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Easing the Pathway to Accountable Care Organizations: Final Administration Policy



By Lara Cartwright-Smith, Jane Hyatt Thorpe, and Sara Rosenbaum

Introduction

On Oct. 20, 2011, the Departments of Health and Human Services (HHS) and Treasury, along with the Department of Justice (DOJ) and the Federal Trade Commission (FTC) jointly released a series of federal policies[1] implementing the Medicare Shared Savings Program,[2] the purpose of which is to improve health care quality and efficiency through formation of Accountable Care Organizations (ACOs). ACOs, which may exist in the private sector as well as under public insurance programs like Medicare, are networks of providers that share in financial rewards for realizing savings in health care spending while maintaining or improving quality of care.[3] This new organizational structure under Medicare is intended to play a central role in the long, but hopefully fruitful journey toward greater clinical and financial integration in U.S. health care, particularly if other public and private payers adopt parallel approaches.

This is not the first time that federal policy has formally pushed for clinical integration. The HMO Act of 1973 had similar aspirations, but it was aimed at recast-

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[1] Final Rule: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802 (Nov. 2, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf; Notice: Medicare Program; Advanced Payment Model, 76 Fed. Reg. 68012 (Nov. 2, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27458.pdf; Interim final rule with comment period: Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf; FTC/DOJ Statement of Antitrust Enforcement Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011), *available at* http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf; IRS Fact Sheet: Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations, FS-2011-11 (Oct. 20, 2011), *available at* http://www.irs.gov/pub/irs-news/fs-2011-11.pdf. The full set of coordinated regulations and policy statements, including proposed and final versions, is also available at http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp.

[2] ACOs are authorized at Section 1899 of the Social Security Act (the Act), as amended by Section 3022 of the Patient Protection and Affordable Care Act, Pub. L. 111-148 (2009), as amended by the Health Care and Education Affordability Reconciliation Act, Pub. L. 111-152 (2010).

[3] Robert A. Benson, Rachel A. Burton, Accountable Care Organizations in Medicare and the Private Sector: A Status Update, Timely Analysis of Immediate Health Policy Issues. *Robert Wood Johnson Foundation and Urban Institute* (Nov. 2011), *available at* http://www.rwjf.org/files/research/73470.5470.aco.report.pdf.

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ing the market for health insurance. ACO policy, on the other hand, is aimed at generating a health care system-driven, ''bottoms-up'' transformation of the way in which health care is delivered. Along with other system reform investments authorized under the Patient Protection and Affordable Care Act (ACA),[4] ACOs reflect a shared conclusion by policymakers – based on a virtual deluge of evidence[5] – that fragmentation in health care does not work in terms of cost, quality, or patient health outcomes.

What is so important about the final policies is not simply their responsiveness to more than 1,300 public comments submitted, but also the extent to which, in fashioning the final regulations and guidance materials, the Administration concluded that a wider road was better. In its final form, the federal ACO model has been made accessible to all communities, whether affluent and well-resourced or poor and medically underserved. It has been modified to foster the growth of not only sophisticated, large, and highly integrated entities, but also smaller undertakings that represent a modest but vital first step toward integration. Rather than seeking immediate payoffs, the federal government has assumed a more thoughtful and expansive investment role, even announcing an Advance Payment Model administered through the Center for Medicare and Medicaid Innovation.[6] Agencies whose regulatory and revenue policies potentially could have inhibited the growth of ACOs ultimately decided to adopt a more expansive approach while keeping a watchful eye on the results.

In short, the final ACO policies represent a collective decision to use the levers of national policy to ramp up a fundamental effort at health system change. Along the way the Administration made certain key concessions and compromises, particularly where specific policies related to ACO operations, such as adoption and meaningful use of health information technology are concerned. The final policies are extremely significant in their conclusion that moving to align all Medicare beneficiaries with more integrated health care delivery systems is a positive step, even for beneficiaries who do not choose to become members of Medicare Advantage plans. At the same time, the Centers for Medicare & Medicaid Services (CMS) finalized other requirements to ensure consumer protections and the comprehensive reporting of quality measures and other data to Medicare for research and oversight.

The final policies are an outgrowth of proposals released at the end of March 2011[7] that were widely criticized as too restrictive and sufficiently burdensome to limit widespread provider participation.[8] Indeed, not only did the American Medical Group Association warn that 93 percent of its members would not participate,[9] but even existing models of an integrated enterprise such as the Cleveland Clinic and Geisinger Health System, indicated that they would not take part in the program.[10] In their final form, the policies seek to reverse this reaction by relaxing previous standards and by adding to the armament of ACO formation inducements. These inducements include an interim final rule by CMS and the HHS Office of the Inspector General (OIG) that waives certain federal fraud and abuse laws for ACOs meeting program requirements,[11] a jointly issued policy statement from the DOJ and the FTC that takes a far more constrained approach to oversight and enforcement,[12] and Internal Revenue Service (IRS)

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[4] Patient Protection and Affordable Care Act, Pub. L. 111-148 (2009), as amended by the Health Care and Education Affordability Reconciliation Act, Pub. L. 111-152 (2010).

