Accountable Care Organization
Member Briefing

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Introduction

When the Patient Protection and Affordable Care Act (PPACA), as amended, was signed into law on March 23, 2010, few of its provisions caused more excitement, debate, and speculation than Section 3022.[1] Under Section 3022, the Centers for Medicare & Medicaid Services (CMS) had fewer than twenty-one months to develop the "shared savings program"—a program that arguably has the potential to transform the very essence of the healthcare delivery system in the United States. At its core, the stated goal of the Medicare Shared Savings Program (MSSP) is to reward value (not volume) by providing better care for individuals, better health for populations, and slower growth in costs through improvements in care.[2]

Section 3022 of PPACA required the creation of the MSSP, which allows qualified groups of providers and suppliers to work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an Accountable Care Organization (ACO). ACOs that meet quality performance standards established by the Secretary of the U.S. Department of Health and Human Services (HHS) will be eligible to receive a portion of any shared savings.

Having received over 1,300 comments in response to the proposed rule (Proposed Rule), on October 20, 2011, CMS released the final rule (Final Rule) establishing ACOs under the MSSP. The first MSSP ACOs will "go live" on April 1, 2012. Before that can happen, a substantial amount of hard work, legal analysis, and capital contribution are required to develop and establish workable and successful ACOs. To assist in this process, the American Health Lawyers Association (AHLA) formed the ACO Task Force to help monitor developments in

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[1] Pub. L. No. 111-148, 124 Stat. 119, § 3022.

[2] *See* Donald M. Berwick, *Launching Accountable Care Organizations—The Proposed Rule for the Medicare Shared Savings Program*, N. ENG. J. MED. 364:E32 (Apr. 21, 2011) ("[the purpose of the ACO] is to foster change in patient care so as to accelerate progress toward a three-part aim: better care for individuals, better health for populations, and slower growth in costs through improvements in care.").

the ACO space and to keep AHLA members up-to-date on the legal issues and challenges associated with establishing and developing ACOs. As part of this effort, the AHLA ACO Task Force and its instrumental subcommittees worked tirelessly to put together this comprehensive ACO resource for all members to utilize. This Member Briefing examines the provisions of the Final Rule to assist with this process.

We have identified and analyzed ten key topic areas under that Final Rule that are critical in the development of a workable ACO under the MSSP. The ten key topic areas are: (1) Organization and Governance of ACOs; (2) Required Processes and Patient-Centered Criteria; (3) ACO Contracting; (4) Federal Regulatory Issues; (5) Antitrust; (6) Tax; (7) Monitoring and Termination; (8) Payment Mechanisms; (9) Performance Measures, Quality, and Accountability; and (10) Health Information Technology. Each of these ten topic areas explores and highlights the relevant preamble discussion and regulations that will have a practical impact on ACOs.

On behalf of the AHLA Task Force and its subcommittees, we hope that you will find this Member Briefing a helpful resource in analyzing issues associated with establishing and developing ACOs under the MSSP. Thank you again to everyone who played a part in putting this resource together.

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We want to sincerely thank the contributors below for their efforts in the production of this Member Briefing. This project would not have been possible without the support and dedication of each any every person who assisted in various ways at the many stages of production.

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Background

Section 3022 of the PPACA instructed the Secretary to establish the MSSP "to encourage the development of ACOs in Medicare."[1] The MSSP is one of the value-based purchasing (VBP) initiatives aimed at linking Medicare reimbursement directly to the quality of care provided to patients.[2] To implement the MSSP, CMS issued an initial Request for Information (RFI) on November 17, 2010.

Based on comments to the RFI, CMS published an MSSP Proposed Rule on April 7, 2011.[3] The Proposed Rule summarized the comments to the RFI and presented CMS' initial policy choices for implementation of the MSSP. Based on the proposed policy, CMS also sought further comments from key stakeholders for development of a final rule. During the comment period, CMS received approximately 1,320 comments.[4]

On November 2, 2011, CMS published its Final Rule that made a number of modifications to the Proposed Rule. These modifications include:

- Greater flexibility in the MSSP;
- Multiple start dates for ACOs interested in joining the MSSP in 2012;
- Establishment of a longer agreement period for ACOs joining in 2012;
- Greater flexibility in the governance and legal structure of an ACO;
- Simpler and more streamlined quality performance standards;
- Adjustments to the financial model to increase the financial incentives to participants;
- Increased shared savings caps;
- No-downside risk and first dollar sharing for some participants;

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[1] 76 Fed. Reg. 67803 (Nov. 2, 2011).
[2] *Id*.
[3] 76 Fed. Reg. 19528 (Apr. 7, 2011).
[4] 76 Fed. Reg. 67804.

- Removal of the initially proposed 25% shared savings withholds;
- Greater flexibility in timing for the evaluation of shared savings;
- Greater flexibility in antitrust review;
- Greater flexibility in timing for repayment of losses; and
- Additional options for participation by federally qualified health centers (FQHC) and rural health clinics.[5]

According to CMS, these modifications significantly reduce the burden and cost of participating in ACOs.[6]

Examples of ACO-like Organizations

The Final Rule for the MSSP seeks to transform the current volume-based, fragmented health delivery system by rewarding coordinated, integrated care and the utilization of health information technology. Integrated delivery systems—organizations that combine hospitals, specialists, primary care physicians, and in some cases health plans—are viewed by many as the ideal model for ACOs. Such systems are equipped with the resources to coordinate the continuum of care and to assume financial responsibility for patient costs.

Furthermore, several large integrated delivery systems, such as the Cleveland Clinic, Geisinger Health System, Intermountain Health Care, and the Mayo Clinic, are routinely cited as national models of the quality, efficiency, and coordination and management of care needed to succeed as an ACO. However, merely assembling a group of primary care physicians, specialists, and hospitals in an integrated corporate structure is neither a necessary nor a sufficient condition for achieving success as an ACO under the MSSP. Rather, the Final Rule makes clear that it is clinical integration, and not

[5] *Id*.
[6] *Id*.

corporate integration, that achieves the efficient, effective delivery of care and costs savings.

PGP Demonstration

Under Section 412 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, CMS implemented the Physician Group Practice (PGP) Demonstration in April 2005. The PGP Demonstration served as the blueprint for the MSSP and was CMS' initial attempt at developing a model to share savings with providers. The PGP Demonstration offered performance payments to ten leading health systems[7] that met performance targets for process and outcome quality measures as well as cost savings.

In 2010, the final year of the PGP Demonstration, seven of the ten systems achieved benchmark performance on all thirty-two performance measures, and the remaining three systems achieved benchmark performance on at least thirty of the thirty-two performance measures. Even though all ten systems achieved benchmark performance in 2010, only four systems achieved cost savings to merit a shared savings bonus. Furthermore, only two systems decreased annual Medicare spending enough to qualify for performance payments in all five years of the project, and three systems failed to qualify for a single bonus. Over the five years of the project, CMS paid $110 million in performance payments to the seven systems.[8]

Many health providers have expressed concern over the results of the PGP Demonstration. Although the specifics between the PGP Demonstration and the Final Rule differ, the fundamentals are the same—shared savings for providers that achieve performance targets for process and outcome quality measures. The concern over the inability of systems to achieve performance payments in the PGP Demonstration is

[7] *Id.*
[8] *Id.*

underscored by the fact that participating systems invested $1.7 million,[9] on average, in the first year of the PGP Demonstration and were not penalized for overspending on patient care.

Former CMS Administrator Gail Wilensky has said that the PGP Demonstration results suggest that it may be premature to implement the MSSP. She asks, "If it was this tough for this group that I had just assumed would be hands-down winners, what does it say for groups that don't have a long history of coming together?"[10] CMS Administrator Donald Berwick remains optimistic about the Final Rule and ACOs despite the fact that the savings from the PGP Demonstration "were unevenly distributed" and "modest."[11]

ACO Workshop

On October 5, 2010, the Federal Trade Commission (FTC), CMS, and the HHS Office of Inspector General (OIG) hosted a public workshop to address potential legal issues raised by ACOs. The workshop featured a series of panel discussions and a listening session for attendees to voice their comments and concerns related to ACOs and the MSSP. Unsurprisingly, representatives from provider and payor organizations requested guidance from the government regarding whether ACOs would be protected from the Stark physician self-referral law, the federal Anti-Kickback Statute (AKS), civil monetary penalties (CMPs) law, and federal antitrust law. Although government officials did not issue definitive guidance during the workshop, they did acknowledge the need to address expedited review of ACO arrangements for antitrust compliance and new anti-kickback safe harbors and Stark law exceptions. Transcripts and audio recording are available at the FTC website.[12]

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[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *See* www.ftc.gov/opp/workshops/aco/index.html.

Triple Aim

As described in the MSSP Final Rule, ACOs are a means to achieving three goals for the Medicare program—better care for individuals, better health for populations, and lower growth in expenditures under the program's Part A and Part B. These goals are a slightly different formulation of the Triple Aim concept developed by the Institute of Healthcare Improvement, which defined the pursuit of healthcare system improvement by three aims: improving the experience of care, improving population health, and reducing per capita healthcare costs.

The Triple Aim became a touchstone for the efforts by CMS under former Administrator Donald Berwick, who discussed the three objectives in a 2008 article in *Health Affairs* magazine.[13] In the article, Berwick identified what he perceived as essential preconditions to accomplishing the Triple Aim, which include the existence of an "integrator," defined as an organization that would accept responsibility for all three components of the Triple Aim for a specified population. Much like an ACO, the integrator would link healthcare providers and promote cooperation and service coordination among them. The integrator's functions would be to establish a care system that is focused on primary care, patient engagement, and collective management and direction of resources to address the causes and incidences of poor health in the integrator's population. Accordingly, healthcare delivery would be shaped by demand and the population's needs rather than by supply. Costs would be reduced and quality promoted by communication, shared decision making with patients, and minimization of redundant, error-correcting, unscientific, or otherwise-valueless procedures, tests, and visits, rather than by imposing access restrictions or other inequitable or inefficient measures.

[13] Donald M. Berwick, Thomas W. Nolan and John Whittington, *The Triple Aim: Care, Health, And Cost,* 27 HEALTH AFFAIRS 759-769 (2008), *available at* http://content.healthaffairs.org/content/27/3/759.full.

As a way of defining the dimensions of healthcare value and expressing the rationale for healthcare delivery and payment reform, including ACOs, the Triple Aim is a concept that all stakeholders in the ACO endeavor—governmental healthcare programs, healthcare providers, commercial payors, and employers—should be able to support. Yet, ACOs raise specific interests and concerns for each category of stakeholders.

ACO Stakeholders

Governmental Healthcare Programs

The MSSP is strictly a Medicare program, although the term “ACO,” along with the principles and structural elements associated with the term, is applied in the context of both governmental healthcare programs other than Medicare and commercial insurance programs. The PPACA authorizes a demonstration project to establish pediatric ACOs for Medicaid populations, and many “safety-net” hospitals are spearheading the creation of ACOs to serve Medicaid beneficiaries and the indigent.

Within the framework of Medicare, ACOs offer several opportunities, chief among them the potential to reduce fee-for-service costs through positive rather than negative methods. By most calculations, approximately one-fifth of the federal budget was spent on federal health insurance programs in 2010, with the largest share of these expenditures being for the Medicare fee-for-service program. The 2011 report of the trustee for the Medicare Hospital Insurance Trust Fund (HI Fund), which pays for Medicare Part A costs and is funded by payroll taxes, projected that, absent the PPACA, the HI Fund would become insolvent (i.e., revenue would not cover 100% of costs) in 2016. The Supplementary Medical Insurance Trust Fund (SMI), which pays for Part B and Part D costs, does not have a projected “insolvency” date because it is funded through general fund revenues and monthly premiums. If costs continue to increase at rates higher than inflation and federal receipts, however, either the federal government or Medicare beneficiaries will need to spend a proportionately higher

amount of their budgets on the SMI program to avoid reimbursement reductions to providers or other cost-saving changes to the Part B program.

The Congressional Budget Office has estimated that the MSSP would save approximately $4.9 billion for the Medicare program through federal fiscal year (FY) 2019. The idea is to structure Medicare provider payments to encourage behavior that results in lower costs but maintains or improves care quality, and thereby to alter the projected course of expenditures. Achieving that, the federal government could sustain the Medicare program as an affordable option for the United States population over age sixty-five for longer than presently anticipated. Although neither a demonstration nor a pilot project, the MSSP is still an experiment in that it does not guarantee savings as direct cost cuts would. Unlike direct cost cuts, however, the MSSP represents an attempt to address the need to produce savings in a care-conscious manner that preserves Medicare beneficiaries' choice of providers. For this reason, CMS has a strong interest in the success of the MSSP. If successful, even in part, the MSSP and the ACO model could be applied to other governmental healthcare programs.

Healthcare Providers

The promise of savings for providers participating in the MSSP has elicited warranted skepticism, given the substantial costs in building and implementing an ACO. These costs range from the "hard" costs of infrastructure investment, such as information technology and clinical systems upgrades, to "soft" costs, such as those necessitated by provider network development, patient outreach, and management oversight. The incentive to incur these costs to participate in the MSSP is also relatively weak, given that providers garner savings only at their own expense by earning lower aggregate fee-for-service payments (reducing Medicare's costs) than in prior years. The decrease in fixed and marginal costs must exceed the portion of Medicare savings returned to a provider plus any incremental expenditures incurred to support MSSP enrollment for MSSP participation to be profitable for that provider.

Whether MSSP participation is likely to yield savings for providers or even be attractive to them depends in significant part on the type of provider and the nature of the provider's local healthcare market. Hospitals that neither employ nor have close affiliations with a sufficiently broad and substantial cohort of physicians, especially physicians who furnish primary care services (the basis for beneficiary attribution), are likely to be disadvantaged in achieving savings or disinclined to apply for the MSSP. Because of the inability to control Medicare beneficiaries' selection of providers, a provider may want to obtain endorsement (or similar agreement) from the other providers who treat the same Medicare patients before committing to participate in the MSSP. This is obviously easier where providers already operate under a common governance structure. ACOs based on existing provider networks and referral patterns are most likely, therefore, to be the initial applicants and the successful "savers." Providers in geographic areas that are already "low-cost" (i.e., have relatively low Medicare fee-for-service rates) may be deterred from MSSP participation, because the possible savings may be insufficient to offset expenses of participating. Providers and integrated delivery systems who have recently achieved reductions in per-Medicare beneficiary costs may also not see the potential for additional efficiency gains. Small, independent physician groups may not treat sufficient patient volume to meet the MSSP patient threshold or to make it economical to implement the measuring, monitoring, reporting, and other systems necessitated by the MSSP.

Although reasons exist not to participate in the MSSP, some providers may realize overall savings. There are also other reasons to undertake the activities required to participate in the MSSP apart from the prospect of immediate savings. Pending "non-voluntary" changes to Medicare reimbursement under the ACA, such as hospital readmission penalties and electronic medical records requirements, as well as competitive pressure and other market forces, are motivating providers to do many of the things that would be necessary for MSSP participation.

Hospitals without close relationships with physicians may view the MSSP as a means to encourage physician alignment. Physicians may reciprocate the interest, attracted by the potential to participate in the savings from reduced inpatient expenditures, which many observers consider the most significant area for cost reductions. Hospital and medical group administrators may also want to implement standard clinical protocols, attend more closely to care transitions, and boost patient satisfaction to enhance quality and reputation. Prioritizing “becoming an ACO” may give momentum to those ventures. In addition, the fraud and abuse waivers introduced by OIG will enable ACO participants to enter into gainsharing and financial subsidy relationships that might otherwise be prohibited.

Commercial Health Plans and Insurers

Commercial payors are not eligible participants in the MSSP and may not exercise control of the governing body of ACOs. The MSSP will, therefore, have only an indirect effect on private-sector health plans and healthcare insurers. Providers’ work to achieve savings in the MSSP may, however, benefit commercial payors and their subscribers by lowering providers’ overhead costs and improving care quality in ways that affect all patients. The MSSP may also cause ACO participants to enter into ACO-like arrangements with commercial payors, because these organizations can provide financial support for the infrastructure (e.g., incentives for implementing electronic health records (EHRs)) needed for MSSP participation. Managed care organizations (MCOs) also have experience and expertise in disease management and financial risk management, which would be useful for providers participating in the MSSP shared-risk model, although how MCOs could share these skills with providers may not be immediately clear. In the future, the MSSP may require that providers enter into shared savings programs with commercial payors, just as the Pioneer ACO Model requires ACOs to commit to entering outcomes-based contracts with purchasers other than Medicare.

As the largest health plan in the United States, Medicare frequently influences the decisions and reimbursement methodologies of commercial payors. It is possible therefore that commercial plans will look to the MSSP for direction on setting performance measures or will try to structure its provider incentive programs to harmonize with the MSSP. On the other hand, many commercial health plans have implemented the ACO concept in advance of CMS. Notable examples include the Blue Cross Blue Shield Alternative Quality Care contract and three shared savings models, dubbed ACOs, launched by Aetna in early 2011 in three different geographic regions. Commercial ACOs may also succeed in attaining their objectives to a greater degree than Medicare ACOs because commercial ACOs have a clearly defined enrollee population and payors have the capacity to provide enrollee incentives such as co-payment and deductible reductions. In the open networks of the MSSP, patients' adherence to the network is more difficult, and, even allowing for certain incentives made possible under the MSSP waivers, ACOs (rather than the payor, Medicare) would bear the direct costs of providing these incentives.

One concern that commercial payors have with programs, including the MSSP, that modify Medicare payment is that they might result in lower Medicare reimbursement to providers, leading to cost-shifting. This hazard is less acute in the MSSP than in other Medicare payment reforms because MSSP participants may elect the MSSP's non-risk-sharing track, but is present in the two-track model.

Employers

As purchasers of health insurance and healthcare through the commercial market, employers have limited interaction with Medicare. They do, however, have a stake in the Medicare program's survival, because Medicare represents an alternative to employer-based coverage for older employees. The promise of health insurance through Medicare also enables many individuals to retire at age sixty-five, thereby making room for younger workers.

Like commercial payors, employers could indirectly benefit from improvements in care and cost-saving delivery mechanisms prompted by the MSSP. Public reporting of ACO quality measures could expose differences in service levels and performance and allow employers to make more informed decisions about whether to structure their benefit offerings to include or exclude certain providers or to designate certain providers as preferred providers. As MSSP providers become more sophisticated in risk management and develop stronger skills in coordinating care, such providers or their ACOs might also consider direct employer-provider contracting.

Employers share with commercial payors the contrary concern, however, that providers will lose Medicare revenue and offset this lost revenue by demanding higher commercial rates and, in turn, making employer health coverage more expensive. Cost-shifting is not the only negative collateral effect to employers that could arise from Medicare payment and delivery reform such as the MSSP. Employers worry that ACOs will increase provider consolidation, which could increase provider negotiating clout and the price of healthcare coverage. Employers also have objectives in healthcare reform that the MSSP does not address, in particular price transparency and changes in maternity care or other types of care that are more prevalent in the segment of the population under age sixty-five. Provider focus on meeting the expectations of Medicare programs may distract attention and resources to these other objectives.

Organization and Governance of ACOs

The general eligibility, legal, and governance requirements under the Final Rule are somewhat more flexible than those under the Proposed Rule. The eligibility provisions are broader than under the Proposed Rule, permitting more types of entities to participate as ACOs. CMS expanded the eligibility rules to include entities organized under federal or tribal laws, as well as FQHCs and Rural Health Centers (RHCs).[1] In addition, the Final Rule permits CMS to give consideration to an organization with an innovative management or governance structure that does not meet the regulatory requirements for operating as an ACO for purposes of the MSSP.

