimum savings rate | Between 2% and 3.9% based on the number of assigned beneficiaries | 2% regardless of ACO size |
| Savings eligible for sharing | All savings exceeding the minimum savings rate. For ACOs with fewer than 10,000 beneficiaries who meet certain requirements, sharing begins at first dollar of savings | First dollar of savings |
| Maximum sharing cap | 7.5% of benchmark | 10% of benchmark |
| Losses eligible for sharing | N/A | First dollar of losses |
| Minimum loss rate | N/A[49] | 2% regardless of ACO size |
| Maximum losses | N/A[50] | Year 1: 5%<br>Year 2: 7.5%<br>Year 3: 10% |

Source, Manatt Phelps and Phillips LLP, CMS Releases Proposed Rule Governing Accountable Care Organizations (April 9, 2011).

## 6. ACOs and Quality Improvement

Meeting quality and continuous improvement measures is a precondition to shared savings. CMS designates the measures to be used to calculate the standard. The rule identifies 5 domains for the quality measurement (patient/caregiver experience, care coordination, patient safety, preventive health, and at risk population/frail elderly health).[51] These domains are similar to the 5 domains

[46] 42 C.F.R. §425.7(d)(6). Again, however, the incentive is tied to assigned patients who use FQHCs or RHCs that are asked to partner, thereby excluding, apparently, all of the registered patients of the FQHC or RHC itself. It is therefore unclear whether an ACO ever could qualify for this incentive.

[47] These limits are 5 percent, 7 percent, and 10 percent respectively in years 1-3. One-sided ACOs who, in their third year, must begin to share losses are capped in year 3 at 5 percent. 42 C.F.R. §425.7(d)(9)

[48] 76 Fed. Reg. 19619

[49] Note however that this becomes relevant in year 2.

[50] See note 39

[51] 42 C.F.R. §425.10(a). In his blog, Lieberman notes that "The quality standards pose major barriers to qualifying as ACOs, create substantial uncertainty, raise serious questions about discriminating against providers serving low-income or vulnerable populations, and may inhibit focused, real-world clinical improvement. Only 11 of the 65

covered by EHR meaningful use program: quality, safety, and efficiency; patient engagement; care coordination; public health; and privacy and safety of personal health information. For each measure (and contingent upon data availability), CMS will designate quality performance standards, "including a performance benchmark and minimum attainment level and [will establish] a point scale for certain measures."[52] In the first year, quality performance is measured by complete and accurate reporting; thereafter the measures are used and performance is tied to measure scores. Measure scoring uses a minimum attainment level. Certain measures will be a matter of "yes/no," while others will be measured in degree of performance in accordance with a sliding scale based on performance level.[53]

An ACO is eligible for shared savings if it "demonstrates to CMS that it has satisfied the quality performance requirements for each domain, the payment requirements . . . are satisfied, and the ACO meets other applicable requirements."[54] The ACO must score above the minimum attainment level to be eligible for any shared savings. Track 1 ACOs, by year 3, must meet performance measures to get shared savings, and no longer can satisfy merely the requirement to report.

7. ACOs and public reporting

Shared savings are contingent on public reporting by ACOs on the following matters, in a CMS-specified standardized format: basic information such as name and location and participants, identification of all joint ventures and governing members, quality performance standard scores, and shared savings and losses including the proportion of shared savings distributed to participants and invested in activities related to quality improvement and achievement of the overall aims of the MSSP program (i.e., better patient care, better population health, and slowed growth in expenditures).

8. Incorporating other quality improvement reporting activities

CMS specifies that separate submissions must be made by the ACO on its physicians' behalf in order to maintain eligibility for the PQRI System incentive that is also available under the MSSP.