[5] *See, e.g.,* F. de Brantes, M. Rosenthal, M. Painter, ''A Bridge from Fragmentation to Accountability — The Prometheus Payment Model,'' NEW ENG. J. MED. 2009; 361:1033-1036 (Sept. 10, 2009); E. Fisher, D. Goodman, J. Skinner, K. Bronner, ''Health Care Spending, Quality and Outcomes: More Isn't Always Better,'' *Dartmouth Atlas Project Topics Brief* (Feb. 27, 2009); J. Wennberg, et al., ''Improving Quality and Curbing Health Care Spending: Opportunities for the Congress and the Obama Administration,'' *Dartmouth Atlas White Paper* (2008); E. Fisher, et al., ''The Implications of Regional Variations in Medicare Spending. Part 1: The Content, Quality, and Accessibility of Care,'' 138 ANNALS INTERN. MED. 273-87 (2003); E. Fisher, et al.; ''The Implications of Regional Variations in Medicare Spending. Part 2: Health Outcomes and Satisfaction with Care,'' 138 ANNALS INTERN. MED. 288-98 (2003). McGlynn, E., et al., ''The Quality of Health Care Delivered to Adults in the United States,'' 348 NEW ENG. J. MED. 2635-45 (2003); J. Wennberg, E. Fisher, J. Skinner, ''Geography and the Debate Over Medicare Reform,'' *Health Affairs Web Exclusive* (Feb. 13, 2002).

[6] *See* Center for Medicare and Medicaid Innovation, Pioneer Accountable Care Organization (ACO) Model Program, Frequently Asked Questions (May 17, 2011), *available at* http://innovations.cms.gov/documents/pdf/FAQ03-Pioneer-ACO-05-19-2011.pdf.

[7] The coordinated policy statements and proposed regulations were released March 31, 2011, although the documents were subsequently published in the *Federal Register* and other official records in April. Proposed Rule: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19528 (April 7, 2011), *available at* http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf; Medicare Program; Notice with comment period: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19665 (April 7, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7884.pdf; Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 21894 (April 19, 2011), *available at* http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf; Internal Revenue Service Notice 2001-20, 201116 I.R.B. 652 (April 18, 2011), *available at* http://www.irs.gov/pub/irs-drop/n-11-20.pdf.

[8] E.g., R. Klar, ''Overweight And Out Of Shape: ACO Regs Need A Major Makeover,'' *Health Affairs Blog* (Apr. 7, 2011). Available at: http://healthaffairs.org/blog/2011/04/07/overweight-and-out-of-shape-aco-regs-need-a-major-makeover/; M. Rosenthal, D. Cutler, J. Feder, ''The ACO Rules — Striking the Balance between Participation and Transformative Potential,'' NEW ENG. J. MED. (July 28, 2011). Available at: http://www.nejm.org/doi/full/10.1056/NEJMp1106012.

[9] Letter from the American Medical Group Association to Donald Berwick, CMS Administrator (May 11, 2011). Available at: http://www.amga.org/Advocacy/MGAC/Letters/05112011.pdf.

[10] These organizations declined to participate even in the alternative incentive program proposed for more sophisticated ACOs. J. Gold, 'Poster Boys' Take a Pass on Pioneer ACO Program, *Kaiser Health News* (Sept. 14, 2011). Available at: http://www.kaiserhealthnews.org/Stories/2011/September/14/ACO-Pioneers-Medicare-hospitals.aspx.

[11] Interim final rule with comment period: Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf.

[12] FTC/DOJ Statement of Antitrust Enforcement Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011),

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policies aimed at easing concerns among ACOs comprised of nonprofit organizations.[13]

The remainder of this article reviews the most significant changes made in the final regulation and regulatory policy statements and assesses the extent to which these policies might advance national goals of greater integration and reforms in health care delivery.

The Final CMS Medicare Shared Savings Program Rule

Expanded Reach of the ACO Model

In a significant change, the final rule has been revised to classify federally qualified health centers (FQHCs) and rural health clinics (RHCs) as eligible to form ACOs.[14] The final rule also recognizes Medicare patients served by FQHCs and RHCs as assignable to ACOs, using a unique assignment methodology that builds on Medicare's special FQHC and RHC bundled payment structure and that permits patient assignment based on attestation of ''attending''[15] status by FQHC and RHC physicians in recognition of the team-based care common in these clinical settings.

