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ACOs, or Else . . . Are ACOs a Strategic Imperative for Providers?

BY PAUL A. DEERINGER

Introduction

On April 7, CMS published its much-anticipated proposed rule for the Medicare Shared Savings Program (SSP), better known as the Medicare ACO program.[1] The proposed rule sets forth the details of a permanent shared savings program between Medicare and accountable care organizations (ACOs), with respect to Medicare fee-for-service (FFS) beneficiaries. In the year between the passage of federal health reform, which created the statutory basis for the SSP,[2] and the release of the proposed rule, an entire cottage industry sprang up, touting advice about ''how to prepare for ACOs,'' with the goal of bootstrapping those efforts into ''how to form an ACO'' once CMS issued the final ACO regulations. Providers, consultants, lawyers, and even YouTube videos focused much time and energy on how best to jockey for position in the new world order that Medicare ACOs would usher in.

However, the proposed rule contains several surprises that have caused even sophisticated providers to re-think their Medicare ACO strategy. The proposed rule imposes even greater up-front and ongoing costs for would-be ACOs than many providers expected, and requires ACOs to meet requirements similar to those of state-regulated managed care plans—but without many of the levers such plans ordinarily have at their disposal to manage care, such as primary care gatekeeping, preferred providers, and cost-sharing differentials for beneficiaries. In addition, the proposed rule, along with its companion notices on antitrust guidance from the Federal Trade Commission (FTC) and Department of Justice (DOJ) and proposed fraud and abuse waivers from CMS and the Office of the Inspector General (OIG),

[1] 76 Fed. Reg. 19527, 19527-19654 (April 7, 2011), *available at* http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf.

[2] *See* Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (PPACA), tit. III, § 3022, tit. X, § 10307, 124 Stat. 395, 940, *codified at* 42 U.S.C. § 1395jjj.

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contain far fewer protections for Medicare ACOs than the provider community previously anticipated.[3]

CMS has set the bar to participate in the SSP very high—possibly too high for many providers. In the wake of the proposed rule, the question many providers are asking themselves is not, ''*How* do I form an ACO?'' but rather, ''*Should* I form an ACO at all?'' And if the answer is ''no,'' what alternatives might providers explore to maintain their competitive edge and keep pace with the larger shift in the Medicare program toward risk-based reimbursement and integrated care?

This article highlights some of the high-level requirements to participate in the SSP, some of the challenges ACOs are likely to face under the proposed rule, and potential alternative strategies to ACO participation for providers to consider.

ACOs: The Basics

What is an ACO? An ACO is a group of providers and suppliers of services (e.g., hospitals, physicians, and others involved in patient care) that:

- work together to coordinate care for the Medicare FFS beneficiaries they serve;
- agree to be accountable for the quality and cost of care for a defined group of Medicare FFS beneficiaries (the ACO's ''assigned beneficiaries''); and
- share in savings (and losses) associated with the care for those assigned beneficiaries.

CMS has articulated a three-part goal under the SSP of better care for individuals, better health for populations, and lower growth in expenditures.

Eligibility. The proposed rule sets forth specific eligibility requirements to participate in the SSP. An ACO must be:

- A distinct legal entity;
- Recognized under applicable state laws; and
- Capable of receiving shared savings payments from CMS.

Given the specific structure and governance requirements for ACOs, it may be easiest to use a new, special purpose entity. The ACO must be composed of an ''eligible group'' of ''ACO participants,'' which essentially includes any Medicare providers or suppliers.[4] However, the ACO must have enough ''ACO professionals'' (i.e., primary care physicians) to serve at least 5,000 Medicare FFS beneficiaries. ACO professionals *must be exclusive* to one ACO, but other ACO participants *cannot be required to be exclusive* to an ACO and must agree to participate for at least three years.