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proposed quality measures can be met with claims data; 54 require potentially expensive data collection from medical records or surveys. Although the 2010 "group plan reporting option" (GPRO) involves 36 large groups reporting 26 measures, CMS would expand it to 47 measures and all ACOs. The timeline appears to require committing substantial resources to develop Medicare ACOs without knowing these group plan reporting option specifications and related CMS reporting requirements.. . . The proposed regulation is silent on validating measures for ACOs and handling the potential impact of race and socio-economic status . . . . The Brookings—Dartmouth commercial pilots all strongly recommended focusing on a limited number of high impact measures that improve quality, rather than a relatively undifferentiated "kitchen-sink" approach.
http://healthaffairs.org/blog/2011/04/06/proposed-cms-regulation-kills-acos-softly/#more-10131

[52] 42 C.F.R. §425.10(b)
[53] 42 C.F.R. §425.10(b)(3)
[54] 42 C.F.R. §425.10(c)

In addition, the rule specifies that at least 50% of an ACO's primary care physicians must be meaningful EHR users, using certified EHR technology in accordance with HITECH.[55]

9. Monitoring ACO activities

The proposed rule provides for monitoring ACOs for compliance with the provisions of law and for "avoidance of at-risk beneficiaries."[56] CMS says that it will look for "trends and patterns suggestive of avoidance of at risk beneficiaries". The rule defines at risk beneficiaries as dually eligible beneficiaries, people considered high cost, people with 2 or more hospitalizations each year or high HCC scores, or with a recent diagnosis expected to result in increased cost.[57] Penalties apply if "trends and patterns" are found. Quality performance, changes to ACO eligibility requirements, beneficiary notifications, and marketing materials also will be monitored

10. Termination of ACO participation

The proposed rule provides extensive standards for the termination, suspension, and sanction of ACOs, including repayment of shared savings. Grounds for termination include avoidance of at risk beneficiaries, failure to meet quality performance standards, failure to completely and accurately report information or failure to make timely corrections to reported information, failure to comply with eligibility requirements (including failures of governance activities and composition), failure to come into compliance with regulatory changes, failure to notify beneficiaries regarding ACO participation, and multiple other violations.[58] The rule spells out procedures that "in its sole discretion" the agency can use if it concludes that an ACO's performance "may subject the ACO to termination from the shared savings program."[59] Penalties range from corrective action plans, to suspension, being barred from shared savings, required repayment of shared savings, and outright terminations by CMS. CMS activities do not apply to the enforcement agencies, which are free to impose their own sanctions. The rule lists eight separate categories of conduct that can trigger sanctions. Suspension of shared savings is the penalty for avoidance of at risk beneficiaries.

11. ACOs and data submission and data sharing

The rule sets out data submission standards and provides for both aggregate and beneficiary identifiable data sharing with ACOs as well as general conditions for sharing data. ACOs must be HIPAA compliant to receive such data and either be a HIPAA covered entity (e.g., a provider, health plan, or health care clearinghouse) or the business associate of HIPAA covered entities (e.g,, physicians participating in the ACO). ACOs (either as a covered entity or the business associate of a covered entity) will be required to execute a data use agreement with CMS that

[55] 42 C.F.R. §425.11
[56] 42 C.F.R. §425.12(a) and (b0
[57] 42 C.F.R. §425.4
[58] 42 C.F.R. §425.14
[59] 42 C.F.R. §425.13

will govern the ACOs use of the data. Beneficiaries are given "opt out"[60] rights to refuse to permit CMS to share claims data with ACOs; but the presumption is data sharing.

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**FTC/DOJ Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program**

It is important to note that the Statements address the FTC/DOJ analytic approach to formed ACOs. One commentator has noted that it is essential that ACOs get private legal advice from the earliest formation stages, since the expedited review process is limited to the point of Medicare market entry only.[61] Furthermore, as this commenter notes, the *Statements* address only new entity formation by independent providers that do not already possess market power but does not address the issue of ACO participation by entities such as major hospitals that already possess market power. [62]

For ACOs that meet CMS eligibility criteria the agencies will apply the rule of reason test *across both the Medicare and commercial markets*[63] rather than apply the per se illegal standard. The agencies justify this on the grounds that the indicia of clinical integration outlined by CMS reflect those used by the agencies in applying the Statements. Specifically the agencies focus on (1) the formal legal structure that allows the ACO to receive and distribute payments for shared savings; (2) a leadership and management structure that includes clinical and administrative processes; (3) processes to promote evidence based medicine and patient engagement; and (4) reporting on quality and cost measures; and (5) coordinated care.