Altering the ACO participation rules effectively encourages the expansion of ACOs into medically underserved rural and urban communities. FQHCs and RHCs together served approximately 3 million Medicare beneficiaries in 2010.[16] In making this change, the final rule may help encourage Medicaid agencies to adopt parallel ACO policies generally and for their dual eligibles in particular, since these populations disproportionately tend to reside in medically underserved communities. The population of dual eligibles, while relatively small in number at 9 million persons, tends to experience higher rates of poor health, multiple chronic conditions, and functional and cognitive impairments, while representing almost 36 and 39 percent of Medicare and Medicaid spending, respectively.[17] Thus, there is great potential for both cost savings and quality improvement through ACOs that serve dual eligibles.

New Prospective Process for Assignment of Beneficiaries

In a major policy shift, the final rule moves from a retrospective patient assignment methodology to a ''preliminary'' assignment process[18] in which beneficiaries will be assigned at the beginning of a performance year. CMS will update the assignments quarterly and will determine final assignments after the end of each performance year based on full-year data.[19] According to CMS, this change was the result of ''overwhelming'' comments[20] in support of prospective assignment as a means of assuring patient choice and promoting better quality management overall. To assign beneficiaries, CMS will look at utilization of primary care services furnished by a physician. In the Preamble to the final rule, CMS noted that evidence indicates the vast majority of patients seen by an ACO primary care physician will have their care correctly attributed to the ACO.[21]

In assigning patients, the final rule replaces the proposed ambiguous ''plurality'' test with one that determines whether the ''allowed charges for primary care services furnished to the beneficiary by all the primary care physicians who are ACO providers/suppliers in the ACO'' simply are ''greater than'' the ''allowed charges for primary care services furnished by primary care physicians who are ACO providers/suppliers in any other ACO'' and ''not affiliated with an ACO and identified by a Medicare-enrolled TIN [taxpayer identification number].''[22] In addition, the final rule creates the special assignment methodology for FQHCs and RHCs noted above. Importantly, the final rule allows FQHC/RHC physicians practice settings to attest to their direct care of assigned patients based on their status as ''attending'' physicians. With this final standard, the rule recognizes the greater use of practice teams in medically underserved settings and physicians' status as part of teams rather than sole providers of care.

Easing the Governance, Structural, and Operational Requirements

The final rule relaxes the shared governance provisions of the proposed rule. In the NPRM, CMS proposed to require the involvement of all participants in governance, with 75 percent control of the governing body to be held by participants and the inclusion of at least one non-conflicted Medicare beneficiary. The final rule eliminates the requirement for a governance role for all participants as long as they have ''meaningful participation'' opportunities. The final rule also allows the governance structure to deviate on the 75 percent participant control standard in order to allow for ''greater flexibility.''[23]

Where ACO structure is concerned, CMS eliminated the proposed requirement that ACOs have a physician-directed quality assurance and process improvement committee. This change – a move that broadens options for structuring quality assurance activities – was made in response to comments that such efforts are often led by non-physicians. The final rule simply requires that ACOs have a quality assurance and improvement program led by a qualified health care professional.[24]

In general, the structural requirements move away from the highly detailed approach taken in the NPRM and toward a more generalized approach that allows entities to demonstrate how their structure and operations achieve the ''required processes and patient-

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available at http://www.ftc.gov/os/fedreg/2011/10/111020aco.pdf.

[13] IRS Fact Sheet: Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations, FS-2011-11 (Oct. 20, 2011), *available at* http://www.irs.gov/pub/irs-news/fs-2011-11.pdf.

[14] 42 C.F.R. § 425.102(a)(6) and (7).

[15] 42 C.F.R. § 425.404(b).

[16] Based on 2010 UDS (HRSA) and CMS data.

[17] G. Jacobson, T. Neuman, A. Damico, B. Lyons, ''The Role of Medicare for the People Dually Eligible for Medicare and Medicaid,'' Kaiser Family Foundation (2011), *available at* http://www.kff.org/medicare/upload/8138.pdf.

[18] 42 C.F.R. § 425.400(a)(2).

[19] 42 C.F.R. § 425.402(a)(1)(i).

[20] 76 Fed. Reg. 67862.

[21] *Id.*

[22] 42 C.F.R. § 425.402(a)(1)(ii)(B).

[23] 76 Fed. Reg. 67821.