Application Process—No Guaranteed Entry. The proposed rule would require an ACO to submit a *detailed application to CMS* that provides extensive information, including details about how the ACO plans to deliver high-quality care at lower costs for the beneficiaries it serves and how it intends to distribute shared savings. If the application is approved, the ACO must sign a three-year agreement with CMS to participate in the SSP. *CMS will not automatically accept an ACO into the SSP*. In addition, if an ACO experiences a net loss during its first three-year agreement period with CMS, the commentary to the proposed rule indicates that CMS will not permit the ACO to reapply to the SSP.

Governance. An ACO must establish and maintain a governing body, which must include:

- ACO participants (or their representatives);
- One or more Medicare beneficiaries who do not have a conflict of interest with the ACO;
- At least 75 percent of the governing body must be controlled by ACO participants (versus an outside entity, such as a health plan); and
- The governing body of the ACO must be independent and separate from the governing bodies of the ACO participants (unless the ACO is composed of a single member, in which case its governing body can be ACO's governing body).

In addition, the proposed rule would require an ACO to have an executive, officer, manager, or general partner with board-level accountability, and a full-time senior-level medical director.

Management. The proposed rule imposes several management requirements on an ACO, including:

- ACO participants and ACO providers/suppliers must make a ''meaningful commitment'' to the ACO (e.g., invest time, effort or money);
- The ACO must have a physician-directed quality assurance and process improvement program;
- ACO participants must agree to comply with evidence-based clinical guidelines;
- The ACO must have information technology infrastructure (including EHR—and at least 50 percent of the ACO's primary care physicians must be ''meaningful users'' of certified EHR technology)
- The ACO must adopt a compliance plan; and
- The ACO must have a written plan for achieving and distributing shared savings, and improving quality of care.

Retrospective Beneficiary Assignment. In one of the more surprising aspects of the proposed rule, CMS would assign beneficiaries to the ACO *retrospectively*, at the end of each performance year, based on whether the beneficiary received the plurality (not majority) of his or her primary care services from the ACO's participating primary care physicians (i.e., internal medicine, general practice, family practice, and geriatrics). Assignment would be based on allowed Medicare Part B charges, and would include specified HCPCS codes and annual and welcome visits. Beneficiary assignment would be transparent to beneficiaries, and neither Medicare nor the ACO would be permitted to restrict beneficiary freedom of choice. ACO participants would be required to post signs in each of their facilities and provide written notification for beneficiaries about their participation in the ACO program.

[3] *See* 76 Fed. Reg. 21894, 21894-21902 (April 18, 2011), *available at* http://edocket.access.gpo.gov/2011/pdf/2011-9466.pdf (FTC/DOJ guidance) and 76 Fed. Reg. 19655, 19655-19660 (April 7, 2011), *available at* http://edocket.access.gpo.gov/2011/pdf/2011-7884.pdf (CMS/OIG guidance). In addition to the antitrust and fraud and abuse notices, the IRS published guidance for tax-exempt organizations regarding participation in the SSP. *See* Internal Revenue Service, Notice 2011-20—*Notice Regarding Participation in the MSSP Through an ACO* (April 18, 2011), http://www.irs.gov/irb/2011-16_IRB/ar07.html (last visited April 26, 2011).

[4] The proposed rule uses the phrases ''ACO participants'' (likely the ACO's founders/owners) and ''ACO providers/suppliers'' (likely others who contract with the ACO), but does not clearly distinguish between these two categories.

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Substantial Quality Performance Requirements. In order to qualify for shared savings, an ACO would be required to meet certain CMS-defined quality and continuous improvement goals. The proposed rule initially establishes *65 quality performance measures across five equally-weighted quality domains*: (1) patient/care giver experience; (2) care coordination, (3) patient safety, (4) preventive health, and (5) at-risk population/frail elderly health. The ACO will be eligible for shared savings in proportion to its achievement of the quality performance domains, and the ACO will be responsible for complying with changing quality performance requirements over the course of its agreement with CMS. CMS will establish quality performance standards for each measure, including a performance benchmark. For the first performance year, the ACO can meet the quality performance requirements by completely and accurately reporting the specified metrics. In subsequent years, achievement will be based on measured scores for each domain, with zero points awarded if the ACO falls below the minimum standard, a sliding scale if above the minimum but below the target benchmark, and two ''all or nothing'' standards.