General Requirements

Under the Final Rule, an ACO must become "accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO" in order to participate in the MSSP.[2] In contrast to the Proposed Rule, an ACO may participate in the one-sided model without taking on any down-side risk.[3] ACOs that operate under the two-sided model and meet or exceed a minimum loss ratio must still share losses with Medicare.[4]

CMS noted that many commenters objected to the Proposed Rule's restriction on FQHCs and RHCs from forming ACOs.[5] The Final Rule permits FQHCs and RHCs to create their own ACOs. In addition, CMS now permits claims for primary care services submitted by these organizations to be considered in the beneficiary assignment process for any ACO that includes an FQHC or RHC.[6]

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[1] 42 C.F.R. § 425.104(a); 76 Fed Reg. at 67804.
[2] 42 C.F.R. § 425.10; 76 Fed Reg. at 67806.
[3] 42 C.F.R. § 425.20; 76 Fed. Reg. at 67907.
[4] 76 Fed. Reg. at 67936.
[5] 76 Fed. Reg. at 67811.
[6] 42 C.F.R. § 425.904.

Subpart E—Assignment of Beneficiaries

-Section 425.400 General-

The Section describes the process by which a Medicare fee-for-service beneficiary will be assigned to an ACO. CMS will employ a “preliminary” prospective assignment methodology with final retrospective reconciliation.

Beneficiaries will be assigned to an ACO in a preliminary manner at the beginning of the performance year based on the most recent data available, and assignment will be updated quarterly based on the most recent twelve months of data. Final assignment then will be determined after the end of each performance year based on data from the performance year.

CMS also indicates that assignment is limited for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable under Subpart F (Quality and Other Reporting Requirements) and whether an ACO has achieved savings under Subpart G (Shared Savings and Losses). Assignment to an ACO therefore in no way diminishes or restricts a beneficiary’s rights to exercise free choice in determining where to receive healthcare services.

Finally, for purposes of assigning beneficiaries, primary care services are identified by selected HCPCS codes and G codes as indicated in the definition of primary care services under Section 425.20.

The agency also clarifies that beneficiaries who are assigned to an ACO will not have diminished or restricted rights to exercise free choice in determining where to receive healthcare services.

-Section 425.402 Basic Assignment Methodology-

This Section describes CMS' approach to the assignment of Medicare fee-for-service beneficiaries to an ACO, which is designed to balance maintaining a strong emphasis on primary care while ultimately allowing for assignment of beneficiaries on the basis of how they actually receive their primary care services. Under this approach, assignment to an ACO first is based on the receipt of primary care services from primary care physicians (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine). Those beneficiaries who have not received primary care services from primary care physicians then may be assigned to an ACO on the basis of primary care services provided by other physicians and practitioners.

To assign Medicare fee-for-service beneficiaries to a particular ACO, CMS will begin by identifying all patients that had at least one primary care service from a physician who is an ACO provider/supplier of an ACO. The agency then will employ the following step-wise methodology:

In the first step, CMS will identify all primary care services rendered by primary care physicians during either: (1) the most recent twelve months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment); or (2) the performance year (for purposes of final assignment). The beneficiary is assigned to an ACO if 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 are greater than the allowed charges for primary care services furnished by primary care physicians

who are: (1) ACO providers/suppliers in any other ACO; and (2) not affiliated with any ACO and identified by a Medicare-enrolled Tax Identification Number (TIN).

In the second step, CMS will consider the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not received a primary care service from any primary care physician, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals (e.g. specialists, nurse practitioners (NPs), physician assistants (PAs), clinical nurse specialists (CNSs) who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by: (1) all ACO professionals who are ACO providers/suppliers in any other ACO; and (2) other physicians, NPs, PAs, and CNSs who are unaffiliated with an ACO and are identified by a Medicare-enrolled TIN.

-Section 425.404 Special Assignment Conditions for ACOs Including FQHCs and RHCs-

This Section describes special assignment conditions for Medicare fee-for-service beneficiaries who receive primary care services from FQHCs and RHCs that are part of an ACO. CMS recognizes the important primary care role played by FQHCs and RHCs. However, FQHCs and RHCs submit claims based on revenue code centers and do not report most of the HCPCS and G codes specified in Section 425.20 that are required to determine if primary care services are being provided for purposes of the Shared Savings Program. FQHCs and RHCs also submit claims that contain limited information as to the type of practitioner providing a service because this information is not necessary to determine payment rates for services provided in FQHCs and RHCs.

With these limitations in mind, CMS will assign beneficiaries to ACOs based on services furnished in FQHCs or RHCs based on the general assignment

methodology in Section 425.402, with two special conditions. First, ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO. Second, under the assignment methodology in Section 425.402, CMS will treat a service reported on an FQHC/RHC claim as a primary care service if: (1) the National Provider Identifier (NPI) of a physician included in the attestation is reported on the claim as the attending provider; and (2) the claim includes a HCPCS or revenue center code that meets the definition of primary care services under Section 425.20 based on a cross-walk between the revenue center codes and the HCPCS primary care codes that CMS will construct for FQHCs and RHCs.

Accountability for Beneficiaries

As in the Proposed Rule, the Final Rule requires an ACO have at least 5,000 beneficiaries assigned to it annually.[7] If at any time during the performance year an ACO's assigned population falls below this number, the ACO will be "issued a warning and placed on a CAP [Corrective Action Plan]."[8] The CAP could include a provision to add more primary care providers to the ACO or other changes needed to increase the number of assigned beneficiaries. While under the CAP, the ACO remains eligible for shared savings and losses during the performance year for which the warning and CAP were issued.[9]

If the ACO's assigned population does not go back up to at least 5,000 or more by the end of the next performance year, the ACO's agreement will be terminated and the ACO will not be eligible to share in savings for that performance year.[10]

[7] 42 C.F.R. § 425.110 (a) (1).
[8] 42 C.F.R. § 425.110 (2) (b).
[9] 42.C.F.R. § 425.110 (2) (b) (1).
[10] 42 C.F.R. § 425.110 (2) (b) (2).

CMS also finalized its proposal that the basis for assignment of beneficiaries to an ACO is where they receive a "plurality of their primary care services."[11] However, CMS made significant changes to the fundamental assignment method. Responding to strong criticism of the retrospective method originally proposed, CMS established a prospective assignment method coupled with a reconciliation process to be performed annually.[12] CMS indicates in the comments that an ACO "will not receive an assignment of those beneficiaries that choose not to receive care from ACO providers."[13]

Correlatively, beneficiaries who choose to receive care from particular providers within an ACO may be assigned to that ACO, "regardless of whether they are 'unmanageable' or noncompliant with treatment."[14] CMS emphasized in the comments that "avoidance of such beneficiaries . . . will result in termination of an ACOs participation agreement."[15] CMS also finalized the requirement that an ACO executive with authority to bind the ACO must certify that the ACO's participants are "willing to become accountable for, and to report to us on, the quality, cost, and overall care" of the beneficiaries assigned to that ACO.[16]

Agreement Requirement

CMS finalized its proposal that the ACO participants must agree to the requirements set forth in the agreement between the ACO and CMS, sign a participation agreement, and submit the signed agreement to CMS.[17] However, CMS modified a number of the agreement requirements from the Proposed Rule, recognizing that a January 1, 2012, start date may not be feasible.[18] Specifically, CMS provides two options for start dates of the participation agreement in 2012:

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[11] 42 C.F.R. § 425.402; 76 Fed. Reg. at 67857.
[12] 42 C.F.R. § 425.400; 76 Fed. Reg. at 67839, 67836.
[13] 76 Fed. Reg. at 67806.
[14] 76 Fed. Reg. at 67806.
[15] 42 C.F.R. § 425,316 (b); 76 Fed. Reg. at 67951.
[16] 76 Fed. Reg. at 67806.
[17] 42 C.F.R. § 425.200 (b) and (c); 76 Fed. Reg. at 67811.
[18] 76 Fed. Reg. at 67836.

an April 1 start date or a July 1 start date.[19] The earlier start date has a longer performance period of 21 months; the latter has an eighteen-month performance period. Both performance periods end on December 31, 2013. In both cases, the agreement term will be three performance periods, ending December 31, 2015.[20]

CMS reserves the right to modify agreement provisions and requirements during the term of the agreement.[21] ACOs will be responsible for all policy and MSSP changes during the agreement, except for eligibility requirements regarding organization and governance of ACOs, determination of the sharing rate, and assignment of beneficiaries.[22] An ACO has the right to terminate its agreement if regulatory requirements are changed, if it feels those modifications will alter its ability to maintain participation in the MSSP.[23]

Sufficient Number of Primary Care Providers and Beneficiaries

An ACO must include an adequate number of primary care providers for the number of assigned Medicare beneficiaries.[24] However, in its comments, CMS noted there were significant objections to CMS' proposal that primary care physicians be exclusive to one ACO, on the grounds that "such exclusivity could be disruptive of their current practice patterns, which may involve the assignment of patients to a number of ACOs."[25]

CMS clarifies in the Final Rule that the primary care physician exclusivity requirement—that a primary care physician be exclusively affiliated with one ACO—only applies in situations where the provider is using his own TIN to bill,

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[19] *Id.*
[20] *Id.*
[21] 42 C.F.R. § 425.212.
[22] 42 C.F.R. § 425.212 (2).
[23] 42 C.F.R. § 425.212 (2) (d).
[24] 42 C.F.R. § 425.110 (a) (1).
[25] 76 Fed. Reg. at 67810.

and which forms the basis for beneficiary assignment.[26] Providers billing through different TINs of one or multiple group practices could participate in multiple ACOs. However, solo practitioners, both primary care and specialists, who provide primary care services upon which beneficiary assignment is based and who bill under their own personal TIN would need to be exclusive to a single ACO.[27] The comments clarify that each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one ACO.[28]

Identification and Required Reporting on Participating ACO Professionals

CMS finalized its proposal to "define the ACO operationally by its Medicare enrolled ACO participants' TINs."[29] CMS clarifies that a large health system with one TIN cannot include only parts of the system in an ACO.[30] CMS notes that this level of exclusivity of providers to an ACO is "necessary in order for the assignment process to function correctly, and especially to ensure the accurate assignment of beneficiaries to one and only one ACO."[31]

The Final Rule requires ACOs to submit both the TINs of all ACO participants and the NPIs associated with ACO providers and suppliers.[32] Each ACO must maintain, update, and annually report to CMS those TINs and NPIs that are participants and providers/suppliers of the respective ACO.[33] CMS clarifies that this information is needed "in order to assign beneficiaries to ACOs appropriately and accurately."[34] CMS reserves the right to request additional information as part of the application process.[35]

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[26] 76 Fed. Reg. at 67810.
[27] 42 C.F.R. § 425.204 (c) (5) (i).
[28] 76 Fed. Reg. at 67810 –67811.
[29] 42 C.F.R. § 425.20; 76 Fed. Reg. at 67809.
[30] 76 Fed. Reg. at 67816.
[31] *Id.*
[32] 42 C.F.R. § 425.204 (c) (5) (i).
[33] 76 Fed. Reg. at 67809.
[34] 76 Fed. Reg. at 67809.
[35] 42 C.F.R. § 455.205 (c) (5) (i) (B) (ii).

Eligible Participants

CMS broadened the eligibility rules in the Final Rule. As a result, the parties eligible to *form* ACOs have been expanded in the Final Rule from the five categories originally proposed to seven categories, as follows: (1) ACO professionals in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; (4) hospitals employing ACO professionals; (5) Critical Access Hospitals that bill Medicare for facility and other professional services; (6) RHCs; and (7) FQHCs.[36]

An "ACO professional" is a physician or a practitioner as provided in the Social Security Act (Act), and a "hospital" is defined as an acute care hospital reimbursed under the hospital inpatient prospective payment system.[37] Other Medicare enrolled entities that are not identified in (1) – (7) above are eligible to participate in the MSSP through an ACO formed by one or more of the eligible formation entities enumerated.[38]

Legal Structure and Governance

An ACO must be constituted as a legal entity for purposes of receiving and distributing shared savings, repaying shared losses, and complying with all MSSP requirements, including governance requirements and quality performance standards.[39]

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[36] 42 C.F.R. § 425.102(a).
[37] 42 C.F.R. § 425.20.
[38] 42 C.F.R. § 425.102(b); 76 Fed. Reg. at 67814 (November 2, 2011).
[39] 42 C.F.R. § 425.104(a).

Legal Entity

The ACO legal entity may be structured as a corporation, partnership, limited liability company, foundation, or other entity permitted under applicable federal, state or tribal law.[40] The entity must be authorized to conduct business in each state in which it operates for the purposes outlined above.[41]

An existing legal entity that is eligible to be an ACO is permitted to continue its use of this structure if it meets the other ACO eligibility and governance requirements.[42] However, CMS clarifies that "if an existing legal entity adds ACO participants that will remain independent legal entities (such as through a joint venture among hospitals or group practices), it would have to create a new legal entity to do so."[43] The comments indicate that an ACO formed by two or more independent ACO participants (such as a hospital and physician group practice) must be established as a new legal entity separate from the other ACO participants with its own TIN.[44]

Distribution of Shared Savings

Shared savings payments will be made directly to the entity designated as the ACO, regardless of whether that entity is enrolled in the Medicare program.[45] While the final rule does not dictate the manner an ACO distributes shared savings among its participants, CMS finalizes the requirement that an ACO must describe in its ACO application its plan for using and distributing shared savings in furtherance of the goals of the MSSP.[46]

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[40] *Id. See* also 76 Fed. Reg. at 67815-67816.
[41] *Id.*
[42] 76 Fed. Reg. at 67815.
[43] *Id.*
[44] *Id*.
[45] 76 Fed. Reg. at 67816.
[46] 42 C.F.R. § 425.204(d); 76 Fed. Reg. at 67816.

Governance

The final rule confirms that an ACO must have a separate and unique governing body (i.e., board of directors, board of managers, etc.) in cases where the ACO "comprises multiple, otherwise independent ACO participants."[47] If the organization designated as the ACO is an existing entity, then the ACO governing body "may be the same as the governing body of that existing entity, provided that it satisfies the other requirements" for shared governance, leadership, and management.[48]

In a change from the proposed rule, the final rule does not require an ACO governing body to provide proportionate representation by ACO participants, representation by all ACO participants, or inclusion of any specific categories of providers, suppliers, or stakeholders.[49] Instead, CMS allows ACOs flexibility in determining the governing body's composition, provided that ACO participants are given the opportunity for "meaningful participation" in the ACO's governance.[50]

The governing body must have a transparent governing process with a conflicts of interest policy and broad responsibility for oversight of the ACO, its clinical and administrative processes, and its strategic direction in furtherance of the goals of the MSSP.[51] In addition, the members of the governing body must have a fiduciary duty to the ACO and act in accordance with that duty.[52]

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[47] 42 C.F.R. § 425.106(b)(4).
[48] 42 C.F.R. § 425.106(b)(5). In such instance, the ACO would have to be fully integrated in order to utilize an existing legal entity.
[49] 76 Fed. Reg. at 67818 (November 2, 2011).
[50] 42 C.F.R. § 425.106(c)(1); 76 Fed. Reg. at 67819.
[51] 76 Fed. Reg. at 67819.
[52] *Id.*

Composition of the Governing Body

To ensure that ACOs are "provider driven," the final rule requires that at least 75% of the ACO's governing body be comprised of ACO participants.[53] This allows for up to 25% participation by non-providers such as health plans, management companies, and community stakeholders.[54] CMS requires that the ACO governing body include one Medicare beneficiary representative who does not have a conflict of interest;[55] however, CMS declines to dictate how voting control is apportioned by an ACO.[56] The Final Rule permits ACO governing body members to "serve in a similar or complementary manner for an ACO participant."[57]

In a change from the proposed rule, the Final Rule permits some flexibility as to compliance with the governance rules. Specifically, in cases in which the composition of the ACO's governing body does not meet the governance requirement, the regulations state that an ACO can describe the differences and how "the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries."[58] The Final Rule requires that "[t]he ACO governing body must have a conflict of interest policy that applies to members of its governing body."[59]

Leadership and Management Structure

The Final Rule requires that an ACO have a leadership and management structure that "includes clinical and administrative systems that align with and

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[53] *Id.* at 67820; 42 C.F.R. § 425.106(c)(3).
[54] 76 Fed. Reg. at 67820.
[55] 42 C.F.R. § 425.106(c)(2).
[56] 76 Fed. Reg. at 67820.
[57] 42 C.F.R. § 425.106(c)(4).
[58] 42 C.F.R. § 425.106(c)(5).
[59] 42 C.F.R. § 425.106(d).

support the goals of the MSSP."[60] CMS also requires management of the ACO's operations by an officer, executive, general partner, or manager capable of influencing or directing clinical practice so as to improve efficiency, processes, and outcomes and whose appointment and removal are controlled by the ACO's governing body.[61] The clinical oversight must be managed by a medical director at a senior level who is a physician and one of the ACO's providers/suppliers and who meets certain other requirements set forth in the regulations;[62] however, this position is not required to be full time as originally proposed.[63] In addition, an ACO must have a quality assurance and improvement program with oversight by a "qualified health care professional" who is not required to be a physician.[64]

Under the Final Rule, ACO participants and providers/suppliers must demonstrate a "meaningful commitment" to the ACO's mission.[65] In the commentary, CMS states that this "meaningful commitment" can be in the form of human capital (such as service on the governing board or committees or participating in operations), financial investment (for example, by contributing capital for infrastructure needs), or a commitment to comply with and implement the ACO's required processes and performance standards.[66]

In a change from the Proposed Rule, the Final Rule permits CMS to consider innovative ACOs with alternate management structures that do not meet the regulatory requirements.[67] This flexibility is similar to that provided in connection with the composition of the governing body.[68] The comments indicate that the intent is to provide greater flexibility on ACO governance and management

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[60] 42 C.F.R. § 425.108(a).
[61] 42 C.F.R. § 425.108(b).
[62] 42 C.F.R. § 425.108(c).
[63] 76 Fed. Reg. at 67823.
[64] *Id.*
[65] 42 C.F.R. § 425.108(d).
[66] 76 Fed. Reg. at 67824-67825.
[67] 42 C.F.R. § 425.108(e).
[68] 76 Fed. Reg. at 67823.

structures where there are other considerations potentially impacting the structure.[69] Documentation of the management and leadership structures is required as part of the ACO application process.[70]

[69] 76 Fed. Reg. at 67823- 67824.
[70] 42 C.F.R. § 425.204(c)(1)(iii).

Required Processes and Patient-Centered Criteria

Statutory Background

Section 1899(b)(2)(G) of the Act[1] requires an ACO to define processes to promote evidence-based medicine, promote patient engagement, report on quality and cost measures, and coordinate care, such as through telehealth, remote patient monitoring, and other enabling technologies. Section 1899(b)(2)(H) of the Act[2] requires an ACO to demonstrate to the HHS Secretary that the ACO meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.

General Required Processes and Patient-Centeredness Criteria

The ACO regulations at 42 C.F.R. § 425.112 implement Section 1899(b)(2)(G), as discussed below. In the preamble to the final ACO regulations, CMS expressed concern that a prescriptive approach to defining the four required processes would be premature and potentially impede innovation and the goals of the MSSP.[3] CMS has emphasized that ACOs retain flexibility to define processes that are suited to their practices and patient populations.[4]

On a general level, the process regulation requires an ACO to: (1) promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care; (2) adopt a focus on patient centeredness that is promoted by the ACO's governing body and integrated into practice by leadership and management working with the organization's healthcare teams; and (3) have defined processes to fulfill these requirements.[5]

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[1] 42 U.S.C. § 1395jjj(b)(2)(G).
[2] 42 U.S.C. § 1395jjj(b)(2)(H).
[3] 76 Fed. Reg. at 67827.
[4] 76 Fed. Reg. at 67827-8.
[5] 42 C.F.R. § 425.112(a)(1).