[24] 42 C.F.R. § 425.112 (a)(2). The final rule continues to require that clinical management and oversight be managed by a ''senior level medical director who is a physician . . . who is physically present on a regular basis at any clinic, office, or other location participating in the ACO and who is a board certified physician and licensed in a state in which the ACO operates.'' 42 C.F.R. § 425.108(c).

centeredness criteria'' applicable to ACOs.[25] The final rule eases the quality improvement and EHR technology requirements. For example, the NPRM required that a ''physician-directed quality assurance and process improvement committee'' oversee an ''action-oriented'' program, a program of evidence-based medical practice meeting the triple aim test, and participant agreement to perform according to these standards with active oversight. The NPRM also required an ACO to maintain an information infrastructure that would collect and evaluate data and provide feedback.[26] The final rule, by contrast, simplifies these requirements, specifying that ACOs have ''care processes'' ''evidence-based medicine,'' beneficiary engagement (undefined), a focus on patient centeredness, and ''defined processes'' to fulfill these requirements.[27] In other words, the final rule is less prescriptive, sketching the broad outlines of operational accountability for quality and efficiency rather than providing a detailed picture by rule. In moving away from detailed requirements related to patient-centeredness, the final rule may hold implications for the level of consumer leadership in ACO governance and operation.

This less particularized and detailed approach to describing the rigor of the ACO model of clinical and practice integration and accountability is especially notable given the fact that the ACO's structural and operational attributes – with its emphasis on accountability for clinical quality, patient-centeredness, evidence-based care, adherence to practice standards, participant governance, a high level of human and financial investment in the ACO, and the potential for expulsion if quality is poor – are the justification for the innovative approach taken by DOJ/FTC in their antitrust enforcement policies (discussed below). With the easing of the ACO model in terms of the rigor demanded of participants, the potential for somewhat relaxed antitrust enforcement policies to further boost ACO market growth becomes clearer.

At the same time, CMS maintains the essential ACO structure while requiring community accountability. The final rule maintains a population health needs assessment requirement, an important basis of interaction with community public health experts. In conducting this assessment, CMS expects that ACOs will consider diversity and will develop plans to address identified health needs.[28] The final rule also requires that ACOs ''coordinate care across and among primary care physicians, specialists, post-acute providers and suppliers'' as well as demonstrate a method to ''coordinate care through an episode of care and during its transition, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO).''[29]

The final rule also relaxes the NPRM's marketing standards, taking a ''file and use'' approach to the clearance of materials rather than the NPRM's pre-clearance approach.[30] In shifting to this new strategy, however, the agency has retained the right to disapprove materials at any time, including after the five-day period.

CMS slightly modifies the NPRM's approach to disclosure and information, adding a ''plain language'' requirement for all written notices and notification of ACO termination. The final rule also adds information and disclosure requirements related to preliminary prospective assignment.

Fewer Quality Measures

ACOs are eligible for shared savings only if they satisfy quality performance requirements, based on certain quality measures selected by CMS. The proposed rule had included 65 measures in five domains of quality. The final rule drops this number to 33 measures across four domains, collapsing two domains (care coordination and patient safety) into one while preserving the remaining three domains of patient/caregiver experience, preventive health, and at-risk population. CMS indicated in the Preamble that it deemed the 32 measures eliminated in the final rule complex, burdensome, or redundant.[31] For example, a proposed measure of oral antiplatelet therapy for patients with cardiovascular disease was not finalized, according to the agency, because it concluded that other retained measures were adequate, specifically the aspirin use component of the diabetes composite measure and the use of aspirin or other antithrombotic measure for ischemic vascular disease. CMS reported that it decided not to finalize a care transitions measure because ACOs that did not include hospitals would have too difficult a time satisfying the measure.[32] CMS declined to finalize the health care acquired conditions composite measure for similar reasons, noting the importance of medical errors measurement but suggesting that not all ACOs have hospitals and for those that do, the proposed measure would be duplicative of hospital value-based purchasing programs.[33] In some cases, CMS removed individual measures in favor of a single composite measure, for example, finalizing composite measures for diabetes and coronary artery disease but eliminating individual measures that had been components of the composite measures.[34]

The final rule preserves the overall approach of the NPRM, measuring ACO performance in relation to a performance benchmark based on Medicare fee-for-service rates, national Medicare Advantage quality measure rates, or a national flat percentage and setting a minimum attainment level (30 percent or the 30th percentile of the performance benchmark). Under final policy, ACOs will receive no points for a measure for which performance is below the minimum attainment level and maximum points for performance at or above 90 percent or the 90th percentile of the benchmark. ACOs that fail to achieve the minimum attainment level on at least 70 percent of the measures are subject to termination. The rule as finalized indicates that an ACO's points will be combined to arrive at an overall performance score and sharing rate.