The agencies then lay out their approach to ACO review. At the initial application stage to become an ACO, the entity must, as indicated in the CMS rule, apply for an antitrust review if it surpasses a certain size. The higher the Primary Service Area (PSA) penetration,[64] the greater the scrutiny.

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[60] The Preamble contains an extensive discussion of the agency's basis for choosing the "opt out" approach (Preamble 19559), as well as an extensive discussion of the HIPAA privacy rule (Preamble 19555-19561) including the Secretary's authority to share both aggregated and beneficiary specific data. The preamble also notes that no substance abuse data will be shared consistent with 42 C.F.R. Part 2's total ban on sharing without express informed consent. The data sharing standard generally follows the broad HIPAA disclosure standard rather than taking a more narrow view of authority to disclose under the Social Security Act ACO provisions, and therefore are potentially quite precedent-setting.

[61] Joe Miller, *Health Affairs* blog http://healthaffairs.org/blog/2011/04/14/the-proposed-accountable-care-organization-antitrust-guidance-a-first-look/#more-10361 (Accessed April 16, 2011)

[62] Id.

[63] The agencies say in the commercial market, but of course there are several other markets and commercial market is vague. I assume they mean across any price-competitive market.

[64] A methodology is set out for determining the PSA.

*Safety Zone:* ACOs in the safety zone (below 30% of the combined share of each common service in each participant's PSA, wherever 2 or more participants provide the same service) don't need to contact the agencies at all. The PSA for each service is defined as "the lowest number of contiguous postal zip codes form which the ACO participant draws at least 75% of its patients." Hospitals and ambulatory surgery centers must be non-exclusive to the ACO to fall within the safety zone, and there are rural exceptions in relation to physicians. The statement also includes a Dominant Provider limitation to ensure that where there are Dominant Providers (greater than 50% share in a PSA) the Dominant Provider must be non-exclusive. ACOs with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer's ability to deal with other ACOs or provider networks.

*Large ACOs:* ACOs that exceed the safety zone are subject to review but are not per se unlawful.

*Very large ACOs:* ACOs that do not qualify for the rural exception cannot participate in the Shared Savings program if their share exceeds 50% for any common service that 2 or more independent ACO participants provide to patients in the same PSA *unless* they have received a mandatory agency review and have gotten a letter indicating no actual or recommended challenge. The Statement makes clear that this review will be a rule of reason review:

> When conducting a review, however, the Agencies will consider any information or alternative data suggesting that the PSA shares may not reflect the ACO's likely market power and also will consider any substantial precompetitive justification for why the ACO needs that proposed share to provide high-quality, cost effective care to Medicare beneficiaries and patients in the commercial market.

Review is expedited.

*Mid-sized ACOs:* ACOs that fall between 30-and 50% on the PSA measurement scale also can go through a review and get a letter or can begin operating and simply refrain from certain anti-competitive conduct: (1) preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers through anti-steering or guaranteed inclusion clauses; (2) tying sales between the ACO providers and other providers (either explicitly or implicitly); (3) exclusive contracting with ACO professionals other than primary care providers; (4) interfering with payer ability to provide value-based purchasing information to members; 5. sharing competitively sensitive pricing information among the ACO participants that could be used to set prices. Because the potential for mid-sized ACOs to run afoul of prohibited conduct standards, it seems likely that no ACO would proceed without a clearance letter.

**Application of Fraud and Abuse Laws to ACOs and ACO Participants**

In their notification on application of the fraud laws, CMS and the Office of the Inspector General propose to grant waivers of the Stark Law, the Anti-Kickback Statute, and the "gainsharing" provisions of the Civil Money Penalties law, which prohibit payments to induce referrals as well as payment to induce the limiting of care. The Anti-Kickback Statute and the Stark Law would be waived with respect to the distribution of shared savings in the case of ACO MSSP participants.