In addition, an ACO must have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program.[6]

For each of the four required processes (discussed below), the ACO must explain how it will require ACO participants, providers, and suppliers to comply with and implement each process.[7] The ACO's explanation needs to address the remedial processes and penalties (including the potential for expulsion) for failure to comply with and implement the required processes.[8] In addition, the ACO must explain how it will employ its internal cost and quality-of-care assessments to continuously improve the ACO's care practices.[9]

Required Processes

Subsection (b) of the process regulation requires each ACO to define, establish, implement, evaluate, and periodically update processes to accomplish the following four objectives: (1) promote evidence-based medicine; (2) promote patient engagement; (3) develop an infrastructure to internally report on quality and cost metrics, evaluate performance, and improve care; and (4) coordinate care.[10]

With respect to evidence-based medicine, the processes must cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.[11] In its commentary, CMS stated that an ACO that meets the requirements for National Committee for Quality Assurance Medical Home recognition would be "well on its way to

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[6] 42 C.F.R. § 425.112(a)(2).
[7] 42 C.F.R. § 425.112(a)(3)(i).
[8] *Id.*
[9] 42 C.F.R. § 425.112(a)(3)(ii).
[10] 42 C.F.R. § 425.112(b).
[11] 42 C.F.R. § 425.112(b)(1).

demonstrating that it has processes in place that support evidence-based guidelines, but we will still need to evaluate them."[12]

The second category of required processes (promotion of patient engagement) must address the following areas: (1) compliance with the patient experience of care survey requirement of 42 C.F.R. § 425.500; (2) compliance with beneficiary representative requirement of 42 C.F.R. § 425.106; (3) a process for evaluating the health needs of the ACO's population, including consideration of diversity in the patient populations, and a plan to address those needs, including a description of how the ACO intends to partner with community stakeholders to improve the health of its population;[13]; (4) communication of clinical knowledge of evidenced-based medicine to beneficiaries in a way that is understandable to beneficiaries; (5) beneficiary engagement and shared decision making that takes into account the beneficiaries' unique needs, preferences, values, and priorities; and (6) written standards for beneficiary access and communication, and a process allowing beneficiaries to access their medical records.[14]

CMS observed in the preamble to the Final Rule that "true patient engagement requires sensitivity to the many diverse factors that can affect a specific patient population and the appropriate care to address the health needs of that population."[15] CMS also noted that educating and engaging patients regarding the decision-making process relating to their healthcare needs should incentivize the patients to actively engage in treatment approaches in light of their values and convictions.[16]

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[12] 76 Fed. Reg. at 67827.
[13] 42 C.F.R. § 425.112(b)(2)(iii) notes that an ACO with a stakeholder organization serving on its governing body will be deemed to satisfy the requirement to partner with community stakeholders.
[14] 42 C.F.R. § 425.112(b)(2).
[15] 76 Fed. Reg. at 67828.
[16] *Id.*

The third process objective is development of an infrastructure for ACO participants, providers, and suppliers to internally report on quality and cost metrics in a manner that enables the ACO to monitor, provide feedback, evaluate ACO participants, providers, and suppliers, and use the results to improve care over time.[17]

Finally, an ACO is required to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers.[18] In particular, 42 C.F.R. § 425.112(b)(4)(i) requires the ACO to define its methods and processes for coordinating care throughout an episode of care and during the transition of care, (e.g., discharge from a hospital or transfer of care from a primary care physician to a specialist, both inside and outside the ACO). In commentary, CMS characterized health information exchanges (HIEs) as "of the utmost importance" and "underscore[d] the importance of robust health information exchange tools in effective care coordination," while also recognizing that ACOs will have varying ability to adopt HIE technologies.[19]

Application Description of Processes and Criteria

As a condition for participation in the MSSP, the regulations require the application to include a description, or documents sufficient to describe, how the ACO will implement the processes and patient-centeredness criteria discussed above.[20] The regulation specifically requires that the application include descriptions of the remedial processes and penalties (including the potential for termination) that will apply if an ACO participant, provider, or supplier fails to comply with and implement the processes.[21]

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[17] 42 C.F.R. § 425.112(b)(3).
[18] 42 C.F.R. § 425.112(b)(4).
[19] 76 Fed. Reg. at 67830.
[20] 42 C.F.R. § 425.204((c)(ii).
[21] *Id.*

The process regulation requires an ACO to submit a description of its individualized care program, along with a sample individual care plan, and explain how this program is used to promote improved outcomes for (at a minimum) its high-risk and multiple chronic condition patients.[22] The application also is required to describe additional target populations that would benefit from individualized care plans, which must take into account the community resources available to the individual.[23]

[22] 42 C.F.R. § 425.112(b)(4)(ii)(A).
[23] 42 C.F.R. § 425.112(b)(4)(ii)(B).

ACO Contracting

Application Procedure

An eligible organization of providers and suppliers may submit an application to become an ACO and participate in the MSSP for a term of not less than three years.[1] The application form and related instructions and deadlines are available on the CMS website.[2]

Before applying, an ACO must submit a Notice of Intent (NOI) to obtain an ACO ID. The application must be submitted in the form and manner (and by the deadline) required by CMS,[3] and must include the content described in the regulations at 42 C.F.R. § 425.204. An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge that the information in the application is accurate, complete, and truthful.[4] CMS will approve or deny an application based on its determination of whether the applicant satisfies the requirements of the ACO regulations and is qualified to participate in the MSSP.[5]

Agreement With CMS

Upon notification of CMS approval to participate in the MSSP, an ACO executive who has the ability to legally bind the ACO must sign and submit to CMS a participation agreement that includes the ACO's agreement to comply with the MSSP regulations.[6] In addition, the ACO must agree, and must require its ACO participants, providers, and suppliers, as well as others performing ACO-related

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[1] 42 C.F.R. § 425.200 (a).
[2] *See* www.cms.gov/sharedsavingsprogram/37_Application.asp.
[3] 42 C.F.R. § 425.202 (a)(1).
[4] 42 C.F.R. § 425.202 (a)(2).
[5] 42 C.F.R. § 425.202(c) and (d). *See also* 42 C.F.R. § 425.206 regarding the CMS evaluation procedure.
[6] 42 C.F.R. § 425.208(a).

functions or services, to comply with all applicable laws.[7] As a condition of participating in the MSSP and receiving any shared savings payment, the ACO must agree that an individual with the authority to legally bind the ACO will certify as to the accuracy, completeness, and truthfulness of any data or information requested by or submitted to CMS, specifically including the application, the participation agreement, and any quality data or other information forming the basis for the calculation of shared savings payments and shared losses.[8]

The start date for a participation agreement beginning in 2012 will be either April 1, 2012 (for a term of three years and nine months), or July 1, 2012 (for a term of three years and six months).[9] For 2013 and all subsequent years, the start date will be January 1, and the participation agreement will span three years.[10]

The initial period for which performance will be measured will depend upon the start date of the ACO. For ACOs that start on April 1, 2012, or July 1, 2012, the first performance period will be twenty-one months and eighteen months, respectively.[11] Other than for those initial performance periods, performance will be evaluated on the twelve-month period immediately preceding January 1.[12] An ACO must provide a copy of its participation agreement to all ACO participants, providers, and suppliers, as well as other individuals and entities involved in governance of the ACO.[13]

Statutory and Regulatory Changes During the Three-Year Period

Changes can be expected as the MSSP develops over time. The Final Rules describe how these changes will affect participants in the MSSP. Medicare

[7] 42 C.F.R. § 425.208(b).
[8] 42 C.F.R. § 425.208(c).
[9] 42 C.F.R. § 425.200 (b) (1).
[10] 42 C.F.R. § 425.200 (b) (2).
[11] 42 C.F.R. § 425.200 (c) (2).
[12] 42 C.F.R. § 425.200 (c) (1).
[13] 42 C.F.R. § 425.210(a).

participation agreements typically include a provision incorporating all statutory and regulatory changes that occur during the agreement's one-year term. Although the MSSP participation agreement is for a minimum of three years, ACOs must comply with all statutory and regulatory changes during the term, except for regulatory changes in the following three areas[14]:

- Eligibility requirements concerning the structure and governance of ACOs;
- Calculation of sharing rate; and
- Beneficiary assignment.

With respect to all changes in law or regulations, an ACO will be required to submit to CMS for review and approval an explanation of how the ACO will modify its processes to address the changes in law or regulations.[15] If the ACO does not modify its processes to address a change in law or regulations, it will be placed on a CAP.[16] If the ACO fails to take appropriate action to adhere to the statutory or regulatory modifications while under a CAP, CMS may terminate the ACO from the MSSP.[17] Similarly if the ACO believes statutory or regulatory changes will impact the ability of the ACO to continue to participate in the MSSP, the ACO may voluntarily terminate the Agreement.[18]

Other Significant Changes

In its commentary to the final regulations, CMS noted that whenever an ACO reorganizes its structure, CMS must determine whether the ACO remains eligible to participate in the MSSP.[19] During the agreement, an ACO may add or remove ACO participants (determined by TINs) and/or ACO providers/suppliers

[14] 42 C.F.R. § 425.212 (a)(2).
[15] 42 C.F.R. § 425.212(b).
[16] 42 C.F.R. § 425.212 (c).
[17] 42 C.F.R. § 425.212 (c).
[18] 42 C.F.R. § 425.212 (d).
[19] 76 Fed. Reg. at 67839.

(determined by NPIs), but the ACO must notify CMS within thirty days of the addition or removal.[20] In addition, ACOs must notify CMS at least thirty days prior to any "significant change" that would cause the ACO to no longer meet the eligibility or program requirements.[21] Significant changes requiring notification include the imposition of sanctions or other actions against the ACO by an accrediting organization, and/or state, federal, or local government agencies.

When CMS receives notification of these significant change events, CMS may respond in one of the following ways:

- Permit the ACO to continue to operate under the new structure;[22]
- Terminate the agreement and require the ACO to submit a new application;[23]
- Terminate the ACO's participation in the MSSP because it no longer meets the eligibility requirements;[24] or
- Permit termination of the Agreement by mutual agreement.[25]

If CMS concludes that termination of an ACO from the MSSP is warranted, then CMS may take any of the following actions prior to terminating the ACO:

- Provide a warning notice to the ACO regarding noncompliance;
- Request a CAP from the ACO; or
- Place the ACO on a special monitoring plan.[26]

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[20] 42 C.F.R. § 425.214 (a).
[21] 42 C.F.R. § 425.214 (b).
[22] 42 C.F.R. § 425.214 (c) (1).
[23] 42 C.F.R. § 425.214 (c) (2).
[24] 42 C.F.R. § 425.214 (c) (3).
[25] 42 C.F.R. § 425.214 (c) (4).
[26] 42 C.F.R. § 425.216(a)(1).

Termination of Participation Agreement

CMS may terminate a participation agreement when the ACO, the ACO's participants, providers, suppliers, or others performing functions or services related to ACO activities, fail to comply with any requirements of the MSSP under the ACO regulations.[27] Grounds for termination by CMS include, without limitation: (1) non-compliance with eligibility and other requirements of the ACO regulations; (2) the imposition of sanctions or other actions taken against the ACO by an accrediting organization or by a government agency leading to inability of the ACO to comply with the ACO regulatory requirements; and (3) violations of the Stark Law, CMPs law, federal AKS, antitrust laws, or other Medicare laws, rules, or regulations that are relevant to ACO operations.[28] CMS is allowed to immediately terminate a participation agreement without taking any of the typically allowable pre-termination actions.[29] CMS will provide written notification of termination of a participation agreement.[30]

An ACO must provide at least sixty days advance written notice to CMS and its ACO participants prior to the ACO's termination of its participation agreement.[31] The regulations state that an ACO will not share in any savings for the performance year during which the ACO notifies CMS of the ACO's termination of its participation agreement.[32] CMS noted in commentary, however, that an ACO will be allowed to terminate its participation agreement without penalty when regulatory changes to the MSSP impact the ACO's ability to continue to participate.[33]

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[27] 42 C.F.R. § 425.218(a).
[28] 42 C.F.R. § 425.218(b).
[29] 42 C.F.R. § 425.218(c).
[30] 42 C.F.R. § 425.218(d).
[31] 42 C.F.R. § 425.220(a).
[32] 42 C.F.R. § 425.220(b).
[33] 76 Fed. Reg. at 67838.

Future Participation of Previously Terminated Participants

An ACO that has been terminated from the MSSP may participate again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated.[34] If the terminated ACO was under the one-sided model, it may reenter the program only under the two-sided model, unless it was terminated less than half-way through its agreement. A terminated ACO that was under the two-sided model may only re-apply for participation in the two-sided model.[35] To be eligible to participate in the MSSP after a previous termination, the ACO must demonstrate in its application that it has corrected the deficiencies causing its termination from the MSSP and that it has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.[36]

[34] 42 C.F.R. § 425.222 (a).
[35] 42 C.F.R. § 425.222 (c).
[36] 42 C.F.R. § 425.222 (b).

Federal Regulatory Issues

Waiver Designs in Connection with the MSSP and the Innovation Center (CMS/OIG)

Contemporaneous with publication of the final regulations governing the MSSP, CMS and the OIG jointly published an interim final rule (Interim Final Rule) identifying several types of transactions for which specified fraud and abuse laws will be waived. Such waivers will be self-implementing: so long as the parties structure a transaction to meet the prescribed requirements outlined below, they will automatically receive waiver protection and do not need to submit an application to CMS or OIG (collectively, the Agencies). CMS solicited comments on the Interim Final Rule.

Background

As noted in detail above, PPACA mandated creation of MSSP as a mechanism to encourage providers to collaborate in improving the health of, and lowering the cost of care for, Medicare beneficiaries. Specifically, the MSSP authorized the provision of certain financial incentives to healthcare providers in furtherance of these goals.

Congress recognized that provision of such incentives could implicate, and, in some cases, violate, the following healthcare fraud and abuse laws:

- The Ethics in Patient Referrals Act (Stark Law). Unless an exception applies, the Stark Law prohibits a physician from referring Medicare beneficiaries to an entity (e.g., a physician practice, hospital, clinic, laboratory) for the furnishing of designated health services (DHS)—e.g., inpatient hospital services, outpatient hospital services, imaging services, laboratory services—if the physician has a direct or indirect financial relationship with the entity.[1] The Stark Law also prohibits

[1] 42 U.S.C. § 1395nn(a)(1)(A); 42 C.F.R. § 411.353(a).

any entity from billing Medicare for DHS furnished pursuant to a prohibited referral.[2] Any payments (including copayments) received in violation of this prohibition must be promptly refunded.[3] A CMP of up to $15,000 may be imposed against any person who: (1) presents or causes presentation of a claim, and (2) knows or should know the claim results from an impermissible referral.[4] Such persons may also be excluded from participation in federal healthcare programs.[5] Though CMS has primary jurisdiction in enforcing the Stark Law, OIG plays the central role in any actions to impose civil penalties for Stark Law violations.

- The Federal Healthcare Program Anti-Kickback Law (AKS). The AKS generally prohibits any person from knowingly and willfully offering or paying any remuneration to induce another to (1) refer patients for the provision of items or services that may be paid for by a federal healthcare program; (2) purchase, lease, or order such items or services; or (3) recommend or arrange for the purchase, lease, or order of such items or services.[6] It also prohibits the knowing and willful solicitation or acceptance of such remuneration.[7] Violation of the AKS is punishable through a criminal or civil action. Criminal sanctions include five years imprisonment, a $25,000 fine, and mandatory exclusion from participation in federal healthcare programs.[8] Civil sanctions include a $50,000 CMP, an assessment of up to three times the amount of remuneration involved, and potential exclusion from all federal healthcare programs.[9] HHS/OIG has primary jurisdiction over the AKS,

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[2] 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b).
[3] 42 U.S.C. § 1395nn(g)(1).
[4] 42 U.S.C. § 1395nn(g)(3).
[5] In addition, a physician or entity participating in a "scheme" to circumvent the Stark Law is subject to a civil monetary penalty of up to $100,000 and exclusion from participation in federal healthcare programs. 42 U.S.C. § 1395nn(g)(4).
[6] 42 U.S.C. § 1320a-7b(b)(2). HHS/OIG defines the term "remuneration" broadly to cover "anything of value." 56 Fed. Reg. 35952, 35958 (1991). The term "inducement" also has been interpreted broadly to cover any act that is intended to "influence" the "reason or judgment of another in an effort to cause the referral of program-related business." *Hanlester Network v. Shalala*, 51 F. 3d 1390, 1398 (9th Cir. 1995). Further, the fact that there are legitimate reasons for the remuneration at issue is irrelevant: OIG and federal courts have taken the position that so long as "one of the purposes" of the payment is to induce the referral of program-related business, the AKS is implicated. *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989).
[7] 42 U.S.C. § 1320a-7b(b)(1).
[8] 42 U.S.C. § § 1320a-7b(1)-(2), 1320a-7(a)(1).
[9] 42 U.S.C. § 1320a-7a(a).

though the U.S. Department of Justice (DOJ) plays the central role in any judicial enforcement actions under the statute.

- The Gainsharing Law. A CMP Law provision, also known as the Gainsharing Law, prohibits any hospital from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care.[10]Hospitals that make (and physicians that receive) such payments are liable for civil penalties of up to $2,000 per patient covered by the payments. OIG has primary jurisdiction to impose these penalties.

- Federal Healthcare Program Beneficiary Inducement Law (Inducement Law). The Inducement Law is another CMP Law provision that generally prohibits the furnishing of remuneration to a Medicare or Medicaid beneficiary if the person furnishing the remuneration "knows or should know" that it is "likely to influence" the beneficiary to order or receive services from "a particular provider, practitioner, or supplier" that may be paid for by Medicare or Medicaid.[11] For purposes of the Inducement Law, the term "remuneration" is generally defined as any item or service furnished to a Medicare or Medicaid beneficiary "for free or for other than fair market value."[12] Each violation of the Inducement Law is punishable by a CMP of up to $10,000, an assessment of not more than three times the amounts claimed from Medicare or Medicaid by the provider, and exclusion from participation in federal healthcare programs.[13]

Given that the risk of penalty under the foregoing laws could stymie constructive attempts at ACO formation, Congress granted the Secretary explicit legislative authority to "waive such requirements" of the above-referenced laws "as may be necessary to

[10] 42 U.S.C. § 1320a-7a(b)(2).
[11] 42 U.S.C. § 1320a-7a(a)(5); 42 C.F.R. § 1003.102(b)(13).
[12] 42 U.S.C. § 1320a-7a(i)(6); 42 C.F.R. § 1003.101. Although certain limited categories of items or services are exempt from implicating the definition of "remuneration" under the Beneficiary Inducement Law (e.g., certain preventative care services, differentials in cost-sharing amounts as part of a health plan design), none of these exceptions are pertinent to the Policy.
[13] 42 U.S.C. § 1320a-7a(a); 42 C.F.R. § 1003.105(a)(1)(i).

carry out" the Program.[14] The Secretary, in turn, has delegated this authority to the Agencies.

In the Interim Final Rule, the Agencies specifically defined several transactions for which they will waive application of the above-referenced laws. They take this action on the basis that the specified transactions should (1) enable ACOs to more effectively advance the goals of the MSSP, and (2) simultaneously pose minimal risk of healthcare fraud. The protected transactions include the two types of transactions referenced in the proposed rule published by the Agencies in April 2011 as well as three new types of transactions.[15] Each is described below.