As with the structure, governance and operations rule, performance measurement and performance requirements are further eased. In addition to reducing the number of reportable measures, the final rule lengthens from two to three years the time period for

[25] 42 C.F.R. § 425.112.
[26] Proposed 42 C.F.R. § 425.5(d)(9).
[27] 42 C.F.R. § 425.112.
[28] 42 C.F.R. § 425.112(b)(2)(iii).
[29] 42 C.F.R. § 425.112(b)(4).
[30] 76 Fed. Reg. 67947.
[31] 76 Fed. Reg. 67871.
[32] 76 Fed. Reg. 67887.
[33] 76 Fed. Reg. 67879-80.
[34] 76 Fed. Reg. 67882.

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transitioning from pay-for-reporting to pay-for-performance.[35] The final rule also relaxes the performance standard for ACOs to qualify for the Physician Quality Reporting System (PQRS) on behalf of their eligible professionals.[36]

This relaxing of the performance model carries over into the use of electronic health records (EHRs). The NPRM barred ACO participation in the Shared Savings Program for a second year unless it could achieve a 50 percent meaningful use rate among its primary care providers under the HITECH EHR incentive program. ACOs also would have been required to participate in the EHR Incentive Program in order to be eligible for PQRS. While this policy was intended to ease burdens by aligning Shared Savings Program and EHR Incentive Program policies, the final rule eliminates this alignment policy and simply encourages ACOs to develop a robust EHR infrastructure, affording extra weight to primary care performance measures in the case of ACO primary care providers who successfully qualify for an EHR Incentive.

More Attractive Incentives

The final rule gives ACOs a choice of two tracks during their initial three-year agreement period, eliminating the risk of loss from Track 1 and instead instituting a bonus system. As in the proposed rule, ACOs will have to share risk of loss after this initial participation period[37] but will not face the prospect of initial downside risk. In addition, in a change of policy from the proposed rule, the final rule allows ACOs experiencing a net loss to continue in the program if they can provide an explanation of the cause of the net loss and identify safeguards to prevent losses in the second agreement period.

In general, the final rule establishes more favorable payment procedures. As proposed, payments will be calculated using benchmarks that are based on the ACO's historical per capita expenditures over the previous three years, resetting for each new three-year agreement period. Under this arrangement, ACOs will be eligible for shared savings if their average per capita expenditures for a performance year fall below the benchmark by at least the minimum savings rate.[38] Commenters had expressed concern that basing the benchmark on an ACO's historical per capita expenditures would discourage already high-performing, efficient organizations from participating because additional savings will be harder to realize. CMS acknowledged these concerns but noted that the benchmark procedure is dictated by the specific terms of the ACA itself.[39]

CMS increased the share of savings that ACOs can receive, rising from 7.5 percent to 10 percent under Track 1 and from 10 percent to 15 percent in Track 2. Simultaneously the final rule reduces the maximum shared loss to 60 percent from 100 percent. The final rule also applies the sharing rate to the total amount of savings realized on a first-dollar basis. Finally, CMS extended the time for payment of shared losses from 30 days to 90 days after notification of losses. The agency also eliminated the requirement to withhold a flat 25 percent of shared savings to offset potential losses, which commenters had complained would tie up capital and penalize ACOs that realize early savings.

Option for Advance Payment

Along with the final rule, CMS announced the testing of the Advance Payment Model through the Center for Medicare and Medicaid Innovation (Innovation Center), which is targeted at organizations such as rural and physician-led ACOs (FQHC-led ACOs may also be able to qualify) that require capital to make the investments necessary for coordinating care. In order to qualify the ACOs must not include any inpatient facilities and must have less than $50 million in total annual revenue (an exception is made for ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals and that have less than $80 million in total annual revenue).

ACOs in the initiative, administered by the Innovation Center, will be eligible to receive three types of payments: (1) an upfront, fixed payment; (2) an upfront, variable payment; and (3) a monthly variable payment depending on the number of Medicare beneficiaries historically attributed to the ACO. Recoupment is possible, but exemptions are made for ACOs that complete the agreement period but realize no shared savings.[40] The Innovation Center will test whether advance payments will increase the amount and speed of Medicare savings generated by ACOs in the program and whether and how pre-payment can increase participation in the shared savings program.

Expanded Data Sharing

The final rule contains an important shift in federal policy regarding the sharing of individually identifiable Medicare claims data for quality improvement and system operations purposes. Consistent with the major shift to prospective preliminary assignment, CMS will share identifiable Medicare claims data for preliminarily assigned (not historically) beneficiaries in addition to aggregate reports.[41] Claims data will include name, date of birth, health insurance claim number (HICN), and sex. ACOs also will be able to secure beneficiary-identifiable claims data for preliminary assigned beneficiaries assuming full HIPAA compliance and the establishment of data use agreements. Use of identifiable claims data is limited to the types of activities that fall well within the HIPAA health care operations exemption, including ''developing care processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries with primary care services at the ACO.'' The final rule will make identifiable claims data available only for beneficiaries whose names either appear on the prospective assignment list or have received primary care from the ACO, and only if a beneficiary has been notified of the ACOs' intent to use identifiable claims data to improve

[35] 76 Fed. Reg. 67875.
[36] 76 Fed. Reg. 67900.
[37] 76 Fed. Reg. 67909.
[38] 42 C.F.R. § 425.604(a).
[39] 76 Fed. Reg. 67913.