Downside Risk Under Either of the Two "Tracks." In another surprising move, the proposed rule contains *no provisions for partial capitation*, but instead provides ACOs with the option of choosing one of two program tracks, *both of which require the ACO to assume downside risk*. The first track (the ''one-sided model'') would allow an ACO to operate on a shared savings-only track for the first two years, but would then require the ACO to assume the risk for shared losses in the third year. The second track (the ''two-sided model'') would allow ACOs to share in savings and risk liability for losses beginning in their first performance year, in return for a higher share of any savings it generates.

Shared Savings Based on Three-Year Benchmark. Under the proposed rule, Medicare would continue to pay individual providers and suppliers for specific items and services as it currently does under the FFS payment systems. In addition, the proposed rule would require CMS to develop a *benchmark for savings* that each ACO must achieve to receive shared savings in each performance year, or else be held liable for losses. The benchmark would be based on per capita expenditures for Medicare FFS beneficiaries who would have been assigned to the ACO for the three most recent years (i.e., based on a rolling three-year average). The benchmark would be subject to several adjustments, including for Medicare claims growth and beneficiary health status.

Shared Savings Subject to Several Restrictions. The proposed rule includes several restrictions on an ACO's ability to qualify and receive shared savings under the SSP. For example, in addition to having to meet the quality performance metrics outlined above, an ACO must achieve a *minimum savings threshold* to qualify for any portion of the shared savings. In addition, an ACO is subject to a *maximum shared savings percentage* of up to 52.5 percent under the one-sided model (subject to a *maximum sharing cap* of 7.5 percent of the ACO's savings benchmark), and up to 65 percent under the two-sided model (subject to a *maximum sharing cap* of 10 percent of the ACO's benchmark). Each of an ACO's annual shared savings payments (if any) also is subject to a *flat 25 percent withhold* in order to offset any losses for which the ACO is responsible during the three-year agreement period. Finally, due to a proposed six-month claims run-out for purposes of calculating Medicare expenditures, shared savings *payments would not be made for at least 18 months* after Jan. 1 of the applicable performance year.

Limited Antitrust Protections. The proposed rule was accompanied by a proposed Statement of Antitrust Enforcement Policy Regarding ACOs to be issued by FTC and DOJ. The proposed antitrust guidance provides ''safety zones'' for ACOs (based on the market share of the ACO participants), ''danger zones'' in which certain ACOs are at risk, and a middle ground in which ACOs are not within a safety zone but are not definitely at risk and can operate, although the ACO may want to seek an advisory opinion to ensure that it is operating in a manner acceptable to the FTC/DOJ. Hospitals and ambulatory surgery centers must not be required or agree to be exclusive to any ACO, irrespective of their market share, although this does not mean that a hospital or ASC must participate in more than one ACO. The proposed antitrust guidance does not preclude private rights of action against an ACO for alleged antitrust violations.

Limited Fraud and Abuse Waivers. The proposed rule also was accompanied by a proposed set of waivers (the ''Joint Notice'') for the federal physician self-referral law (the ''Stark'' law), the federal anti-kickback statute, and the federal civil monetary penalty (CMP) law, which prohibits hospital payments to physicians to reduce or limit the delivery of services or items to Medicare or Medicaid beneficiaries. The proposed waivers are narrow, and protect only (1) distributions of shared savings; and (2) certain financial relationships with physicians within the ACO. The Joint Notice requests comments on the scope of the proposed waivers, the timing of waivers, and 10 additional topics related to potential waivers.