Please note that protection under one or more of the waivers outlined below will not immunize an arrangement from scrutiny under state fraud and abuse laws or any other federal or state laws (e.g., antitrust laws, laws governing operation of tax-exempt entities, etc.).

Waiver for Certain "Start-Up Arrangements"

The Agencies will waive application of the Stark Law, AKS, and the Gainsharing Law in connection with certain "start-up" arrangements that pre-date an ACO's participation in the MSSP. These might include, among other things, the provision of EHR support, care coordination resources, and data reporting systems. To receive protection, however, a start-up arrangement must satisfy all of the following requirements:

- Eligible Remuneration. The ACOs governing body must make—and contemporaneously document—a determination that the underlying remuneration and overall arrangement are "reasonably related" to one or more of the following purposes of the MSSP (collectively, the Program Purposes):

[14] 42 U.S.C. § 1395jjj(f).
[15] 76 Fed. Reg. 67992, 67993.

  - Promoting accountability for the quality, cost, or overall care for a Medicare patient population;
  - Managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and/or
  - Encouraging investment in infrastructure and redesigned care processes for high-quality and efficient service delivery for Medicare beneficiaries and other patients.

- Eligible Participants. The arrangement must include only those who (1) maintain a good-faith intent to develop an ACO to participate in the MSSP in a specified target year and (2) take diligent steps to develop the ACO to be eligible for MSSP participation in the target year (including satisfaction of the MSSP requirements related to governance, leadership, and management). At least one of the participants must be eligible to "form" an ACO under CMS rules (e.g., a physician, a hospital employing a physician, a joint venture between a hospital and one or more physicians, an RHC, a FQHC). Participants may not, however, include a home health agency, durable medical equipment (DME) supplier, or a person who manufactures or distributes drugs or medical devices. The other participants to the transaction must be either (1) ACO suppliers, providers, or participants or (2) those outside the ACO who have a role in coordinating and managing care for ACO patients.
- Waiver Duration. The waiver period for an arrangement meeting the foregoing requirements begins one year before the application due date for the target year (or immediately in the case of those looking at 2012 as the target year). The waiver period would end on the start date of the resulting MSSP participation agreement. If CMS denies the ACO's application, however, the waiver period would end on the date of the denial notice. If the ACO should fail to submit an application for a target year, the waiver period would expire on the earlier of (1) the application due date or (2) the date on which it submits its statement of reasons for non-submission. Under such circumstances, the ACO could seek an extension of the waiver if it could

demonstrate a likelihood of successfully developing an ACO for participation in the MSSP in the ensuing year.

- Contemporaneous Documentation. The Agencies mandate that the following documentation be developed contemporaneously with the arrangement, maintained for a period of ten years after completion of the arrangement, and made available upon request by the Agencies:
    - A description of the arrangement (including a list of the parties, underlying items and services, effective date, and financial terms).
    - A description of the diligent steps taken to develop the ACO in compliance with the MSSP's governance, management, leadership, and other requirements.
    - The date and manner of the governing body's authorization of the arrangement (including the basis for the governing body's determination that the arrangement is "reasonably related" to one or more of the Program Purposes described above).
    - A description of diligent steps taken to develop the ACO.

An ACO may use the pre-participation waiver—including any extensions—only one time.

If the ACO fails to subsequently submit an application for participation in the MSSP for the target year, the ACO must submit a statement describing the reasons it was unable to submit an application. It should be noted that the Agencies will require that the ACO disclose the nature of—and parties to—each such arrangement on the ACO's website. The Agencies intend to issue further guidance regarding the disclosure requirement in the near future.

This “Start-Up Arrangements Waiver” should afford significant flexibility to Medicare providers and suppliers who are committed to form a new ACO to participate in the MSSP as well as to those who are part of an existing ACO that has not yet participated in the MSSP. Specifically, in its final year of “ramp up” entering the Program for the first time, the ACO and its participating providers and suppliers (other than drug, device, home health, and DME suppliers) may exchange items, services, and facility access on a non-fair market value basis. Notably, however, these transactions may not commence until the ACO has a governing body that is duly constituted and, thereby, capable of providing the mandatory contemporaneous determination that the transaction is “reasonably related” to the Program Purposes.

It is important to note that an exchange of items, services, or facilities can only be protected under this waiver if at least one of the following are parties to the arrangement: (1) the ACO or (2) a physician, hospital with employed physicians, an RHC, or a FQHC intending to participate in the ACO. So long as this requirement is met, however, the other parties to the arrangement may even be outside providers or suppliers (i.e., those providers or suppliers not participating in the ACO but who assist in coordinating and managing care for ACO participants).

If properly utilized, this waiver will give ACO participants significant flexibility to engage in non-market exchanges to develop and roll out the infrastructure needed to facilitate ACO participation in the Program. This could include the development and roll out of electronic medical records, clinical protocols, mechanisms for data exchange, common operational policies, recruitment incentives, funding pay-for-performance pools, as well as other key items and services that the ACO governing board contemporaneously deems “reasonably related” to ACO participation in the Program. The waiver could also protect funding for in-kind items or services provided by ACO participants, providers, or suppliers for redistribution within the ACO network.

Though the ACO is not required to maintain a written agreement with each party to an approved arrangement, ACO management may want to demand such documentation as a matter of policy. Each such agreement would be signed by the parties involved and identify all material terms. Maintenance of such documentation will be invaluable if the arrangement is questioned in future years.

The Agencies also indicate that they will afford a six-month "tail period" for participants to "unwind" or "restructure" arrangements that were in place at the time a waiver expired or was terminated by the ACO. (It should be noted that the tail period would not be available for arrangements that are terminated by CMS.) This begs the question, however, as to whether the Agencies will demand that capital items previously furnished under the waiver (e.g., EHR hardware, data systems) would have to be returned to the donor (or purchased or leased on a prospective basis from the donor).

Waiver for "Program Participation Arrangements"

The Agencies will waive application of the Stark Law, AKS, and Gainsharing Law in connection with certain arrangements undertaken during the course of an ACO's participation in the Program:

- Eligible Remuneration. The ACOs governing body must make (and contemporaneously document) a determination that the remuneration (and overall arrangement) is "reasonably related" to one or more of the Program Purposes described above. The waiver is available regardless of whether the Medicare program serves as the source of the distributed remuneration. Thus, the waiver may be used to protect qualified arrangements resulting from commercial payor contracts.
- Eligible Participants.

    - The ACO must (1) have entered into—and remain in "good standing under" a Program participation agreement and (2) meet MSSP requirements relating to ACO governance, management, and leadership.
    - The arrangement may involve any combination of (1) the ACO, (2) ACO participants, (3) ACO providers, and/or (4) ACO suppliers.
    - Those outside the ACO who have a role in coordinating and managing care for ACO patients may also participate in the arrangements protected by this waiver.
- Waiver Duration. The waiver period for an arrangement meeting the foregoing requirements begins on the start date of the participation agreement and ends six months following the earlier of (1) expiration of the MSSP participation agreement (including any renewals) or (2) the date on which the ACO voluntarily terminates its MSSP participation agreement. If CMS terminates the ACO's participation agreement, however, the waiver will end on the date of the termination notice.
- Contemporaneous Documentation. The Agencies mandate that the following documentation be developed contemporaneous with the arrangement, maintained for a period of ten years after completion of the arrangement, and made available upon request by the Agencies:
    - A description of the arrangement (including a list of the parties, underlying items and services, effective date, and financial terms).
    - The date and manner of the governing body's authorization of the arrangement (including the basis for the governing body's determination that the arrangement is "reasonably related" to one or more of the Program Purposes described above).

The Agencies will require that the ACO disclose the nature of—and parties to—each such arrangement on the ACO's website. The Agencies intend to issues further guidance regarding the disclosure requirement in the near future.

Though the ACO is not required to maintain a written agreement with each party to an approved arrangement, ACO management may want to demand such documentation as a matter of policy. Each such agreement would be signed by the parties involved and identify all material terms. Maintenance of such documentation will be invaluable if the arrangement is questioned in future years.

The Program Participation Waiver affords ACO participants the broad ability to exchange items, services, or facilities on a non-fair market value basis so long as the ACO governing body determines that the transaction is reasonably related to at least one of the Program Purposes. The exception could be used, for example, to provide free or subsidized improvements to EHR platforms, training on new clinical techniques, new evidence-based protocols, and other items. Items or services exchanged on a non-market value basis under the protection of the Start-Up Arrangements waiver will receive continued protection under the Program Participation Waiver once the ACO is accepted into the Program. One remaining question is whether capital items provided under this exception must be purchased or returned at the end of the ACO's participation in the MSSP.

Waiver for "Shared Savings Distributions"

The Agencies will waive application of the Stark Law, AKS, and Gainsharing Law in connection with certain distributions by an ACO of shared savings payments received through the MSSP:

- Eligible Remuneration. Shared savings payments received by the ACO from the MSSP during the term of the ACO's participation agreement (even if distributed after the expiration of the participation agreement). Shared savings payments received from those outside the MSSP—perhaps from commercial payors—are not protected

under this exception (but could be structured to qualify for protection under the waiver for Program Participation Arrangements).

- Eligible Participants.
    - The ACO must have been a party to—and remained in "good standing" under—a MSSP participation agreement when the MSSP distributions were earned (even if the payout occurs after the MSSP participation agreement has since expired or been terminated by the ACO).
    - Distributions may involve those who qualified as any of the following in the year in which the MSSP payments were earned by the ACO: (1) ACO participants, (2) ACO providers, and/or (3) ACO suppliers.
    - Those outside the ACO who have a role in coordinating and managing care for ACO patients may also receive distributions protected by this waiver.
- Payments from Hospital to Physician. Payments made directly or indirectly from a hospital to a physician must not knowingly be made to induce the physician to reduce or limit medically necessary items or services to patients under his/her care.

This waiver protects only those distributions paid out by the Program. Distributions originating from other payors are not protected under this exception.

Those arrangements structured to comport with a Stark Law exception requiring a signed written agreement with the parties must—of course—abide by the requirement. Even in the rare circumstance in which a written agreement is not explicitly required by Stark (e.g., distribution of shared savings from a hospital to an employed physician), the parties to the arrangement should develop and maintain such written documentation as a matter of policy given that maintenance of such documentation will be invaluable if the arrangement is questioned in future years.

The Agencies also indicate that they will afford a six-month “tail period” for participants to “unwind” or “restructure” arrangements that were in place at the time a waiver expired or was terminated by the ACO. (The tail period would not be available for arrangements that are terminated by CMS.)

Waiver for “Use of Shared Savings”

- Eligible Remuneration. Any use of shared savings payments from the Program (other than outright monetary distribution) that the ACO’s governing body has deemed “reasonably related” to one or more of the Program Purposes described above.
- Contemporaneous Documentation. The Agencies mandate that the following documentation be developed contemporaneously with the arrangement, maintained for a period of ten years after completion of the arrangement, and made available upon request by the Agencies:
    - A description of the arrangement (including a list of the parties, underlying items and services, effective date, and financial terms).
    - The date and manner of the governing body’s authorization of the arrangement (including the basis for the governing body’s determination that the arrangement is “reasonably related” to one or more of the Program Purposes described above).

This waiver is available only for use of shared savings distributions received from the Medicare program. To the extent the ACO intends to use shared savings payments from a commercial or other payor, such an arrangement could be structured to comport with the waiver for Program Participation Arrangements.

Waiver for Stark-Compliant Arrangements

The Agencies will waive application of the AKS and Gainsharing Law in connection with the following arrangements:

- Eligible Remuneration. Any remuneration that simultaneously: (1) gives rise to a financial relationship under the Stark Law; (2) satisfies a Stark Law exception (so as not to trigger the Law's billing and referral prohibitions); and (3) is "reasonably related" to the Program Purposes described above.
- Eligible Participants.
    - The ACO must have been a party to, and remained in "good standing under," a MSSP participation agreement.
    - The other parties to the arrangement must have involved some combination of the ACO, ACO participants, ACO providers, and/or ACO suppliers.
- Payments from Hospital to Physician. Payments made directly or indirectly from a hospital to a physician must not knowingly be made to induce the physician to reduce or limit medically necessary items or services to patients under his/her care.

In effect, the Agencies are taking the position that payments to a physician from an ACO or its providers, participants, or suppliers pose minimal risk under the AKS if such payments: (1) qualify as a protected financial arrangement under the Stark Law; and (2) are made within the framework and structure of the MSSP. They are similarly taking the position that, when such arrangements involve payment from a hospital to a physician, the payments will not violate the Gainsharing Law so long as they are not intended to limit medically necessary care. When relying on this exception, the hospital and physician would be well-advised to maintain documentation establishing why the financial incentives should not affect medically necessary care.

Waiver for Patient Incentives

The Agencies will waive application of the AKS as well as the Inducement Law in connection with the following arrangements:

- Eligible Remuneration.
    - Items provided to a federal healthcare program beneficiary by an ACO, ACO participant, ACO provider, or ACO supplier for free (or below market value).
    - There is a “reasonable connection” between the items or services and the medical care of the beneficiary.
    - The items or services are in kind (the items are not cash or cash equivalents).
    - The items or services promote any of the following:
        - Preventative care.
        - Adherence to a treatment regime.
        - Adherence to a drug regime.
        - Adherence to a follow-up care plan.
        - Management of a chronic condition.
- Eligible Participants. The ACO has entered into a participation agreement (and remains in good standing) with CMS.
- Waiver Duration. For arrangements meeting the foregoing requirements, the waiver period would begin on the start date of the participation agreement. The waiver period will end six months following the earlier of the expiration (including any renewals) or termination of the ACO’s participation agreement.

The Agencies issued this exception to enable ACOs to engage patients in better managing their own healthcare.

Overlap with Other CMS Shared Savings Initiatives

Shared Savings Program Eligibility

In the PPACA, Congress took steps to prevent double-dipping and to assure that providers of services or suppliers that participate in certain programs are not eligible to participate in the MSSP. Section 1899(b)(4) of the Act excludes participants in "(A) [a] model tested or expanded under section 1115A [the Innovation Center] that involves shared savings under this title or any other program or demonstration project that involves such shared savings; (B) [t]he independence at home medical practice pilot program under section 1866E."

CMS has cited as a principal reason underlying the prohibition against participation in multiple initiatives involving shared savings is to prevent a provider or supplier from being rewarded twice for achieving savings in the cost of care provided to the same beneficiary. In the Proposed Rule,[16] CMS identified the following programs as overlapping with the MSSP:

- The Independence at Home Medical Practice Demonstration program;[17]
- Medicare Health Care Quality Demonstration Programs;[18]
- Multipayor Advanced Primary Care Practice demonstration;[19] and
- The Physician Group Practice (PGP) Transition Demonstration.[20]

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[16] 76 Fed. Reg. at 19631.
[17] 42 U.S.C. § 1395cc-5.
[18] 42 U.S.C. 1395cc–3.
[19] 42 U.S.C. § 1395b-1, currently operating in Maine, Vermont, New York, Rhode Island, Pennsylvania, North Carolina, Michigan, and Minnesota.
[20] *See* www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Transition_Design_Summary.pdf.

CMS notes that providers and suppliers would not be prohibited from participating in the MSSP if they are also participating in demonstrations and initiatives that do not involve Medicare patients or do not involve shared savings, such as state initiatives to provide health homes for Medicaid enrollees with chronic conditions.[21]

In the Final Rule, CMS concluded that it is not appropriate to extend this prohibition to individual providers and suppliers. Accordingly, an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the MSSP under one ACO participant TIN and another shared savings program under a different non-ACO participant TIN if the patient population is unique to each program.[22]

Further, to prevent duplication of beneficiary assignment under multiple programs, CMS will compare the participating TINs in each program or demonstration with those participating in the MSSP to ensure that TINs used for beneficiary assignment to an ACO participating in the MSSP are unique and that beneficiaries are assigned to only one shared savings program.[23]

Additional Overlapping Programs

In the Final Rule, CMS identified the following additional programs as overlapping with the MSSP:

- The Indiana Health Information Exchange (IHIE);
- North Carolina Community Care Network (NCCCN);[24]
- The Care Management for High-Cost Beneficiaries Demonstrations; and[25]

[21] Section 2703 of the PPACA.
[22] 76 Fed. Reg. at 67830.
[23] *Id.*
[24] Once a Medicare-enrolled TIN completes its participation in the IHIE or NCCCN, it may apply for the MSSP and would no longer be prohibited from participation because of duplication.
[25] 42 U.S.C. § 1395b-1.

- The Pioneer ACO Model through the Center for Medicare and Medicaid Innovation.[26]

CMS intends to update its list of duplicative shared savings efforts periodically to inform prospective MSSP participants and as part of the application.

Duplicate TIN Screening

CMS will review applications for participation in the MSSP to assess for overlapping TINs. TINs that are already participating in another Medicare program or demonstration involving shared savings will be prohibited from participating in the MSSP. An ACO application that contains TINs that are already participating in another Medicare program or demonstration involving shared savings will be rejected.

Transition of the PGP Demonstration Sites Into the Shared Savings Program

Beginning on April 1, 2011, the Physician Group Practice Transition Demonstration (PGP TD) will be rebased and extended for an additional two years with revised terms and conditions.[27] The performance period started January 1, 2011. All ten group practices who participated in the original PGP Demonstration have signed up for the Transition Demonstration.[28] The modifications include: shifting spending benchmarks to the national rather than regional level, aligning beneficiaries first with primary care physicians and then specialists, and implementing a patient experience of care survey.

The practices participating in the PGP TD will have the option to transition to the MSSP or an initiative in the Innovation Center when they are available. CMS intends to reconcile a performance period for the PGP TD if an organization participates in the Demonstration for a complete year. If the PGP elects to transition to another shared savings program during the middle of a performance year, CMS will work with that

[26] *See* http://innovations.cms.gov/initiatives/aco/pioneer/.
[27] *See* www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Transition_Design_Summary.pdf.
[28] CMS Press Release, August 8, 2011, www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_PR.pdf.

program to make arrangements to reconcile on the complete year on a program-specific basis.

PGP TD participants will not be permitted to participate in the MSSP concurrently. A condensed application form will be provided that will capture the information that is required for the standard MSSP application but that was not already obtained through its application for or via its participation in the PGP demonstration, and also allow the applicant to update any information as necessary.

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

The Innovation Center has recently implemented or is exploring several ACO-related initiatives:

- Pioneer ACO Model;
- Accelerated development learning sessions; and
- Advance Payment Model

CMS will take steps to ensure that there is no duplication of participation in shared savings programs through provider or supplier participation in both the MSSP and any Medicare shared savings models tested by the Innovation Center, or duplication of shared savings payments for beneficiaries aligned with providers and suppliers in both the MSSP and any current or future models tested by the Innovation Center.[29] Certain ACOs participating in the MSSP may be able to apply to participate in the Advanced Payment Model.

[29] 76 Fed. Reg. at 67834.

Antitrust

DOJ and the FTC (collectively, the Antitrust Agencies) have long asserted that "competition is one of the strongest motivations for firms to lower prices, reduce costs, and provide higher quality."[30] Passage in 2010 of PPACA required the Antitrust Agencies to articulate an antitrust policy that supports the MSSP without abandoning their traditional commitment to competition. In December 2010, a representative of the Antitrust Division assured a Senate subcommittee that the "Department believes that antitrust should not be an impediment to legitimate clinical integration and is focused on addressing the concerns of those contemplating the formation of beneficial ACOs."[31]

The Antitrust Agencies first attempted to address those concerns in March 2011, when they issued their Joint Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (JPPS).[32] The JPPS addressed five issues: (1) which ACOs would be covered by the policy; (2) how the Antitrust Agencies would analyze potential threats to competition posed by ACOs; (3) how ACOs could qualify for an antitrust safety zone; (4) which ACOs would need to obtain antitrust clearance from the Antitrust Agencies; and (5) how ACOs that were not required to obtain antitrust clearance but did not qualify for a safety zone could obtain greater antitrust clarity, including an expedited review by one of the Antitrust Agencies. For a variety of reasons the JPPS did little to relieve the antitrust concerns of most interested parties.