[40] CMS Fact Sheet: Advance Payment Accountable Care Organization (ACO) Model, p. 3. Available at http://www.innovations.cms.gov/documents/payment-care/AdvancePaymentsFactSheet_10_20_2011.pdf.

[41] Compare proposed § 425.19(c) relating to historically assigned beneficiaries to final § 425.702(c) related to preliminarily assigned beneficiaries.

the quality of care and has not affirmatively declined to allow data sharing (*i.e.*, opted out of data sharing).[42]

With this new data release rule, CMS signals a major transition from previous agency positions on data sharing.

With this new data release rule, CMS signals a major transition from previous agency positions on data sharing. Historically, CMS has interpreted Section 1106 of the Social Security Act to bar the agency from releasing what would be classified as protected health information under HIPAA in the absence of express legal authorization. As such, the agency generally has only released individually identifiable data for expressly authorized purposes related to payment, research, and quality improvement. Furthermore, it has released this data only to contractors, researchers who meet specific requirements, and statutorily authorized quality improvement organizations for these purposes. The final rule indicates the agency's willingness to rely on the ''permissive'' nature of HIPAA to release Part A and B claims data to ACOs for health care operations purposes.[43] This interpretation of HIPAA as serving as the legal basis for the release of Parts A and B claims data is a major development because it recognizes the extent to which HIPAA represents a fundamental shift in health information law to encourage greater use of data for health care operational improvements.

Antitrust Enforcement Policy

In keeping with the effort to open the door more broadly to ACO formation, the final DOJ/FTC Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program eliminates the Agencies' proposed requirement for mandatory antitrust review for certain types of ACOs as a condition of entry into the Shared Savings Program. Furthermore, whereas the proposed policy applied only to ACOs formed after March 23, 2010, the final policy applies to ACOs formed at any time.

In announcing this shift, the Agencies took care to underscore their intentions to vigilantly monitor the health care market for evidence of anticompetitive conduct. But at the same time, the Agencies make clear that, consistent with a rule of reason test, they will rely on CMS oversight to measure and understand the resulting market benefits in the areas of quality and efficiency that flow from ACO formation:

> To assess whether an ACO has improved quality and reduced costs to Medicare, CMS will collect and evaluate cost, utilization, and quality metrics relating to each ACO's performance in the Shared Savings Program. The results of this monitoring will help the Agencies determine whether the CMS eligibility criteria have required a sufficient level of clinical integration to produce cost savings and quality improvements and may help inform the Agencies' future analyses of ACOs and other provider organizations.[44]

What is remarkable about this shift away from mandatory pre-reviews for dominant ACOs (voluntary expedited review procedures are maintained) is that this change in policy is coupled with CMS' decisive move away from a highly prescriptive set of requirements for ACOs and toward a position that takes a more relaxed and evolutionary approach to the ACO model. Under the CMS final rule, the bar for ACO formation and operation effectively has been lowered. Even in the face of this lowered bar, the antitrust Agencies have elected to use their considerable discretion to fundamentally and decisively favor, as a matter of national policy, greater collective action on the part of health care providers, even if the results of the decision ultimately create post-formation problems in certain markets.

Additional Waivers of Fraud and Abuse Laws – Interim Final Rule with Comment (IFC)

In addition to the relaxation of antitrust enforcement policy, CMS and the HHS Office of the Inspector General (OIG) also significantly relaxed the requirements of several fraud and abuse laws that govern financial relationships and other beneficial referral arrangements between and among providers, such as the sharing of savings contemplated by the ACO model. These laws are the Physician Self-Referral Law,[45] the federal anti-kickback statute,[46] the Gainsharing Civil Money Penalty (CMP) law,[47] and the Beneficiary Inducements CMP,[48] which impose restrictions on arrangements between physicians, hospitals, beneficiaries and other entities, including remuneration for referrals, self-benefitting financial interests in health care organizations to which a physician refers, remuneration for limiting services to Medicare beneficiaries, and remuneration for influencing a beneficiary's healthcare decision-making. All of these laws are implicated by the Shared Savings Program and in the past have limited the development and implementation of programs that linked the financial interests of hospitals, physicians and other providers. As such, the ACA authorized CMS and OIG to waive specific requirements that previously prevented physician-hospital financial collaboration as well as the provision of financial incentives to beneficiaries.