Challenges for Providers Under the SSP

As the foregoing discussion illustrates, the SSP is not a ''test field'' for providers interested in experimenting with care integration and management strategies on their Medicare FFS beneficiaries. To the contrary, the details of the proposed SSP indicate that even sophisticated providers with experience in managing care under capitated contracts may find success under the proposed SSP elusive. The following aspects of the proposed SSP may present particular challenges for aspiring ACO participants, providers, and suppliers:

- **Extensive up-front and ongoing participation requirements.** ACOs will require substantial up-front capital, personnel (e.g., a full-time medical director and management staff), and organization (e.g., full-fledged compliance and QAPI programs). Based on findings from the federal Government Accountability Office, *CMS estimates that the total average start-up investment and first year operating expenditures for an ACO will total roughly $1.8 million.*[5] In addition, ACOs will be subject to ongoing quality performance reporting requirements, public reporting obligations, and

[5] 76 Fed. Reg. 19527, 19638-19639 (April 7, 2011).

potential CMS audits. Many providers may lack the capital, organization, and discipline to achieve consistent compliance with the SSP's many requirements. One exception to this may be large capitated IPAs, particularly in states like California, where such organizations are already heavily regulated much like insurance companies.

- **No guaranteed admission to the SSP.** An ACO's initial investment and organization may come to naught if CMS refuses to admit the ACO to the SSP. CMS has not clarified whether an ACO that otherwise meets the SSP requirements will be admitted, but the proposed rule indicates that CMS will have (and will exercise) discretion in which ACOs it permits to participate in the SSP.
- **Retrospective beneficiary assignment.** CMS appears to be promoting an ''all boats rise'' approach by combining population-level data reporting with retrospective beneficiary assignment. In addition, CMS estimates that a maximum of 5 million Medicare FFS enrollees will be assigned to an ACO[6]—*less than 15 percent of all Medicare FFS enrollees*.[7] Accordingly, an ACO may expend resources managing Medicare FFS beneficiaries who ultimately are never assigned to it—while overall quality may rise and Medicare program costs may decrease, CMS's proposed approach may diminish an ACO's ability to fully recoup its investment in clinical integration.
- **Harsh consequences for underperforming ACOs.** CMS's comments indicate that an ACO that suffers a net loss in the first three-year agreement period will be permanently barred from reapplying to the SSP. If the projected return on investment horizon for the systemic changes the SSP requires providers to make is greater than three years, or if an ACO is simply the victim of bad luck, this ''net loss'' restriction could create a substantial disincentive for an ACO to participate in the SSP as presently structured. Given the SSP's strong roots in the Medicare Physician Group Practice (PGP) demonstration project methodology and provider experiences under that program, some data suggest that many organizations may lose money in the first three years under the proposed ACO model.[8] In addition, the use of a rolling three-year benchmark may create diminishing returns for ACOs as they become more efficient over time. Thus, while ACOs may offer potential long-term cost savings, the ''net loss'' restriction under the SSP may create too short a horizon for ACOs to achieve a meaningful return on investment.
- **True downside risk under either of the two models.** Whether in year three under the one-sided model, or in all three years under the two-sided model, an ACO bears substantial risk under the SSP for incurring costs in excess of its benchmark. While CMS proposes to cap an ACO's downside risk to some extent, the SSP as proposed places significant risk on ACOs and their participants, particularly in the absence of limiting downside risk through partial capitation. Such an approach, when combined with retrospective beneficiary assignment and the ''net loss'' restriction discussed above, may cause providers to think twice about whether their organization can manage care effectively enough on a population basis to ultimately come out ahead under the SSP.
- **Shared savings are subject to many restrictions and delayed payout.** The various qualification thresholds, percentage limitations, withholds, and delayed payout (under the proposed six-month claims run-out) collectively create substantial uncertainty about whether and to what extent shared savings will materialize at all, let alone in sufficient amounts to permit an ACO to recoup its startup and operating costs.
- **Limited antitrust and fraud protections.** While the proposed antitrust guidance may help insulate ACOs from FTC and DOJ enforcement, the guidance does not appear to foreclose private individuals (e.g., physicians excluded from the ACO's network of ''ACO professionals'') from instituting private causes of action against an ACO or its participants for violation of federal and state antitrust laws.
- **Limited fraud and abuse protections.** The narrow proposed fraud and abuse waivers do not appear to protect many of the financial arrangements an ACO likely would require to acquire start-up capital and to fund operating costs and/or losses, unless those financial relationships are with a physician and meet the applicable requirements of the proposed waivers. In addition, financial arrangements that do not involve distribution of shared savings generally fall outside the scope of the proposed waivers. As a result, shared-risk, resource pooling, incentive payments, and other financial arrangements an ACO might want to establish internally to promote efficient operation of the ACO generally also would be unprotected.
- **No preemption of state laws.** Finally, nothing in the Joint Notice proposes federal preemption of state laws. Accordingly, state regulatory schemes still apply to ACOs, and ACOs must comply with these laws, such as state self-referral and antikickback restrictions. Many of these state laws are not the same as their federal counterparts. Thus, an ACO must take into account and comply with