On October 20, 2011, the Antitrust Agencies issued their final Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the MSSP (Policy Statement).[33] The Policy Statement covers the same issues as the JSSP, but contains two major

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[30] Statements of Antitrust Enforcement Policy in Health Care, U.S. Department of Justice and Federal Trade Commission (1996) at p. 48.
[31] Dept. of Justice Statement of Sharis A. Pozen, Chief of Staff Antitrust Division, Before the Subcommittee On Antitrust, Competition Policy And Consumer Rights Committee On the Judiciary, United States Senate (Dec. 1, 2010) at p. 8.
[32] *Available at* www.justice.gov/atr/public/guidelines/269155.pdf. *See also* 76 Fed. Reg. 21894.
[33] *Available at* www.justice.gov/atr/public/health_care/276458.pdf. *See also* 76 Fed. Reg. 67026.

changes. First, the scope of the Policy Statement is not limited to ACOs created after passage of PPACA. Second, no ACO applicant is required to obtain antitrust clearance from the Antitrust Agencies as a condition for entry into the MSSP. How these changes will affect the antitrust concerns of ACO applicants remains to be seen.

Applicability of the Policy Statement

The JPPS limited its applicability to "collaborations among otherwise independent providers and provider groups, formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate, in the Shared Savings Program."[34] The term "collaboration" previously has been defined as "a set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in economic activity, and the resulting economic activity."[35] The Antitrust Agencies refer in the Policy Statement to all such "collaborations" as ACOs, and to their constituent providers and provider groups as "ACO participants," regardless of their approval status in the MSSP.[36]

The Antitrust Agencies deleted any reference in the Policy Statement to a starting date and expanded its coverage to all "collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Shared Savings Program."[37] In simple terms, therefore, the Policy Statement applies to any set of non-merger agreements among otherwise-independent entities for the purpose of engaging in joint economic activity and participating in the MSSP. Merger agreements remain subject to antitrust evaluation under the Antitrust Agencies' revised *Horizontal Merger Guidelines.*[38] The analytical principles underlying the Policy Statement also "apply to any ACO initiatives undertaken by the Innovation

[34] JPPS at p. 2.
[35] U.S. Dept. of Justice & Fed. Trade Comm'n, Antitrust Guidelines For Collaborations Among Competitors § 1.1 (2000).
[36] Policy Statement at p. 3.
[37] *Id*.
[38] U.S. Dept. of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines (rev. ed. 2010).

Center within CMS so long as those ACOs are substantially clinically or financially integrated."[39]

Applicability of Rule-of-Reason Antitrust Analysis

Courts routinely condemn agreements among competitors to set prices or allocate territories as being unreasonably anticompetitive and, therefore, per se violations of the antitrust laws.[40] The per se designation constitutes a legal presumption that the anticompetitive effects of such agreements always outweigh potential benefits, rendering analysis of individual facts and proposed justifications unnecessary. Agreements among competitors that are not condemned outright as per se antitrust violations—such as merger and joint venture agreements—are evaluated based on facts specific to the affected parties and markets to determine the reasonableness of any resulting reduction in competition. The standard used in making such individual determinations is called the "rule of reason."

In their 1996 Statements of Antitrust Enforcement Policy in Health Care, the Antitrust Agencies identified specific criteria that proponents of multi-provider network agreements must meet to merit rule of reason evaluation rather than per se condemnation. In summary, proponents of such agreements must demonstrate that their proposed combinations are likely to produce significant efficiencies that benefit consumers, and that any resulting price or market allocation agreements are reasonably necessary to achieve those efficiencies.[41] Agreements that require participants to share substantial financial risk generally meet those requirements because they establish efficiency goals as well as provide performance incentives.[42] Agreements that do not require financial risk sharing must provide for "meaningful clinical integration" sufficient

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[39] Policy Statement at p. 3, FN 7.
[40] *See, e.g., Arizona v. Maricopa County Med. Society*, 457 U.S. 332, 342(1982).
[41] U.S. Dept. of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care (1996) at pp. 42, 44.
[42] *Id.* at p. 28.

to produce significant performance efficiencies.[43] Meaningful clinical integration includes programs that evaluate and modify when necessary the practice patterns of provider participants, as well as programs that control costs and ensure quality by promoting interdependence and cooperation among providers.[44]

The Antitrust Agencies confirm in their Policy Statement that the ACO eligibility criteria established by CMS are consistent with the criteria specified in the 1996 Statements for rule of reason treatment of multi-provider agreements. The Antitrust Agencies further concede that organizations that meet the eligibility requirements of the MSSP are "reasonably likely" to produce the benefits of higher quality and lower cost healthcare services for consumers. Finally, the Antitrust Agencies note that CMS will monitor and evaluate the performance of approved ACOs, thereby providing an additional safeguard against unreasonable anticompetitive conduct. These findings, the Antitrust Agencies explain, support their decision in the Policy Statement to treat "joint negotiations with private payors as reasonably necessary to an ACO's primary purpose of improving health care delivery."[45] Accordingly, the Antitrust Agencies will provide rule of reason consideration to any ACO that participates in the MSSP and uses the same organizational structures as well as clinical and administrative processes to serve patients in the general commercial market.

Antitrust Safety Zone Criteria

The Policy Statement defines an antitrust safety zone for ACOs that satisfy the criteria established by CMS for participation in the MSSP. Meeting the safety zone criteria, however, provides no antitrust immunity. At most, ACOs that meet the safety zone criteria are deemed to present little competitive threat and, therefore, are highly unlikely to receive an antitrust challenge from the Antitrust Agencies.

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[43] *Id.*
[44] *Id.*
[45] Policy Statement at p. 5.

The process for determining safety zone eligibility requires calculating an ACO's share of services in the Primary Service Area (PSA) of each participant in that ACO. This is a multi-step process. Step one requires the identification of all services furnished by each participant in the ACO. Physician services correspond to the primary specialties designated on each physician's Medicare Enrollment Application as identified by its Medicare Specialty Code. Services for inpatient facilities correspond to the CMS Major Diagnostic Codes, and services for outpatient facilities will correspond to CMS defined categories. In step two, those services that are provided by at least two independent participants in the ACO are identified. These are the ACO's "common services." Step three requires the assignment of a PSA to each participant in the ACO that provides a common service. A PSA is the lowest number of contiguous postal zip codes from which the common service participant draws at least 75% of its patients for that service.

Calculation of the ACO's percentage share of each common service in each PSA occurs in step four. This is done by determining the total volume of common services provided by all ACO participants in a given PSA during the most recent calendar year for which data are available and dividing that number by the total volume of services provided by all providers—not just ACO participant—in that PSA during the same period. For the purpose of this calculation, "volume of service" means Medicare fee-for-service allowed charges or payments. CMS has agreed to provide the financial data necessary to make these calculations. ACOs whose combined common service share in each participant's PSA is 30% or less qualify for the antitrust safety zone, with certain qualifications and exceptions. Hospitals and ambulatory surgery centers that choose to participate in an ACO must do so on a non-exclusive basis to qualify for the safety zone. Physicians, regardless of their status as hospital employees, can be exclusive to a particular ACO and still qualify for the safety zone unless they fall within the Rural Exception or Dominant Participant Limitation.

The Rural Exception permits one physician per specialty from each rural county to participate in an ACO on a non-exclusive basis without affecting the ACO's safety zone

status, even if that physician's participation raises the applicable PSA share for that service above 30%. Rural hospitals, defined as a sole community hospital or a critical access hospital, also may participate in an ACO on a non-exclusive basis regardless of the 30% threshold without affecting the ACO's antitrust safety zone status.

The Dominant Provider Limitation applies to ACOs that include participants whose PSA share exceeds 50% for a service that no other participant provides in that PSA. Such ACOs may still qualify for the antitrust safety zone if their contracts with the dominant providers and commercial payors are non-exclusive. Qualified ACOs will remain in the safety zone for the duration of their agreements with CMS absent some significant change to the ACO's provider network. An ACO that exceeds the 30% PSA limitation due solely to patient growth will not lose its safety zone status.

Additional Antitrust Guidance

The Antitrust Agencies recognize that ACOs with high PSA shares may nevertheless be procompetitive and lawful. Noting that an "ACO that does not impede the functioning of a competitive market will not raise competitive concerns,"[46] the Antitrust Agencies identified the following conduct that ACOs with high PSA shares should be careful to avoid:

- Adopting clauses or provisions in contracts with commercial payors that prevent or discourage them from directing or incentivizing patients to choose certain providers, including providers outside of the ACO.

- Tying sales of the ACO's services to the purchase by commercial payors of other services, including services from providers outside of the ACO or providers affiliated with an ACO participant.

[46] *Id.* at p. 9.

- Contracting with ACO hospitals, ambulatory surgery centers, physician specialists other than primary care physicians, or other providers on an exclusive basis.

- Restricting a commercial payor's ability to provide cost, quality, efficiency, and performance information to aid health plan enrollees if such information is similar to the cost, quality, efficiency, and performance measures that are used in the MSSP.

- Sharing competitively sensitive data that an ACO's provider participants could use to set prices or other terms for services they provide outside of the ACO.

Newly formed ACOs—namely ACOs that had not signed or negotiated contracts with private payors or participated in the MSSP prior to March 23, 2010—can obtain additional antitrust guidance by requesting an expedited ninety-day review from one of the Antitrust Agencies. ACOs requesting such a review must first provide the following information to the Agency that will be conducting the review:

- All documents submitted by the ACO to CMS as part of its application to participate in the MSSP, including sample participation agreements, any financial arrangements between or among the ACO and its participants, as well as the ACO's bylaws and operating policies.

- Documents or agreements relating to the ability of the ACO's participants to compete with the ACO, either individually or through other ACOs or entities, or relating to any financial or other incentives that encourage ACO participants to contract with CMS or commercial payors through the proposed ACO.

- Documents discussing the ACO's business strategies or plans to compete in the Medicare and commercial markets and the ACO's likely impact on the prices, cost, or quality of any service provided by the ACO to Medicare beneficiaries, commercial

health plans, or other payors.

- Documents showing the PSA calculation for each ACO participant and either PSA share calculations or other data showing the current competitive significance of the ACO or its participants within the relevant geographic service area of each participant.

- Any restrictions that prevent ACO participants from obtaining information regarding prices charged by other ACO participants to commercial payors that do not contract through the ACO.

- Information showing the identity, including points of contact, of the five largest commercial health plans or other payors, actual or projected, for the ACO's services.

- The identity of any other existing or proposed ACO known to operate, or known to plan to operate, in any PSA in which the ACO will provide services.

Within ninety days after the information is received, the reviewing Antitrust Agency will notify the requesting ACO that its formation is not likely to raise competitive concerns, has the potential to raise competitive concerns, or is likely to raise competitive concerns. ACOs that raise competitive concerns are subject to further investigation by the Antitrust Agencies as well as antitrust enforcement action.

Conclusion

The Policy Statement assures potential ACO participants that their participation in the MSSP will be evaluated for compliance with federal antitrust law under the rule of reason. Healthcare providers who form and operate ACOs in a good-faith effort to lower the cost and improve the quality of healthcare should encounter little antitrust resistance. Providers who acquire market power as a result of participating in the MSSP

should expect to have their collective efforts closely monitored by the Antitrust Agencies.

One question that remains unanswered is whether more rather than less antitrust enforcement is necessary to lower healthcare costs while increasing quality. A 2010 report issued by the Massachusetts attorney general, for example, identified market leverage, measured by the relative market position of individual hospital or provider groups compared with other hospitals or provider groups within a geographic region, as a relevant factor in explaining the cause of significant price variations for healthcare in the state.[47] More recently, in a Policy Brief issued by the Committee for Economic Development, Alain C. Enthoven, Marriner S. Eccles Professor of Public and Private Management, Emeritus, at the Stanford University Graduate School of Business, called for the development and enforcement of an effective antitrust policy for healthcare as a necessary policy change, noting that "[m]any large hospital systems have formed with the result, if not the intent, of greatly increasing market power."[48] It appears that the role of antitrust enforcement in healthcare reform may be just beginning.

[47] Examination of Health Care Cart Trends and Costs Drivers, Report For Annual Public Hearing, Office of Attorney General Martha Coakley, March 16, 2010, at p. 4.
[48] To Reform Medicare, Reform Incentives and Organization, Alain C. Enthoven, Committee for Economic Development, 2011.

Tax

In coordination with the Final Rule, the Internal Revenue Service (IRS) released a Fact Sheet[1] providing further guidance for tax-exempt charitable organizations participating in the MSSP and other shared savings arrangements through an ACO. The Fact Sheet confirms that the earlier released Notice 2011-20[2] continues to reflect how the IRS expects existing tax laws to affect the charitable organization's participation in an ACO. Notice 2011-20 identified three important issues a charitable organization must consider when participating in the MSSP or other shared savings arrangements. The first is whether participation will fulfill a charitable purpose to support tax exemption under Section 501(c)(3) of the Internal Revenue Code (Code). Second, the charitable organization must avoid private benefit/inurement. Third and finally, the IRS also considered whether distributing shared savings from an ACO to the charitable organization would result in unrelated business income tax (UBIT).

Charitable Purposes

To maintain tax exemption under Section 501(c)(3) of the Code, the charitable organization must be both organized and operated exclusively for one or more exempt purposes.[3] Exempt purposes for a charitable organization, such as a tax-exempt hospital, include relief of the poor and distressed or of the underprivileged, advancement of religion, advancement of education or science, and lessening the burdens of government.[4] Furthermore, the IRS acknowledges that the "promotion of health has long been recognized as a charitable purpose" under certain circumstances.[5]

A charitable organization may jeopardize its tax-exempt status if more than an insubstantial part of its activities are not in furtherance of a charitable purpose.[6] However, activities that do not further a charitable purpose will not jeopardize the

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[1] FS-2011-11, *available at* www.irs.gov/pub/irs-news/fs-2011-11.pdf.
[2] 2011-16 I.R.B. 652, *available at* www.irs.gov/pub/irs-drop/n-11-20.pdf.
[3] Treas. Reg. § 1.501(c)(3)-1(a)(1).
[4] Notice 2011-20 (citing Treas. Reg. § 1.501(c)(3)-1(d)(2)).
[5] Notice 2011-20 (citing Rev. Rul. 98-15 and Rev. Rul. 69-545).
[6] Treas. Reg. § 1.501(c)(3)-1(b)(1) and § 1.501(c)(3)-1(c)(1).

organization's tax-exempt status if such activities are not attributable to its tax-exempt participants. For example, the IRS will generally treat an ACO structured as a separate nonprofit corporation as a separate taxable entity from the charitable organization.[7] Alternatively, if the ACO is structured as a partnership (or a limited liability company electing treatment as a partnership or disregarded for tax purposes), its activities will generally be attributable to the charitable organization.[8]

The Fact Sheet confirms the IRS' position in Notice 2011-20 that participation in the MSSP or similar arrangements with Medicaid are substantially related to the performance of a charitable purpose. Congress has stated that the goals for the MSSP are to increase the quality of care provided to Medicare beneficiaries and to lower the growth in Medicare expenditures.[9] Because these goals benefit the Medicare program and the provision of Medicare is the federal government's burden,[10] the charitable organization's activities toward meeting the MSSP goals will fulfill the charitable purpose of lessening the burdens of government.[11] The IRS similarly views participation in a shared savings arrangement with Medicaid as fulfilling the charitable purpose of relieving the poor and distressed or the underprivileged.[12]

Less certain is whether participation in a shared savings arrangement with commercial payors will fulfill a charitable purpose. The IRS recognizes in the Fact Sheet and Notice 2011-20 that some activities furthering the promotion of health are charitable. However, not every activity that promotes health furthers a charitable purpose.[13] The IRS' position is that regardless of whether participation in a commercial shared savings program aims at reducing costs in healthcare delivery, negotiating with private health insurers on behalf of unrelated parties generally is not a charitable activity. As such, an ACO

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[7] *See Moline Properties, Inc. v. Commissioner*, 319 U.S. 436 (1943).
[8] *See* Rev. Rul. 2004-51 and Rev. Rul. 98-15.
[9] 76 Fed. Reg. 67803.
[10] Rev. Rul. 81-276.
[11] *See* Treas. Reg. § 1.501(c)(3)-1(d)(2).
[12] *See id*.
[13] *See Federation Pharmacy Serv., Inc. v. Commissioner*, 72 T.C. 687 (1979), *aff'd* 625 F.2d 804 (8th Cir. 1980); and *IHC Health Plans Inc. v. Commissioner*, 325 F.3d 1188, 1197 (10th Cir. 2003).

looking to support its own tax-exempt status or that of its members should determine whether another charitable purpose is appropriate.

In fact, the IRS has reiterated this position in a subsequent private letter ruling (PLR)[14] denying tax exemption for an ACO. In the PLR, a tax-exempt hospital formed a nonprofit corporation. The purpose of the ACO was to negotiate and enter into payor agreements on behalf of the hospital and physicians that joined the ACO by paying a membership fee. Under the payor agreements, the ACO would receive and distribute savings to members when costs for covered services were less than budgeted amounts. The IRS compared the corporation to a health maintenance organization (HMO) in that it did not provide any healthcare services itself and it did not ensure that people who are not subscribers have access to healthcare or information about healthcare. In sum, the IRS concluded that the ACO's primary activity was to arrange for the provision of medical services only to those with whom the ACO stands in a contractual relationship, which is not charitable within the meaning of Section 501(c)(3) of the Code.[15] Based on this ruling, it is difficult to determine what commercial ACO activities, if any, the IRS will consider charitable.

Private Benefit/Inurement

According to Notice 2011-20, the IRS "anticipates that tax-exempt organizations typically will be participating in the MSSP through an ACO along with private parties." As a result, the ACO must be careful to avoid the charitable organization's net earnings inuring to the benefit of insiders,[16] such as physicians, or operating the ACO for the benefit of private rather than public interests.[17] Private benefit/inurement issues may arise for an ACO under a number of circumstances. For example, the charitable organization may provide a disproportionate amount of the start-up capital compared to

[14] PLR 201145025 (Nov.10, 2011).
[15] *Id*. (citing *Geisinger Health Plan v. Commissioner*, 985 F.2d 1210 (3d Cir. 1993).
[16] Treas. Reg. § 1.501(c)(3)-1(c)(2).
[17] Treas. Reg. § 1.501(c)(3)-1(d)1(ii).

its expected share in any savings or administrative services to manage payor contracts for ACO participants for little or no cost.

For purposes of the MSSP, the IRS provided five factors in Notice 2011-20 that a charitable organization should follow to avoid private benefit/inurement. The five factors, as further clarified in the Fact Sheet, are:

- The terms of the organization’s participation in the MSSP through the ACO (including the methodology for determining the share of MSSP payments or losses and expenses for all participants) are set forth in advance in a written agreement negotiated at arm’s length.

- CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP. If the ACO is terminated from the MSSP, the charitable organization should determine whether the ACO would continue to further charitable purposes.

- In the totality of the circumstances, the charitable organization's share of economic benefits from the ACO (including its share of MSSP payments) is proportional to the contributions the charitable organization provides to the ACO. If the charitable organization has an ownership interest in the ACO, the ownership interest is proportional to its capital contributions and returns of capital, allocations, or distributions. In determining capital contributions, the IRS will take into account all contributions made by the charitable organization and other ACO participants, in whatever form (including cash, property, or services).