In the original waiver design notice[49] released in March 2011, CMS and OIG proposed several waivers and solicited comments on what other possible waivers would be necessary to carry out the provisions of the Shared Savings Program, the duration of such waivers, and the scope of the waivers. The waivers proposed ad-

[42] 42 C.F.R. § 425.708. Beneficiaries also must be given forms allowing them to decline data sharing as part of their ''first primary care service visit with an ACO participant on whom assignment is based during the assignment period.''

[43] As the agency does not constitute a HIPAA-covered entity for purposes of Part D – the Prescription Drug Benefit program – the agency is relying on its authority under the Part D data rule released in May 2008.

[44] Joint Statement, p. 5.

[45] Social Security Act (SSA) § 1877 (42 U.S.C. 1395nn).

[46] SSA § 1128B (42 U.S.C. 1320a-7b).

[47] SSA § 1128A(b)(1) and (2).

[48] SSA § 1128A(a)(5).

[49] Notice with comment period: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19665 (April 7, 2011), available at http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7884.pdf.

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dressed specific provisions of the Physician Self-Referral Law, federal anti-kickback statute, and Gainsharing CMP to allow shared savings distributions.

The interim final rule greatly expands upon these waivers to include activities beyond the distribution of shared savings. The new waivers include the ACO Pre-Participation Waiver (a one-time-only waiver of certain provisions of the Physician Self-Referral Law,[50] the Gainsharing CMP,[51] and the federal anti-kickback statute[52] only available to start-up arrangements that predate an ACO's participation agreement) and the ACO Participation Waiver (a waiver of the same laws but available to ACOs for six months from the date of start-up). The Waiver for Patient Incentives waives provisions of the Beneficiary Inducement CMP, in addition to the federal anti-kickback statute as had been proposed in the Notice, with respect to items or services provided by an ACO, its participants, or its providers/suppliers to beneficiaries for free or below fair-market-price for in-kind items or services reasonably related to a beneficiary's medical care that are for preventive care or advance adherence to a treatment or drug regimen, adherence to a follow-up care plan, or management of chronic disease or condition.

The two waivers in the IFC that had also been proposed in the Notice are the Shared Savings Distribution Waiver (which waives certain provisions of the Physician Self-Referral Law, the Gainsharing CMP, and the federal anti-kickback statute with respect to distributions or use of shared savings earned by an ACO pursuant to the Shared Savings Program during the term of participation) and the Compliance with the Physician Self-Referral Law Waiver (which waives certain provisions of the Gainsharing CMP and the federal anti-kickback statute with respect to any financial relationship among or between the ACO, its participants, and its providers/suppliers that implicates the Physician Self-Referral Law, if the financial relationship is reasonably related to the purposes of the Shared Savings Program and complies with an exception to the referral prohibition).

Together, these waivers represent a significant movement away from restrictive standards perceived as impairing the type of incentivized collective action that lies at the heart of the ACO vision of collaborations across independent entities united in a common health care enterprise. As with the ACO rule and the Statement of Antitrust Enforcement, the Interim Final Rule on fraud and abuse is designed to allow leeway in the case of ACO undertakings that would be impermissible in the case of collaborations that lack the formal relationships envisioned by the rule.

Tax Policy

The IRS released a fact sheet offering guidance for tax-exempt organizations considering participating in an ACO, clarifying how the agency will analyze the structure and activities of such organizations for purposes of establishing or maintaining tax-exempt status.[53] An ACO may be structured as either a corporation or a partnership for federal tax purposes, and the organization may be either taxable or tax-exempt under federal regulations.[54] Not surprisingly, the IRS follows the other Agencies in taking a relaxed approach, explaining that the agency will use the broadest ''facts and circumstances'' test to evaluate the revenues derived from ACO participation by nonprofit tax exempt organizations. The fact sheet also clarifies that participation in an ACO furthers a tax exempt organization's charitable purpose ''of lessening the burdens of government'' within the meaning of the 501(c)(3) regulation, thereby opening the door to tax-exempt status by virtue of the organization's participation in the Shared Savings Program, if it meets all other requirements.[55]

Conclusion

Although the CMS rule defines an ACO simply as a legal health care entity that possesses certain characteristics in structure, governance, and operations, the model aspires to a far greater goal: bringing organizational presence and meaning to disparate players in the health care industry in order to promote quality and efficiency.