[6] *Id.* at 19534.

[7] *See* Centers for Medicare and Medicaid Services, Medicare and Medicaid Statistical Supplement, 2010 Edition—*Table 2.2, Medicare Enrollment: Hospital Insurance and/or Supplementary Medical Insurance Programs for Total, Fee-for-Service and Managed Care Enrollees, by Demographic Characteristics as of July 1, 2009*, http://www.cms.gov/MedicareMedicaidStatSupp/09_2010.asp (last visited April 26, 2011).

[8] *See* Trent T. Haywood, et al., *The ACO Model— A Three-Year Financial Loss?* 364 New Eng. J. Med. 14, e27 (April 7, 2011) (based on PGP experience, assuming an average first-year investment of $1.7 million, ACOs would require an ''unlikely'' 20 percent margin to break even in three years), *available at* http://www.nejm.org/doi/full/10.1056/NEJMp1100950. *See also* Centers for Medicare and Medicaid Services, *Physician Group Practice Demonstration: Performance Year 1 through Performance Year 4 Summary Results* (indicating that although the 10 participating multispecialty group practices met at least 29 of the 32 quality goals, only five of them produced savings in their fourth and latest year of reported findings, and four of them had not produced any savings by the end of their third performance year), http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Summary_Results.pdf (last visited April 26, 2011).

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these state laws when structuring and operating the ACO, because complying with the proposed waivers for Stark, the AKS, or the CMP statute will not necessarily mean that the ACO complies with comparable state laws. Similarly, some states, like California, have strong corporate practice of medicine prohibitions, which heavily restrict the ability of a lay corporation to influence or control the delivery of health care. These prohibitions stand in tension with the goals of the SSP—one of the elements of the SSP is that the ACO implement evidence-based medicine standards and impose those standards on its participants. As a result, notwithstanding the good intentions of the federal program, more restrictive state laws may pose additional obstacles to the formation and operation of ACOs.

ACO Alternatives

If SSP participation is ultimately unattractive or infeasible, several alternatives exist that may provide levers for providers to drive their organizations' clinical integration efforts. For example, by Jan. 1, 2013, Medicare will introduce a national payment bundling demonstration that will offer providers opportunities to experiment with ACO-like strategies on specific service lines for certain episodes of care that CMS will specify (e.g., cardiology services, post-acute care).[9] Additionally, non-Medicare ACO models have shown promise, such as CIGNA's collaborative ACO pilot initiatives in New Hampshire and Arizona[10] and the CalPERS ACO pilot with Catholic Healthcare West and Hill Physicians in California,[11] although such models must comply with federal and state fraud and abuse laws without any special protections. Moreover, gainsharing and pay-for-performance (P4P) programs, service line co-management arrangements, and similar programs all remain possible outside the SSP, although such programs must be carefully structured to fit within the current regulatory scheme, which was not designed with these innovative models in mind. Finally, Medicare's existing clinical integration demonstration and incentive programs, such as the Physician Quality Reporting System (PQRS) and Acute Care Episode (ACE) programs, may be extended, reopened, or expanded, and such developments may afford providers opportunities to develop their care management skills in a lower-cost, lower-risk environment than the SSP.[12]

[9] *See* PPACA, tit. III, § 3023, tit. X, § 10308(a) and (b)(1), 124 Stat. 399, 942, *codified at* 42 U.S.C. § 1395cc-4.