- The charitable organization's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of potential economic benefits to which the charitable organization is entitled from the ACO.

- All contracts and transactions entered into by the charitable organization and the ACO, including contracts between the ACO and other participants or parties, are at fair market value.

Although an ACO should attempt to meet all of these factors, the Fact Sheet clarified that "no particular factor must be satisfied in all circumstances to prevent inurement or impermissible private benefit." Instead, the IRS will analyze all ACOs under its particular facts and circumstances.

Charitable organizations participating in non-MSSP programs should also structure the ACO to meet these factors to avoid private benefit/inurement. Nevertheless, it is still unclear how an ACO can avoid private benefit/inurement when negotiating payor contracts on behalf of independent physicians. In the same PLR where the IRS compared an ACO to an HMO, the IRS also compared the ACO to an independent practice association (IPA). Like an IPA, the IRS determined that the ACO does not actually provide care to patients, but only negotiates contracts with commercial payors, and receives and distributes payments from the commercial payor to physician members.[18] In this context, the IRS concluded that the ACO was similar to IPA organizations carried on for profit "for the primary benefit of its member physicians rather than the community as a whole."[19] Furthermore, although the ACO conducted educational activities for patients and physician members to improve the quality of healthcare, the educational activities were "primarily for the purpose of providing guidance to Participating Physicians and, thus, provide an additional private benefit to those physicians."[20]

Based on the IRS' strict application of private benefit/inurement principles and comparison of an ACO to an IPA, it is difficult to determine under what circumstances

[18] PLR 201145025.
[19] *Id*.
[20] *Id*.

an ACO involving a charitable organization and private individuals can avoid impermissible benefit/inurement. However, even if impermissible private benefit/inurement occurs, the amount that is attributable to the charitable organization will determine the overall effect on tax-exempt status. Therefore, if the ACO's activities are attributable to the charitable organization, it is important to determine whether the ACO activities resulting in private benefit/inurement represent no more than an insubstantial part of the charitable organization's total activities.

Unrelated Business Income Tax

UBIT is tax on a charitable organization's income earned from regularly carrying on an unrelated trade or business.[21] An unrelated trade or business is any activity that is not substantially related to the performance of the organization's charitable purposes.[22] A trade or business is substantially related to the organization's charitable purposes, and thus not subject to UBIT, if the activity contributes "importantly to the accomplishment of [charitable] purposes."[23] If the activity is not substantially related to a charitable purpose, the organization's taxable income is its share (whether or not distributed) of the gross income from the unrelated trade or business.[24]

In the absence of impermissible private benefit/inurement, the IRS anticipates that any MSSP payments received by a charitable organization from an ACO are substantially related to the charitable purpose of lessening the burdens of government. As such, the payments would not subject the charitable organization to UBIT. It logically follows then that because a Medicaid ACO fulfills the charitable purpose of relief of the poor, the IRS would not treat payments from a Medicaid ACO as UBIT either.

[21] 26 U.S.C. § 512.
[22] 26 U.S.C. § 513(a).
[23] Treas. Reg. § 1.513-1(d)(2).
[24] 26 U.S.C. § 512(c).

However, the concern again arises as to other non-MSSP shared savings programs. In the Fact Sheet, the IRS stated that non-MSSP activities could be substantially related to a charitable purpose and UBIT will depend on a variety of factors. The IRS notes that certain kinds of income, such as dividends and interest, may not be unrelated business income under Section 512(b) of the Code. Nevertheless, the difficulty for most ACOs participating in commercial shared savings programs will be relating the income to activities that further a charitable purpose. For reasons already discussed, the IRS appears to construe the activities of ACOs that do not directly provide care, but merely negotiate and manage contracts, as not furthering a charitable purpose. As such, it will be important for an ACO participating in non-MSSP activities to clearly articulate the charitable purposes it fulfills.

Other Tax-Exemption Guidance for ACOs

In addition to re-confirming and clarifying the earlier guidance provided in Notice 2011-20, the Fact Sheet also addressed two additional topics that were the subject of multiple comments. First, the IRS confirmed that an ACO organized as a distinct entity can obtain tax exemption if it meets all of the requirements under Section 501(c)(3) of the Code. However, the ACO should follow the same guidance the IRS provided for other charitable organizations participating in an ACO. In that respect, it is likely that an ACO participating in the MSSP or similar program with Medicaid would fulfill charitable purposes and qualify for tax exemption. If the ACO also participates in shared savings programs with commercial payors, it must ensure that the non-MSSP activities are not the predominant purpose of the ACO.

Additionally, the IRS confirmed that earlier guidance relating to EHRs will still apply to charitable organizations participating in the MSSP. In a May 2007 Memorandum,[25] the IRS stated that it will not treat the EHR benefits a hospital provides to its medical staff as inurement or impermissible private benefit if provided in compliance with the

[25] *Available at* www.irs.gov/pub/irs-tege/ehrdirective.pdf.

Memorandum and regulations issued by HHS. The IRS will continue to apply the guidance provided in the Memorandum to charitable organization providing EHR benefits in the context of participation in an ACO with its medical staff.

Monitoring and Termination

Section 425.316 - Monitoring of ACOs

The effective monitoring of ACOs, ACO participants, and ACO providers/suppliers, for financial and quality performance, as well as for continued compliance with the eligibility requirements of the MSSP and other applicable laws and regulations, is necessary to assure both the success and the integrity of the MSSP. Provisions of the Final Rule require the ACO to submit data, certified as to completeness and accuracy, that CMS will use to monitor ACOs and measure performance. Areas of focused monitoring include: (1) avoidance of at-risk beneficiaries and (2) compliance with quality performance standards.

Monitoring for Avoidance of At-Risk Beneficiaries

Section 425.316 of the Final Rule sets forth the "range of methods" that CMS will use to monitor and assess the performance of ACOs, ACO participants, and ACO providers/suppliers. These methods are those already employed by CMS in other contexts and include: (1) analysis of financial and quality data and aggregated annual and quarterly reports; (2) analysis of beneficiary and provider complaints; and (3) audits, including analysis of claims, chart review, beneficiary surveys, coding audits, and on-site visits.

Under PPACA, if the Secretary determines that an ACO "has taken steps to avoid patients at-risk in order to reduce the likelihood of increasing costs to the ACO," the Secretary may "impose an appropriate sanction" on the ACO, including "termination from the program."[1]

CMS is particularly concerned that ACOs may try to boost financial performance by avoiding at-risk beneficiaries. CMS may use the monitoring methods described above to

[1] *See* 76 Fed. Reg. 67950, citing Section 1899(d)(3) of the Act.

identify such behavior. Section 425.20 provides the following indicators of “at-risk beneficiaries”:

- Has a high risk score on the CMS-hierarchical condition categories (HCC) risk adjustment model;
- Is considered high cost due to having two or more hospitalizations or emergency room visits each year;
- Is dually eligible for Medicare and Medicaid;
- Has a high-utilization pattern;
- Has one or more chronic conditions;
- Has had a recent diagnosis that is expected to result in increased cost;
- Is entitled to Medicaid because of disability; or
- Is diagnosed with a mental health or substance abuse disorder.

If CMS identifies trends or patterns suggesting that an ACO has avoided at-risk beneficiaries, it will investigate further and follow-up as necessary, not only with the ACO and its ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACOs activities, but also directly with beneficiaries themselves. Such behavior may result in sanctions, up to and including termination from the MSSP.[2]

If CMS determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO’s activities avoids at-risk beneficiaries, it may immediately terminate the ACO or take any of the pre-termination actions under Section 425.216, discussed below. CMS may require the ACO to submit a CAP, which addresses the actions the ACO will take to assure that such avoidance of at-risk beneficiaries stops. The ACO will not receive any shared savings payments during the period of the CAP and will not be eligible to receive shared savings for the performance year attributable to the time period during which the

[2] *See* 42 U.S.C. 1395jjj(d)(3).

ACO avoided at-risk beneficiaries. Both during and after the CAP period, CMS will re-evaluate the ACO to determine if such behavior has, in fact, stopped.

CMS will terminate the ACO if the ACO has continued to avoid at-risk beneficiaries during or after the CAP implementation period. An ACO should self-monitor its own practices, as well as those of its ACO participants, ACO providers/suppliers, and others performing functions or services related to the ACO, to assure that such behavior does not take place, as the consequences are severe.

Monitoring for Compliance With Quality Performance Standards

CMS will monitor compliance with quality performance standards by reviewing an ACO's submission of quality measurement data under Section 425.500, and may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers. If an ACO does not meet quality performance standards (or fails to report on any quality measures), in addition to invoking the pre-termination and termination procedures at Sections 425.216 and 425.218, CMS may give the ACO a warning for the first failure to attain the minimum level in one or more domains (determined under Section 425.502), and impose a CAP. CMS has the discretion to forgo a warning and move to pre-termination and termination procedures. Following a warning or imposition of a CAP, CMS will re-evaluate the ACO's compliance with the quality performance standards the following year and continued failure will result in termination from the MSSP.

Other areas of monitoring are interference with the beneficiary's freedom of choice by improperly limiting or restricting referrals and care to ACO participants or ACO providers/suppliers in the same ACO and review of data to detect patterns that indicate cost shifting.

Termination and Reapplication

Sections 425.216-425.222

-Sections 425.216–425.218. Actions Prior to Termination; Termination by CMS-

CMS may terminate the ACO's participation agreement when an ACO, the ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the MSSP. Grounds for termination include the following: (1) non-compliance with eligibility and other requirements set forth in the Final Rule; (2) the imposition of sanctions or other actions taken against the ACO by an accrediting organization, state, federal, or local government agency leading to inability of the ACO to comply with the requirements for ACO participation; or (3) violations of the Stark Law, CMP law, and the AKS (each to the extent not subject to waiver regarding applicable waivers), antitrust laws, or any other applicable Medicare laws, rules, or regulations.[3]

CMS may immediately terminate an ACO. However, CMS may, in its discretion, take steps short of termination, but is not obligated to do so. These steps may include providing a warning notice to the ACO regarding non-compliance, requesting a CAP, and placing the ACO on a special monitoring plan.

-Section 425.220—Termination by the ACO-

An ACO may voluntarily terminate its agreement to participate in the MSSP by giving not less than sixty days prior written notice to CMS and its ACO participants. The ACO will not share in any savings for the performance year in which it notifies CMS of its decision to terminate the participation agreement. Note that this makes timing of the notice of voluntary termination an important consideration.

[3] *See* Final Rule at 580.

-Section 425-222—Reapplication After Termination-

An ACO that has been terminated from the MSSP, whether as a result of an involuntary or voluntary termination, may participate again only after the date on which the term of the original participation agreement would have expired but for the termination. If the termination was caused by or related to deficiencies, its application to participate must demonstrate that the ACO has corrected such deficiencies.

Payment Mechanisms

Overview

Under the MSSP, providers and suppliers furnishing Medicare Part A and Part B services to ACO beneficiaries will continue to bill and receive Medicare fee-for-service payments for those services. However, ACOs can receive an additional payment from CMS in the form of a shared savings distribution if the ACO meets certain MSSP requirements and realizes savings that exceed a "minimum savings rate" (MSR). As discussed in further detail below, the savings are calculated by analyzing the ACO's expenditures in comparison to an expenditure benchmark. Each ACO will determine, based on its unique agreements with its participants, providers, and suppliers, how any shared savings payments may be distributed among them. However, the MSSP does require that ACOs use part of the shared savings payment to further CMS' triple aim of better health, better healthcare, and reduced costs.

Arguably one of the most dramatic and well-received differences between the Proposed Rule and the Final Rule is the improved financial opportunities for ACOs participating in the MSSP, and in particular, the greater incentives and protection afforded to ACOs that elect the "Track 1" or one-sided risk model. Notably, as explained in further detail below, under the Proposed Rule, participants in the one-sided model only shared in savings after the first 2% of savings and were automatically transitioned to the two-sided risk sharing model in the third year of participation (i.e., they were required to share in losses as well as savings in the third year). Under the Final Rule, one-sided model participants' share of savings will be calculated as of the first dollar saved and there are no penalties or sharing in losses for the duration of the initial agreement period (i.e., the one-sided model is now upside only for the first three years of participation), thus providing a longer "on-ramp" for less-experienced ACOs.

The Final Rule included Table 5 that provides a comprehensive overview and comparison of the differences between the Proposed Rule and the Final Rule in terms of the shared savings determinations and payments.[1]

Selection of Risk Model[2]

For its initial participation agreement period, an ACO must elect to operate under either Track 1 (the one-sided model sharing savings with CMS in all three years) or Track 2 (the two-sided model sharing both savings and losses with CMS in all three years) for the agreement period. In any subsequent agreement periods, ACOs must operate under Track 2.

In a change from the Proposed Rule, the Final Rule modified Track 1 so that it is a shared savings only model for the duration of the initial three-year participation term. By contrast, under Track 2, ACOs will share in both savings and losses with CMS in all three years.

The Final Rule provides that if an ACO experiences a net loss during its first agreement period, it may reapply to participate in the MSSP under Track 2 under specified conditions. However, the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings during the subsequent agreement period.

Establishing the Benchmark[3]

In the Proposed Rule, CMS proposed two options for establishing the benchmark with the key difference between the two options being the beneficiary population used to determine historical expenditures. For the Final Rule, CMS chose “option 1”—looking at

[1] 76 Fed. Reg. at 67909-67910.
[2] *See* preamble discussion at 76 Fed. Reg. at 67904-67909.
[3] *See* preamble discussion at 76 Fed. Reg. at 67912-67927.

the beneficiaries that *would have been assigned* to the ACO in each of the three years preceding the start of the ACO's agreement period.

For each ACO participating in the MSSP, CMS will establish a per capita benchmark for Part A and Part B expenditures for the three-year agreement period. The benchmark is used to determine whether the ACO has achieved savings during the three performance years of the agreement. Generally, to set the benchmark, CMS must identify which expenditures are included and the applicable patient populations on which the benchmark is calculated. It must also make certain adjustments, such as adjustments for beneficiary characteristics, and establish an appropriate methodology for trending the three-year benchmark over the three performance years to update it for growth in national per capita Part A and B expenditures.

To determine whether the ACO has achieved any savings and may be eligible for a shared savings payment, CMS will compare the benchmark to the actual assigned beneficiary per capita Medicare expenditures in each of the three performance years. A new benchmark will be established consistent with these requirements at the start of each new participation agreement term. Under the Final Rule, CMS will compute the ACO's fixed historical benchmark by determining the per capita Parts A and B fee-for-service expenditures for beneficiaries that *would* have been assigned to the ACO in any of the three most recent years prior to the agreement period. CMS will use the ACO participants' TINs provided at the start of the agreement period to identify the applicable beneficiaries. The expenditure benchmark will be reset at the start of each agreement period.

More specifically, CMS will take the following eight steps to establish benchmarks:

- Calculate the historical payment amounts under Parts A and B fee-for-service claims for assigned beneficiaries using a three-month claims run-out period (the Proposed Rule used a six-month claims run-out period, which was deemed too long) with a

completion factor to address the time lag between the date of service and the date of payment. Included in this calculation are payments made under demonstration pilots or time limited programs, payment adjustments for Part A and B claims (such as geographic payment adjustments), and hospital VBP payments; however, payments for indirect medical education and disproportionate share hospital adjustments, hospital outlier payments, Part C and D payments, graduate medical education (GME), physician quality reporting system (PQRS), e-prescribe, and EHR incentive payments are not included;

- Make separate expenditure calculations for special populations of beneficiaries (end-stage renal disease (ESRD), disabled, aged/dual eligibles, and aged/non-dual eligibles);

- Adjust expenditures for changes in severity and case mix using prospective CMS-HCC risk scores;

- Truncate an assigned beneficiary's total annual Parts A and B fee-for-service per-capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for each benchmark year to minimize variation from catastrophically large claims;

- Determine national growth rates and trends expenditures for each of the first two benchmark years to the third benchmark year using CMS Office of the Actuary national Medicare expenditure data, and trend forward the benchmark to current year dollars to set the benchmark, using separate calculations for special expenditure categories (ESRD, disabled, aged/dual eligible beneficiaries, aged/non-dual eligible beneficiaries);

- Restate benchmark years one and two trended and risk adjusted expenditures in benchmark year three proportions for the special expenditure categories (ESRD,

disabled, aged/dual eligibles etc.);

- Weight each year of the benchmark as follows: benchmark year three at 60%: benchmark year two at 30%; benchmark year one at 10%; and

- Adjust the ACO's benchmark to account for the addition and removal of ACO participants or ACO providers/suppliers during the agreement period.

Once the initial benchmarks are set, using CMS' Office of the Actuary data, CMS will update the historical benchmark annually for each year of the agreement based on the flat dollar equivalent of the projected absolute amount of the growth in national per-capita expenditures for Parts A and B services under the Medicare fee-for-service program. To update the benchmark, CMS will make calculations for special categories of assigned beneficiaries (ESRD, disabled, aged/dual eligibles, aged/non-dual eligibles). Finally, CMS will reset an ACO's benchmark at the start of each participation agreement period.

Determining Shared Savings[4]

Under the MSSP, the existence of savings, if any, is first determined based on a comparison of the benchmark against the estimated average per-capita Medicare expenditures for Parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO, adjusted for beneficiary characteristics. If the expenditures are below the benchmark (i.e., there is a savings), the amount of savings must meet or exceed the MSR before an ACO can share in the savings.

Under the Final Rule, for Track 2 ACOs, the MSR is fixed at 2%. For Track 1 ACOs, CMS adopted its proposal to use a sliding scale MSR, based on the number of

[4] *See* preamble discussion at 76 Fed. Reg. at 67927-67936.

beneficiaries assigned to the ACO. Thus, under the Final Rule, the MSR for Track 1 ACOs is as follows:

Number of Beneficiaries	MSR (low end of assigned beneficiaries)	MSR (high end of assigned beneficiaries)
5,000 - 5,999	3.9%	3.6%
6,000 - 6,999	3.6%	3.4%
7,000 - 7,999	3.4%	3.2%
8,000 - 8,999	3.2%	3.1%
9,000 - 9,999	3.1%	3.0%
10,000 - 14,999	3.0%	2.7%
15,000 - 19,999	2.7%	2.5%
20,000 – 49,999	2.5%	2.2%
50,000 – 59,999	2.2%	2.0%
60,000 +	2.0%	

Under the Proposed Rule, Track 1 ACOs (the one-sided model) would only share in savings beyond the MSR, while Track 2 ACOs' shared savings would be determined as of the first dollar of savings. Under the Final Rule, both Track 1 ACOs and Track 2 ACOs will share on first dollar savings once the ACO achieves savings in excess of the MSR.

If there is a savings and if the savings exceed the applicable MSR, Track 2 ACOs can receive a greater share of the savings than Track 1 ACOs. Depending on the quality performance score the ACO receives (discussed in Quality Section of Member Briefing), once the savings exceed the applicable MSR, Track 2 ACOs can earn up to 60% of total savings while Track 1 ACOs can earn up to 50% of total savings. These sharing rates were the same under the Proposed Rule.

In a change from the Proposed Rule, CMS chose not to include an increase in the sharing rates for ACOs that involved a FQHC or RHC. In the Proposed Rule, the sharing rates for ACOs with FQHC or RHC participation increased on a sliding scale basis up to an additional 2.5% (for a total sharing rate of 52.5%) under Track 1 and up to an additional 5.0% (for a total sharing rate of 65%) under Track 2. Further, CMS

declined to adopt any additional incentives for other factors, such as care of dual-eligibles, composition of the ACO, or participation in similar shared savings arrangements with other payors.