Together, the policies released on Oct. 20, represent a major effort on the part of the Administration to stimulate a major breakthrough in how care is organized, delivered and assessed, using its enormous Medicare policymaking powers to create change. This use of Medicare to achieve transformation in health care delivery is of course a common theme in U.S. health policy; what makes this latest episode remarkable is the breadth of the change, the degree to which the major agencies involved in health care regulation acted in concert, and the degree to which the pathways they open position the health care system for deeper cross-payer reform.

The final ACO policy can be understood as a response to Congressional desire, as reflected in the ACA, to increase collaborations in health care among different types of providers, and to do so throughout the country and across payment systems. Thus, the final rule paves the way for transformation in all communities, even those that are medically underserved and that lack the resources found in communities with great health care advantage. The final regulations also relax the more rigid ACO scaffolding envisioned in the proposed rules, excising the details of what the collaborations must look like while holding on to the broad themes of the proposed rules in the areas of quality and efficiency improvement, performance measurement, incorporation and active use of HIT, patient-centeredness, and active engagement by ACO participants. The final policies also sweeten the pot for entities that come together by increasing financial incentives, creating an initial capitalization strategy, eliminating the need for pre-clearance review in the case of large enterprises with market dominance, and allowing favorable financial arrangements that would be barred if undertaken outside the ACO structure. In the end, the Administration, responding to both the breakthrough nature of the ACO concept and the overwhelming sentiment of commenters, has chosen to use its regulatory powers to incentivize change rather than (as was the

[50] SSA § 1877(a).
[51] SSA § 1128A(b)(1) and (2).
[52] SSA § 1128B(b)(1) and (2).
[53] IRS Fact Sheet: Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations, FS-2011-11 (Oct. 20, 2011), *available at* http://www.irs.gov/pub/irs-news/fs-2011-11.pdf.
[54] 26 C.F.R. § 1.501(c)(3)-1(d)(2).
[55] Fact Sheet, *supra* note 62, at Q9.

case in the proposed rules) limit the reach of the legislation to a handful of communities with highly sophisticated pre-existing entities. No doubt the less than warm embrace of the proposed policies by the very entities that, in theory, fit the ACO mold helped reinforce the Administration's decision to expand its reach.

Important aspects of this policy merit close evaluation in the coming years, particularly because the initial rigorous model has been replaced by one that allows greater formation while perhaps sacrificing the comprehensive strategy, with high attention to quality, participant engagement, active governance, and the advancement of EHR transformation envisioned in the proposed rule. Put another way, an important issue for long-term evaluation is the impact of the deliberate tradeoff between high value purchasing standards and a ''go-slower'' strategy whose purpose is to make the model as attractive as possible to a medical community that may in many cases be at the initial stages of engagement in value based purchasing.

One question that arises is whether the final combination of incentives will be enough to stimulate a broad market response, particularly among providers that have had relatively limited experience with collective practice. Will the new policies induce a response by health care professionals and organizations without a deep history of collaboration, and if so, which aspects of the new policy will prove to be the most important?

A **second question** is whether other payers will begin to align with Medicare policy. Will Medicaid agencies recognize and begin to incentivize ACO formation and operations, and if so, for which beneficiaries? How will Medicaid ACO changes dovetail with Medicaid managed care arrangements which today account for 70 percent of all beneficiaries served by the program? Will insurers continue to build on their own ACO policies and attempt to dovetail with Medicare standards?

A **third question** is how state Medicaid programs will react. The final rules make clear that the federal government will not displace state regulatory policies that do not directly conflict with federal law. Will states begin to build an ACO regulatory framework of their own, and if so, what will this framework look like?

A **fourth question** is whether ACOs will grow in medically underserved communities. Will safety net providers join with other health care professionals and institutions in their communities, or will there be growth of separate ''safety net'' ACOs? Both models are possible under the final policies and responses may vary depending on the concentration of medically underserved residents within geographic market areas.

A **fifth question** is how Medicare beneficiaries will react to ACOs. Will many choose to receive care from providers that elect not to participate? In many communities the practical problems associated with finding a primary care physician may prevent this result. One sign of beneficiary unhappiness may be frequent decisions to opt out of data sharing. Past demonstrations, however, suggest that beneficiaries may in fact embrace the ACO model as an initiative designed to make their health care better.

Finally, how will the Agencies, especially CMS, measure ACO readiness for certification and monitor ongoing ACO performance? Are the agency's resources really sufficient to assure the level of careful attention to quality improvement and performance efficiency that the ACO model promises? And more importantly, will the strength of CMS monitoring be sufficient to satisfy the level of scrutiny expected by other federal agencies charged with enforcement of antitrust, tax, and fraud and abuse laws and necessary to justify the potential anticompetitive consequences of the concentration of market power in large multi-provider collaborations? Perhaps the ultimate test of this question will be the cost of health insurance in communities with and without active ACO participation in the coming years.

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