[10] *See* CIGNA Newsroom, *Accountable Care Organizations (ACOs)*, http://newsroom.cigna.com/KnowledgeCenter/ACO (last visited April 26, 2011).

[11] *See* CalPERS Press Room, *Integrated Health Care Pilot Exceeds Expectations* (April 12, 2011), http://www.calpers.ca.gov/index.jsp?bc=/about/press/pr-2011/april/integrated-health.xml (last visited April 26, 2011).

[12] For example, CMS paid more than $234 million in Physician Quality Reporting System bonuses in 2009, and $148 million to 48,354 physicians and other eligible professionals in 2009 under CMS's e-prescribing incentive program. *See* Centers for Medicare and Medicaid Services, Press Release, *CMS Data Show Gains In Key Quality Indicators Through Physician Quality Reporting System and ePrescribing Incentive Program* (April 19, 2011), *available at* http://www.cms.gov/apps/media/press_releases.asp (last visited April 26, 2011).

Conclusions

ACOs are the most recent development in the ongoing convergence of reimbursement and quality under the Medicare program. Despite being a "permanent" program, the SSP, as currently proposed, is clearly a transitional play by CMS. ACOs are one of several strategies CMS is employing that indicate a broader shift toward a risk-based reimbursement model under the Medicare program with an emphasis on care integration and quality performance measures. Other examples include incentive programs like the PGP, ACE, value-based purchasing, and national payment bundling demonstrations, and reimbursement penalties for hospital-acquired conditions (HACs) and so-called "never events."

The proposed rule will generate substantial comments (and probable outrage) from would-be ACO participants and their consultants and advisors. Given the political stakes associated with the success of the SSP, we anticipate that CMS may substantially revise the shape of the program in the final rule. We would advise providers to review the final rule to see whether CMS has mitigated the harsher aspects of the SSP in a way that makes participation more attractive.

Given the short ramp-up period for ACOs to meet the initial implementation date of Jan. 1, 2012, we believe that CMS may delay the full implementation of the SSP to allow time to rework the program's requirements. Even in the proposed rule, CMS indicated a possible "interim" start date of July 1, 2012. In this regard, providers may want to consider waiting six to 12 months from the commencement of the SSP before making a final decision about whether to take on the risk of becoming an ACO participant (ACOs can add or remove "ACO providers/suppliers" throughout the three-year agreement, but cannot add "ACO participants").

If the final rule on Medicare ACOs looks similar to the proposed rule, the universe of providers for whom participation under the SSP is attractive—or even feasible—may be relatively small. Accordingly, providers should view ACOs as one of a number of potential strategies available to help a provider drive its organization's clinical integration efforts. Whether and to what extent participating in an ACO makes sense will depend on a variety of market-specific factors. In the final analysis, many providers may determine that it is either too costly or too uncertain a proposition to participate in an ACO.

However, regardless of whether a provider participates in an ACO, the elements of the proposed SSP offer a window into the probable future shape of the Medicare program. For example, the proposed rule specifically mentions telehealth, remote patient monitoring, and electronic records as "modern technologies" that CMS expects ACOs to implement "to continually reinvent care in the modern age." CMS may well make many of the SSP quality reporting measures mandatory for all Medicare providers in the future, and may implement partial capitation and withholds for selected components of the Medicare FFS program that show particular promise under the SSP. Thus, even for those who decide not to participate in the SSP, finding opportunities to strengthen an organization's competencies in clinical integration, patient-centeredness, and care management should pay dividends as Medicare's payment model ultimately moves in a direction that demands such skills to succeed.