The MSSP sets a maximum limit on the amount of savings distributions an ACO can receive. The limit is set as a percentage of the ACO's updated benchmark and is known as the "Performance Payment Limit." The Final Rule raises the Performance Payment Limits for both Track 1 ACOs and Track 2 ACOs. The Performance Payment Limit is now 10% of the benchmark for Track 1 ACOs (up from the 7.5% in the Proposed Rule) and 15% of the benchmark for Track 2 ACOs (up from the 10% in the Proposed Rule).

Calculating Sharing in Losses[5]

In the Proposed Rule, Track 1 ACOs were automatically transitioned to the two-sided risk sharing model (Track 2) in the third year of participation and had to repay a share of the losses if expenditures exceeded the benchmark by more than 2% in that third year. In the Final Rule, CMS acknowledged that its proposal for Track 1 ACOs would have deterred participation and, therefore, eliminated the provisions requiring Track 1 ACOs to accept the downside risk of sharing in losses. Thus, Track 1 ACOs have no risk of sharing in losses for any of the three years permitted for Track 1 participation.

The calculation for sharing in losses for Track 2 ACOs remains largely the same in the Final Rule and mirrors the methodology for calculating savings. First, a Track 2 ACO must have expenditures that exceed a minimum percentage around the benchmark to trigger losses. This percentage is known as the Minimum Loss Rate (MLR) and is a flat 2%. If an ACO has expenditures exceeding the MLR, the ACO will be required to pay a share of those excess expenditures, on a first dollar basis. The ACO’s share of the

[5] *See* preamble discussion at 76 Fed. Reg. at 67936-67937.

losses is calculated by multiplying the amount of excess above the updated benchmark by the "Shared Loss Rate," which is defined as one minus the final sharing rate. The Shared Loss Rate is capped under the Final Rule at 60% (which is consistent, as an inverse, with the maximum rate for shared savings). Also, CMS finalized the proposed shared loss limits of 5% in the first performance year, 7.5% in the second performance year, and 10% in the third performance year.

Repayment[6]

The Final Rule retains the requirement that Track 2 ACOs demonstrate that they are capable of repaying CMS for costs exceeding the benchmark. While Track 2 ACOs can specify their preferred method for repaying potential losses, CMS will determine the adequacy of the proposed repayment mechanism at the start of each year. The repayment mechanism must be sufficient to ensure repayment of losses equal to at least 1% of total per capita Medicare Parts A and B fee-for-services expenditures for assigned beneficiaries. Track 1 ACOs requesting interim payments must also demonstrate a satisfactory repayment mechanism at the time of application.

Under the Proposed Rule, an ACO would have been required to repay losses within thirty days of notification. The Final Rule increases the payment period to ninety days from notification. CMS eliminated entirely the concept of withholding payments to Track 2 ACOs to ensure their ability to repay losses. Thus, the proposed 25% withhold of payments for Track 2 ACOs is not part of the Final Rule.

[6] *See* preamble discussion at 76 Fed. Reg. at 67937-67942.

First-Year Performance in 2012[7]

Under the Final Rule, ACOs with start dates of April 1, 2012, or July 1, 2012, may opt for an interim payment calculation as of the end of their first twelve months of MSSP participation. Generally, the same methodology for determining shared savings and losses will apply to the interim calculation. However, for ACOs with start dates of April 1 or July 1, 2012, reconciliation for the first performance year will occur after the ACO's completion of its first performance year (which is defined as twenty-one months for an ACO with a start date of April 1 and 18 months for an ACO with a start date of July 1).

[7] *See* preamble discussion at 76 Fed. Reg. at 67942-67944.

TABLE 5. SHARED SAVINGS PROGRAM OVERVIEW[1]

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

[1] 76 Fed. Reg. at 67909-67910.

performance year expenditures;			payments for hospitals.	
Other adjustments	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments	Finalize proposal	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments	Finalize proposal
Maximum Sharing Rate	Up to 52.5% based on the maximum quality score plus incentives for FQHC/RHC participation	Up to 50% based on the maximum quality score	Up to 65% based on the maximum quality score plus incentives for FQHC/RHC participation	Up to 60% based on the maximum quality score
Quality Sharing Rate	Up to 50% based on quality performance	Finalizing proposal	Up to 60% based on quality performance	Finalizing proposal
Participation Incentives	Up to 2.5 percentage points for inclusion of FQHCs and RHCs	No additional incentives	Up to 5 percentage points for inclusion of FQHCs and RHCs	No additional incentives
Minimum Savings Rate	2.0% to 3.9% depending on number of assigned beneficiaries	Finalizing proposal based on number of assigned beneficiaries	Flat 2%	Finalizing proposal: Flat 2 percent
Minimum Loss Rate	2.0%	Shared losses removed from Track 1	2.0%	Finalizing proposal
Performance Payment Limit	7.5%	10%	10%	15%
Performance payment withhold	25%	No withhold	25%	No withhold
Shared Savings	Sharing above 2% threshold once MSR is exceeded	First dollar sharing once MSR is met or exceeded.	First dollar sharing once MSR is exceeded.	First dollar sharing once MSR is met or exceeded.
Shared Loss Rate	One minus final sharing rate	Shared losses removed from Track 1	One minus final sharing rate	One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate not to exceed 60 percent.
Loss Sharing Limit	5% in first risk-bearing year (year 3).	Shared losses removed from Track 1.	Limit on the amount of losses to be shared phasedin over three years starting at 5% in year 1; 7.5% in year two; and 10% in year three. Losses in excess of the annual limit would not be shared.	Finalizing proposal

Performance Measures, Quality, and Accountability

Title II, Subtitle A, Part I of PPACA sums up one of the driving forces for healthcare reform, linking payment to quality outcomes under the Medicare program.

Various initiatives have been underway in the last several years for collecting and reporting quality data, advancing the meaningful use of EHRs, and penalizing adverse outcomes such as medical errors and hospital-acquired conditions (HACs). Providers and suppliers have been focusing on quality dashboards, scorecards, evidence-based medicine clinical protocols, and disease registries to improve care and assess quality outcomes.

Hand-in-hand with these initiatives is the goal to advance transparency and accountability in provider and supplier performance and outcomes by implementing quality reporting, Hospital Compare,[1] Nursing Home Compare, Home Health Compare, and Dialysis Facility Compare, followed in 2011 by Physician Compare.[2] The VBP Program, the MSSP, and the more-flexible Pioneer ACO Shared Savings Programs initiatives also further these goals.

“You can’t manage what you can’t measure,” says Morris Cohen, Wharton professor and co-director, Fishman-Davidson Center of Service and Operations. So too of quality and quality improvement. The healthcare industry has an ever-growing cadre of metrics and quality and performance measures to move quality healthcare delivery forward in this millennium.

[1] Hospital Compare was created by CMS and the Hospital Quality Alliance, a public-private collaboration. It displays quality data for certain conditions and compares the quality of care provided by hospitals.
[2] Physician Compare, authorized by Section 10331 of PPACA, currently displays professionals’—eligible to participate in the Physician Quality Reporting System—practice information but will in the near future also publicly report quality data.

The Reporting Hospital Quality Data for Annual Payment Update program (now called the Hospital Inpatient Quality Reporting Program), mandated by Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[3] authorized CMS to pay hospitals a higher annual update when they successfully report designated quality measures. Initially, the MMA provided for a 0.4 percentage point reduction in the annual market basket (the measure of inflation in costs of goods and services used by hospitals in treating Medicare patients) update for hospitals that did not successfully report. The Deficit Reduction Act of 2005 (DRA) increased that reduction to two percentage points. Hospitals also have the Hospital Outpatient Quality Data Reporting Program.

Furthering quality care delivery, the DRA authorized, for discharges on or after October 1, 2008, Medicare and Medicaid not to make additional payment for cases in which one of the selected conditions, known as HACs, was not present on admission. That is, the case would be paid as though the secondary diagnosis were not present.

In addition, quality reporting has been expanded to include physicians under the Physician Quality Reporting Initiative (PQRI), now known as the PQRS. Quality reporting also was rolled out to nursing homes and home health agencies. Quality reporting for long term care hospitals, inpatient rehabilitation hospitals, psychiatric hospitals and hospices, and Prospective Payment System-exempt cancer hospitals will begin in FY 2014. Quality reporting is the prelude to the VBP Program.

The VBP Program authorized under the PPACA allows CMS to pay hospitals based on their performance. The VBP Program rule was published in the *Federal Register* on

[3] Pub. L. No. 108-173, § 501(b) (2003), amending Social Security Act § 1886(b)(3)(B)(vii), established the original authority for the hospital inpatient quality reporting program as amended by the Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5001(a) (2006), amending Social Security Act § 1886(b)(3)(B)(viii).

May 6, 2011.[4] It includes twelve clinical process of care measure sets for the VBP Program.[5] It also includes patient experience of care measures for the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.[6] An achievement performance standard (achievement threshold) for each measure is set out in the rule.[7] The benchmarks for each measure also are set forth in the rule.[8] CMS is considering publishing the baseline achievement thresholds and benchmarks on Hospital Compare.[9]

CMS proposes to add an additional clinical process of care measure, Medicare spending per beneficiary, for the FY 2014 VBP Program.[10] There also are outcome measures for the 2014 Hospital VBP Program, which include mortality claims-based measures, complications/patient safety/inpatient quality indicators, composite measures, and HAC measures.[11] There also are three achievement thresholds and benchmarks related to mortality outcome measure for the 2014 VBP Program.[12]

The Physician Resource Use Measurement and Reporting Program now referred to as the Physician Feedback/Value Modifier Program was initiated under Section 131 of the Medicare Improvements for Patients and Providers Act of 2008 as expanded by Section 3003 of PPACA. Under the Physician Feedback/Value Modifier Program, CMS gathers claims data to measure resources and quality of care. CMS then provides feedback reports to physicians.

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[4] 76 Fed. Reg. 26490-26547 (May 6, 2011), Medicare Program; Hospital Inpatient Value-Based Purchasing Program Final Rule.
[5] *Id.* at 26510, Table 2—Final Measures for FY 2013 Hospital VBP Program.
[6] *Id.* at 26510.
[7] *Id.* at 26512, Table 4—Achievement Thresholds That Apply to the FY 2013 Hospital VBP Program Measures.
[8] *Id.* at 26515-26516, Table 6—Benchmarks That Apply to the FY 2013 Hospital VBP Program Measures.
[9] *Id.* at 26511.
[10] *Id.*
[11] *Id.*, Table 3—Finalized Outcome Measures for the FY 2014 Hospital VBP Program.
[12] *Id.* at. 26513, Table 5—Achievement Thresholds for the FY 2014 Hospital VBP Program Mortality Outcome Measures (Displayed as Survival Rates); *Id.* at 26516, Table 7 Benchmarks That Apply to the FY 2014 Hospital VBP Program Mortality Outcome Measures (displayed As Survival Rates).

Section 3003 of PPACA expands this Program by requiring CMS to include quantification and comparisons of patterns of resource use/cost among physicians. In addition, under Section 3007 of PPACA, CMS must include the cost and quality data when calculating payments for physicians by applying a value-based payment modifier under the Physician Fee Schedule starting in 2015 and phased in by 2017. CMS will use this modifier to initiate the Physician Value Based Purchasing Program.

The MSSP is a voluntary initiative aligning both hospitals and physicians in a "value based" Medicare healthcare quality delivery system. Under Section 3022 of PPACA, the ACO participants will share in the cost savings when they meet certain performance measures and cost-savings benchmarks. Additionally, the PQRS requirements are aligned with the quality performance standards for the MSSP.

The intent of the MSSP is to: "(1) promote accountability to Medicare beneficiaries;(2) improve coordination of FFS items and services; and (3) encourage investment in infrastructure and redesigned care processes to achieve high health care quality and efficient service deliver."[13] CMS has adopted three aims for improving healthcare to Medicare beneficiaries and the American population: "(1) better care for individuals; (2) better health for populations; and (3) lower growth in expenditures."[14]

Under the MSSP Final Rule, CMS establishes thirty-three individual quality performance standard measures in four domains.[15] CMS also designates quality performance standards for each measure.[16] The recurring theme, between the VBP Program and the PPACA reform measures, which include the MSSP, is prevention, disease

[13] 42 C.F.R. pt. 425 Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations Final Rule; 76 Fed. Reg. 67802-67990; 76 Fed. Reg. 67804.
[14] *Id.*at 67804.
[15] *Id.* at 67889-67890 - Table 1: Measures for Use in Establishing Quality Performance Standards That ACOs Must Meet for Shared Savings.
[16] *Id.*

management, patient-centered care, and patient safety. This section of the Member Briefing discusses the quality and other reporting requirements under the MSSP.

ACO Quality and Other Reporting Requirements

Perhaps no other area of healthcare has been more debated than the issue of "quality." Just following commercials in the media by health providers, the public is led to believe that healthcare in the United States is in a sea of quality with each provider giving its patients the best care possible. There are factors that indicate otherwise. Section II.F. of the MSSP regulations, in interpreting the requirements of Section 1899(b)(3)(A) of the Act, as added by the PPACA, lays out measures to assess the quality of care provided by an ACO. By requiring the submission of certain data, the Secretary intends to measure the quality of care furnished by ACOs as well as the value provided. This section of the regulations is intended to address two of the three goals mentioned above: (1) better care for individuals, and (2) better health for populations.[17]

Measures to Assess the Quality of Care Furnished by an ACO

ACOs will be required to report the data and meet the quality performance criteria described. The Final Rule responded to criticism over the extent and complexity of quality reporting by reducing the number of quality measures from sixty-five to thirty-three, which will be scored as twenty-three measures. Further, as mentioned earlier, the Final Rule indicates that CMS intends to monitor patterns of avoiding at-risk beneficiaries and misuse, underuse, and overuse of services over time. This monitoring will be done with internal data without requiring additional reporting.

Considerations in Selecting Measures

Value based purchasing is viewed as an important step in revamping how services are paid for as CMS moves toward rewarding better value outcomes and innovations. CMS

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[17] *Id.* at 67889-67890.

concluded it is most appropriate to focus on quality measures that directly assess overall quality of care furnished to beneficiaries.

Quality Measures for Use in Establishing Quality Performance Standards That ACOs Must Meet for Shared Savings

As noted above, the Final Rule reduced the sixty-five quality measures in the Proposed Rule for the purpose of calculating the ACO quality performance to 33 measures total or 23 scored measures of which seven are collected via the patient experience survey modules, three are collected via claims, one is calculated from EHR Incentive Program data, and 22 are collected via the Group Practice Reporting Option (GPRO) web interface.[18] ACOs will report quality measures and must meet the performance criteria to share in savings during each of the three years within the three-year agreement period.

For the first year, CMS defines quality performance as the completed accurate reporting of all quality measures. For subsequent years, pay for performance will be phased in. The ACO will continue to report all measures, but the ACO performance will be determined based on the minimum attainment level of measures.

CMS has identified four key domains within the dimensions of improved care and improved health that will serve as the basis for assessing, benchmarking, rewarding, and improving ACO quality performance:[19]

Better Care of Individuals

1. Patient/Caregiver Experience
2. Care Coordination
3. Patient Safety

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[18] 76 Fed. Reg. 67891.
[19] 76 Fed. Reg. 67873; 76 Fed. Reg. 67899 Table 4 – Total Points for Each Domain Within the Quality Performance Standard.

4. At-Risk Population

ACOs must report all measures within a domain. If an ACO does not achieve attainment levels on 70% of measures in each domain, CMS will take action as described in Section 425.216(c). If the ACO achieves the minimum attainment level for at least one measure in each of the four domains and also satisfies requirements for realizing shared savings under Subpart G, the ACO may receive the proportion of shared savings for which it qualifies. If the ACO fails to achieve minimum attainment level in all measures in a domain, it will not be eligible to share in any savings.

The Final Rule provides Table 1: Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings" and Table 2 "ACO Agreement Period Pay for Performance Phase in Summary."[20]

Requirements for Quality Measures Data Submission by ACOs

While CMS has initially identified thirty-three quality-of-care measures to be submitted by ACOs, the number and type of measures may vary over time. The measures in the initial measure set are mostly drawn from existing measure sets, including those used for the PQRS and the HCAHPS survey. CMS recognizes that claims-based reporting systems are inadequate to capture all of these measures (for example, lab claims data do not include lab test values, which are needed to score the measures), and will build out the GPRO survey tool used on a test basis in the PQRS. Initially, CMS will obtain all claims-based measures from claims data, so ACOs will not be required to report the same information twice. HCAHPS surveys will be conducted by a contractor at CMS expense for 2012 and 2013. ACOs will retain CMS-approved CAHPS contractors thereafter.

Some GPRO measures will be based on provider attestation and thus will require CMS to validate them. Other data may be validated as well, as CMS did during the PGP demonstration project.

[20] *Id.* at 67889-67890.

Quality Performance Standards

In establishing a methodology to determine whether an ACO delivers care of a high enough quality to allow it to share in any savings, CMS adopted the requirement that an ACO must achieve the relevant performance standard on at least 70% of the quality measures in each of four domains. Failure to meet that threshold for one year would require the ACO to implement a corrective action plan. Failing to meet the standard two years in a row would result in MSSP agreement termination. The performance score approach would allow an ACO to earn more of the shared savings the better it scores on quality measures. In the first year, however, the sharing of any savings would be based on a pay-for-reporting approach, rather than a pay-for-performance approach. This is intended to give ACOs time to ramp up to full operations, and to give CMS the opportunity to refine benchmarks and targets based on year one reporting.

As stated above, the thirty-three quality performance standard measures are broken down into four domains: (1) Patient/Caregiver Experience (seven measures, (2) Care Coordination/Patient Safety (six measures), (3) Preventive Health (eight measures), and (4) At-Risk Population (twelve measures). Each domain will have equal weight in determining the percentage of shared savings ultimately payable to an ACO—up to 50% in the case of the one-sided model, or 60% in the case of the two-sided model. Weighting the domains equally serves a policy goal of allowing all ACOs an equal opportunity to share in savings despite the fact that different ACOs may emphasize different programmatic efforts based on the unique characteristics of their patient populations. It also makes the point that each domain is equally important to the quality of care.

In year one, this is a pay-for-reporting scheme, and 100% reporting will yield a 50% or 60% share of shared savings, depending on the ACO's model. In future years, an ACO may earn a maximum of two points for each quality measure, assuming it achieves a

ninetieth percentile performance level, when compared against a Medicare fee-for-service and Medicare Advantage population performance benchmark. Lower performance will yield lower quality point scores, as follows: eightieth percentile = 1.85 points, seventieth percentile = 1.7 points, etc., down to thirtieth percentile = 1.10 points. Performance below the thirtieth percentile (the minimum attainment level) on any given measure earns no points. One measure is given double weight: EHR adoption (maximum of four points). CMS abandoned as unrealistic its proposed baseline requirement of 50% of PCPs using EHRs to qualify as an ACO, but the double-weighting signals the metric's importance.

For example, if a one-sided model ACO (50% of shared savings) achieved a composite quality score of 70% in each of three domains (1.7 quality points x 3 = 5.1 quality points, or 70%), and 100% in the last one (ninetieth percentile = two quality points = 100%); then the ACO share of any savings would be the weighted average of 70% x 3 + 100% x 1 / 4 = 77.5% of the 50%, or 38.75 %.

An ACO that fails to meet the minimum attainment level for one or more domains in any year will be given a warning and the opportunity to resubmit its data; failure to meet this criterion in two years running may result in the termination of the ACO agreement. ACOs with a pattern of inaccurate or incomplete reporting may also be terminated.

Two chronic disease measures—for diabetes and coronary artery disease—are actually composite measures, with five submeasures for diabetes and two for coronary artery disease.

Remember, the measures and quality point allocation may change from year to year. CMS has indicated that the quality point allocation or other aspects of the quality performance standard requirements will be adjusted in future years by future rulemaking to meet the legislative mandate of continuous improvement of the quality of care.

The Incorporation of Reporting Requirements Under Section 1848 of the Act for the Physician Quality Reporting System

Section 1899(b)(3)(D) of the Act, as added by the PPACA, gives the Secretary authority to "incorporate reporting requirements and incentive payments related to the PQRI, under Section 1848, including such requirements and such payments related to electronic prescribing, EHRs, and other similar initiatives under Section 1848 . . . " and "to use alternative criteria than would otherwise apply under section 1848 for determining whether to make such payments."[21]

The Secretary has chosen to exercise its authority to permit certain of the PQRS requirements to be aligned with the quality performance standards for the MSSP. Specifically, the PQRS GPRO I will be incorporated under the MSSP and "eligible professionals" that are "ACO participating providers/suppliers will constitute a group practice under their ACO participant TIN for purposes of qualifying for a PQRS incentive under the Shared Savings Program." The ACO will be responsible for reporting the required measures on behalf of these group practice "eligible professionals" defined under Section 1848(K)(3)(A) of the Act as "(1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist, or a qualified speech-language pathologist; or (4) a qualified audiologist."[22]

Such eligible professionals may qualify for a PQRS incentive under the MSSP "only as a group practice and not as individuals. ACO participants and ACO providers/suppliers may not seek to qualify for the PQRS incentive payment outside of the MSSP.

[21] *See id.* at 67900.
[22] *Id.*

For this reporting alignment, the 2011 PQRS GPRO I option reporting through the GPRO web interface will be adopted with a few modifications.[23]

The ACO will report on the beneficiaries actually assigned in 2012. Therefore, the ACO will use the assigned beneficiaries to populate the GPRO data collection tool and will report on all measures required within the tool for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measure set, or individual measure if a separate denominator is required such as in the case of preventive care measures. If the assigned beneficiary pool is less than 411, then 100% of the beneficiaries' data will be reported under the tool.[24]

The calendar year reporting period for the ACO GPRO quality measures also aligns with the PQRS GPRO reporting period "for purposes of qualifying ACO TINs for a 2012 PQRS payment incentive."[25] The ACO, on behalf of eligible professionals within an ACO participant TIN, that satisfactorily reports the ACO GPRO measures during the reporting period will qualify under the MSSP for the PQRS incentive. As a byproduct, the "satisfactory reporting" of the GPRO measures also means that the ACO fulfills a portion of the quality performance standard for shared savings eligibility. The Final Rule does clarify that the ACO also must completely and accurately report the quality measures and meet the lower growth in costs criteria to be eligible for shared savings. However, the Final Rule does not make it all or nothing. If an ACO fails to meet the MSSP quality performance standard, eligible professionals who are in a group practice that is also an ACO participant TIN may still receive the PQRS incentive payment if the ACO meets the "satisfactory reporting requirements." No extra reporting will be required for eligible professionals or the ACO to earn the PQRS incentive under the MSSP if the ACO reports the measures required and meets the requisite standards. However, there will be no shared savings for eligible professionals who do not meet the MSSP quality

[23] 76 Fed. Reg. 67895.
[24] *See* 76 Fed. Reg. 67893-67894. *See also id.* at 67889-19571-19591,Table 1: Proposed Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings.
[25] *Id.* at 67948.

performance standard and lower growth in costs criteria. ACOs that are not composed of these “eligible professionals” will not participate in this alignment option.[26]

Requirements for Public Reporting

The myriad of Medicare reporting requirements under the PPACA not only have been initiated to improve quality within the program but also to foster transparency of care delivery.[27] CMS asserts that transparency of information can “facilitate patient choice” and is consistent and supports the” requirement of Section 1899 (b)(2)(A) of the Act for an ACO to be willing to ‘become accountable for the quality, cost and overall care’ of Medicare beneficiaries assigned to it.”[28] PPACA has implemented several additional reporting initiatives to further foster transparency in program care delivery. Section 3003 of PPACA makes aggregate information on physician resource use public; Section 3004 makes long term care hospital, inpatient rehabilitation facility, and hospice quality data public; Section 3005 makes certain cancer hospital quality data public; and Section 10331 requires the Secretary by January 1, 2011, to develop a Physician Compare Internet website for physicians similar to those adopted for nursing homes and hospitals.[29] This will include Medicare-participating physicians and eligible professionals reporting under the PQRI. Additionally, no later than January 1, 2013, the Secretary is to implement a plan to make information on quality and patient experience measures publicly available. This must include a transition plan to a value based purchasing program for physicians and other practitioners. Further, Section 10332 requires the Secretary to make certain standardized claims data under Medicare Parts A, B, and D available to entities qualified by the Secretary to use the data to evaluate provider and supplier performance based on measures of quality, efficiency, effectiveness, and use.[30]

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[26] *Id.* at 67902-67903.
[27] *Id.* at 67948.
[28] *Id.* at 67948.
[29] *See supra* note 2.
[30] CMS issued final rules implementing Section 10332 of the PPACA on December 7, 2011. *See* Medicare Program; Medicare Data for Performance Measurement, Final Rule, 76 Fed. Reg. 76542-76571 (Dec. 7, 2011) (to be codified at 42 C.F.R. pt. 401).

While not required by the PPACA, CMS, in its Final Rule, requires the ACO to report publicly certain information including: its name, location, and primary contact; organizational information, including ACO participants, any joint venture partners, members of an ACO board and its committees and committee leadership; MSSP performance payments received by the ACO and shared savings losses owed to CMS; the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources required to support the ACO goals of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion distributed among ACO participants; and results of patient care experience surveys and claims based measures.[31] In addition, "because an ACO will be considered a group practice under the Physician Quality Reporting System GPRO under the Shared Savings Program," CMS intends to report ACO quality performance GPRO measures on Physician Compare along with the performance of all other PQRS group practices.[32]

Aligning ACO Quality Measures with Other Laws and Regulations

The quality standards for hospitals have recently been released and the quality standards for ACOs outlined above under the PPACA provide a working dialogue for developing a "framework for ensuring quality care."[33] CMS has set forth in Table 1 of the regulations quality domains, categories of quality measures, and distinct frameworks to measure performance.[34] The National Quality Initiative was released on March 21, 2011.[35] CMS' MSSP final measurement set is aligned with the National Quality Strategy. The final set of measures also is closely aligned with PSQR. CMS will

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[31] 42 C.F.R. § 425.308; 76 Fed. Reg. 67981.
[32] *Id.* at 67948.
[33] *Id.* at 67903-67904. *See also* Final Rule, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education 76 Fed. Reg. 51476-51846 (Aug. 18, 2011) (42 C.F.R. pt. 412, 413, and 476); Final Rule, Medicare Program; Hospital Inpatient Value-Based Purchasing Program 76 Fed. Reg. 26490- 26547 (May 6, 2011) (to be codified at 42 C.F.R. pt. 422 and 480), as corrected 76 Fed. Reg. 39006-39007 (July 5, 2011).
[34] 76 Fed. Reg.67889-67890.
[35] U.S. Department of Health and Human Services, Report to Congress: National Strategy for Quality Improvements in Health Care (Mar. 21, 2011).

continue to work to align its measurement sets with other programs. CMS also intends to "further align the Shared Savings Program with the EHR Incentives Program."[36]

Informatics for Quality Reporting and EHR Compliance

The field of biomedical and health informatics brings together professionals in healthcare, computer science, management and decision science, biostatistics, engineering, and information technology to address issues in healthcare delivery, biomedical and health sciences research, health education, and clinical/medical decision making.[37]

Informatics tools that facilitate compliance with ACO provisions include:

- EHRs make patient data available to a range of healthcare providers for multiple uses, such as disease screening rate monitoring, treatment adherence, outcomes tracking, drug formulary management, and marketing.[38]

- Computerized Provider Order Entry facilitates creation of medical orders for implementation by nurses, pharmacists, and allied health staff immediately and over days or weeks after order creation.[39]

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[36] 76 Fed. Reg. at 67903.
[37] American Medical Informatics Association, About AMIA, *available at* www.amia.org/about-amia.
[38] V.L. Patel, A.W. Kushniruk, S. Yang, & J.F. Yale, *Impact of a Computer-Based Patient Record System on Data Collection, Knowledge Organization, and Reasoning*, J. AM. MED. INFORM. ASSOC., 2000 Nov-Dec; 7(6): 569-85; C.A. Caligtan & PC Dykes, *Electronic Health Records and Personal Health Records*, SEMIN. ONCOL. NURS., 2011 Aug; 27(3):218-28.
[39] S. Eslami, A. Abu-Hanna, & N.F. de Keizer, *Evaluation of Outpatient Computerized Physician Medication Order Entry Systems: A Systematic Review*, J. AM. MED. INFORM. ASSOC., 2007 Jul-Aug; 14(4):400-06; J.S As, P.Z. Stavri, & G.J. Kuperman, *AConsensus Statement on Considerations for Successful CPOE Implementation,* J.AM.MED. INFORM. ASSOC., 2003 May-Jun: 10(3):229-34; T.H. Payne, P.J. Hoey, P. Nichol, & C. Lovis, *Preparation and Use of Precostructed orders, Order Sets, and Order Menus in a Computerized Provider Order Entry System,* J. AM. MED. INFORM. ASSOC., 2003 Jul-Aug: 10(4):322-29.

- Clinical Decision Support Systems assist healthcare providers with diagnosis, treatment planning, medication and dosage selection, care guideline adherence, and other medical care-related decisions.[40]

- Patient portals support retrieval of test and treatment information, appointment scheduling, disease management education, and other health-related tasks by patients.[41]

- Critical pathways specify expected occurrences and treatment plans for conditions and procedures. When implemented within informatics applications, they can facilitate adherence to and flag deviations from best practice-based care.

Some advantages associated with use of informatics-based technologies include:[42]

- Records of all patients in a practice, rather than a sample, can be reviewed for adherence to quality measures.[43]
- Patient care and outcomes data maintained and transmitted in an electronic format can be analyzed more easily and in greater depth than data maintained in non-electronic formats.

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[40] D.W. Bates, G.J. Kuperman, S. Wang, T. Gendhi, A. Kittler, C. Spurr, R. Khorasani, M. Tanasijevic; and B. Middleton, *Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-Based Medicine a Reality*, J AM. MED. INFORM. ASSOC., 2003 Nov-Dec; 10(6): 523-30; G.J. Kuperman, A. Bobb, T.H. Payne, A.J. Avery, T.K. Gandi, G. Burns, D.C. Classen, & D.W. Bates, *Medication-Related Clinical Decision Support in Computerized Provider Order Entry Systems: A Review,* J AM. MED. INFORM. ASSOC., 2007 Jan-Feb; 14(1):29-40; J.M. Teich, J.A. Osheroff; E.A. Pifer; D.F. Sittig, R.A. Jenders, & The CDS Expert Review Panel, *Clinical Decision Support in Electronic Prescribing: Recommendations and an Action Plan*, J AM. MED. INFORM. ASSOC., 2005 Jul-Aug; 12(4):365-76.
[41] T.Y. Koonce, D.A. Guise, J.M. Beauregard, and N.B. Guise, *Toward a More Informed Patient: Bridging Health Care Information Through an Interactive Communication Portal*, J. MED. LIBR. ASSOC., 2007 Jan; 95(1):77-81; C.Y. Osborn; L.S. Mayberry; S.A. Mulvaney; & R. Hess, *Patient Web Portals to Improve Diabetes Outcomes: A Systematic Review,* CURR. DIAB. REP., 2010 Dec; 10(6): 422-35.
[42] D.W. Bates, E. Pappius, G. J. Kuperman, D. Sittig, H. Burstin, D. Fairchild, T.A. Brennan, & J.M. Teich, *Using Information Systems to Measure and Improve Quality*, INT. J. MED. INFORM., 1999 Feb-Mar; 53(2-3): 115-24.
[43] D.W. Bates & A.A. Gawande, *Improving Safety with Information Technology*, N.E.J.M., 2003; 348: 2526-2534.

- Patients requiring screening or treatment interventions can be more easily identified for follow-up.
- Electronic data formatting and storage can reduce duplicative and/or unnecessary test ordering.

All of these technologies, and others currently in development, aim to facilitate healthcare quality reporting.

Health Information Technology (HIT) and the Final Rule for ACOs

CMS made significant changes in its approach to HIT in the Final Rule. The Final Rule scales back on the level of infrastructure and investment required of ACOs participating in the Medicare MSSP while aligning closely with the CMS EHR Incentive Program[1] and maintaining much of the data sharing concepts in the Proposed Rule.

HIT and EHR Infrastructure

Under the Final Rule, ACOs participating in the MSSP will not be required to make the immediate IT investment contemplated by the Proposed Rule. At the same time, CMS makes clear its view that success under the MSSP will be easier by using HIT to coordinate care, have clinical and administrative systems in place, and handle the reporting required by statute.[2]

CMS initially proposed as a threshold requirement that at least 50% of an ACO's primary care physicians be "meaningful users" under the Medicare and Medicaid EHR Incentive Program by the beginning of the second performance year, with the goal of achieving full participation over time.[3] The quality measures proposed under the Care Coordination/Information Systems domain included success rates for becoming a meaningful user, using clinical decision support and e-prescribing. CMS also proposed that ACOs would need to have in place or under development a pathway to electronically exchange summary care information inside and outside the ACO consistent with the EHR Incentive Program. As a result of significant IT infrastructure and other data sharing expectations, industry analysts projected significant front-end HIT costs for ACOs exceeding several million dollars.[4]

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[1] 42 C.F.R. pt. 495 (EHR Incentive Program Rule).
[2] PPACA requires ACOs to "have in place a leadership and management structure that includes clinical and administrative systems" and to "define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care through the use of telehealth, remote patient monitoring, and other such enabling technologies. PPACA § 1899(b)(2)(F),(G).
[3] 76 Fed. Reg. 19528, 19600.
[4] *See* "The Work Ahead: Activities and Costs to Develop an Accountable Care Organization," American Hospital Association (Apr. 2011).

Section 425.506 of the Final Rule specifically "encourages" ACOs, ACO participants and ACO providers/suppliers to develop a robust EHR infrastructure without requiring it as a condition of participation. CMS will allow ACO participants who are Eligible Professionals in the EHR Incentive Program to participate in both programs and to receive meaningful use payments as well as distributions of any MSSP shareable savings.

Although CMS removed EHR participation as a threshold matter, it maintained one EHR participation requirement in the quality performance metrics. As part of the quality performance score, ACOs will report the percentage of primary care providers who successfully qualify for EHR incentive payments. This expansion in the measure allows first year EHR Incentive Program participants who qualify by adopting, implementing, or upgrading certified EHR technologies to contribute toward the MSSP quality measure before they become "meaningful users." For scoring purposes, EHR adoption is weighted twice that of other quality measures.[5]

With respect to data reporting, CMS limits many of the remaining quality care metrics in the preventative and the chronic care metrics to those included in the EHR Incentive Program for Stage 1 of Meaningful Use. The Final Rule maintains use of the CMS GPRO web interface tool for registry and EHR submission of clinical information, but recognizes other reporting methods such as claims data.

Overall, CMS recognized the growing capability for providers to use HIT without mandating overly specific information tools and systems. Nonetheless, as a practical matter, ACOs and ACO participants will need to make significant IT investments to bring physicians online with EHR, connect the ACO components, and enable data-sharing over the continuum of care in real time. As a result, the provisions in the OIG and CMS Shared Savings Waiver Program that allow for pre-participation start-up investments will be particularly desirable for ACOs. In addition, smaller ACOs without large institutional

[5] 42 C.F.R. § 425.506.

participants that are eligible for the new Advance Payment ACO model can receive shared savings from CMS upfront to help provide funding for HIT infrastructure.

Data Sharing

In its Final Rule, CMS lays out three core elements to facilitate data sharing under the MSSP. To a great degree, CMS adopted its Proposed Rule, with modifications related to the preliminary prospective identification of an ACO's beneficiary population and the timing for sharing certain reports. Responding to potential participants' concerns regarding a beneficiary's ability to decline detailed claims data sharing, CMS also has granted ACOs greater flexibility in how they contact beneficiaries, potentially helping ACOs to minimize the number of "opt-outs."

First, CMS will share aggregate reports with the ACO that, by definition, include only de-identified data under the Health Insurance Portability and Accountability Act (HIPAA). Second, CMS will share certain beneficiary-identifiable data with those ACOs who request it and are willing to comply with additional requirements. Finally, ACOs must not impede data sharing by limiting or otherwise restricting appropriate health information sharing among providers and suppliers, both within and external to the ACO.[6] CMS recognizes that robust data sharing is critical, at least initially, for ACOs to coordinate care and successfully participate in the MSSP. Nonetheless, CMS makes clear in the Final Rule that ACOs must develop their own HIT systems and further adopt health information exchange to gain real-time insight.[7] Throughout the data sharing rules, CMS also emphasizes fair information practices and adherence to the Privacy Rule under HIPAA.

Within the framework of "aggregate" and "beneficiary-identifiable" data, CMS will share three forms of data with ACOs, imposing an increasing level of requirements and obligations as those data range from aggregate to detailed beneficiary claims data. First, CMS will provide aggregate reports, including only de-identified data with respect to the ACO's beneficiary population and their utilization and expenditures, at the

[6] *See* 42 C.F.R. § 425, subpt. H.
[7] *See the discussion of "Data Sharing"* at 76 Fed. Reg. 67844.

beginning of the ACO's agreement and then continually, on a quarterly basis, throughout the agreement period.[8]

Next, ACOs may request identification lists for their preliminary prospectively assigned beneficiary populations at the beginning of their agreement period, quarterly, and at the beginning of each performance year.[9] These population lists will include four data elements: beneficiary name, date of birth, HICN, and sex. Before CMS will share these data, ACOs must meet three requirements: (1) the ACO must issue a request for the data to CMS; (2) the ACO data request must be for the purposes of population-based activities that relate to improving health or reducing healthcare costs, process development, case management, or care coordination; and (3) the ACO must certify, either as a HIPAA-covered entity or as the business associate of its participants and providers/suppliers, that its request constitutes the minimum necessary data required to conduct healthcare operations that fall under the first or second paragraphs of the healthcare operations definition found at 45 C.F.R. § 164.501 (e.g., primarily quality assessment/improvement activities and professional reviews).[10]

Finally, CMS will share beneficiary-identifiable claims data with ACOs monthly, including those claims made outside the ACO, provided five requirements are met.[11] Similar to the population list requirements, ACOs must: (1) formally request beneficiary-identifiable claims data; (2) limit their requests to certain defined purposes; and (3) make specific certifications with respect to the HIPAA rules and the ACO's uses of the claims data. In addition, ACOs also must: (4) execute a Data Use Agreement with CMS; and (5) may only request claims data about beneficiaries for whom they have provided notice and a meaningful opportunity to decline having their claims data shared. However, in contrast to the Proposed Rule, ACOs need not wait until a beneficiary makes an in-office primary care visit to provide that notice and meaningful opportunity to opt-out. Under the Final Rule, an ACO may also send written notice to preliminarily prospectively assigned

[8] 42 C.F.R. § 425.702.
[9] 42 C.F.R. § 425.702(c).
[10] *Id*.
[11] 42 C.F.R. § 425.704.

beneficiaries, and if the ACO does not receive an opt-out request within thirty days after the letter is sent, it may request claims data for those beneficiaries.[12] Although, the ACO must still present such beneficiaries with notice and an opt-out opportunity as part of their first in-office primary care services visit during the agreement period. This expanded approach has the potential to increase the ACO's ability to obtain detailed claims data and target specific populations and needs.

[12] 42 C.F.R. § 425.708(b).