



**ACCOUNTABLE CARE ORGANIZATION *FINAL REGULATIONS*:
ANALYSIS AND IMPLICATIONS***

Prepared by Hooper, Lundy & Bookman, P.C.

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TABLE OF CONTENTS

Page

INTRODUCTION AND EXECUTIVE SUMMARY1

 ACOs: The Basics1

 Challenges for Providers Under the SSP4

 ACO Alternatives.....5

ORGANIZATION OF AN ACO6

 Type of Entity6

 ACO Participants6

GOVERNANCE OF THE ACO.....7

 Governing Body.....8

 Executive Management.....8

BENEFICIARY ASSIGNMENT.....9

QUALITY REPORTING AND PERFORMANCE12

 Quality Domains and Measures12

 Quality Data Reporting.....13

 Performance Scores13

 The Impact of Performance Scores on Shared Savings15

 Audits of Quality Data.....15

OPERATIONAL REQUIREMENTS: PROCESSES AND PATIENT-CENTEREDNESS CRITERIA16

 Quality Assurance and Improvement Program (“QA Program”).....16

 Data Collection and Reporting Systems16

 Plan for Achieving and Distributing Shared Savings17

 Compliance Plan17

 Public Reporting and Transparency.....17

 Notification to Beneficiaries17

Marketing Materials and Activities	18
Auditing/Retention of Books and Records	18
Analysis of Potential Implications	18
AGREEMENT WITH CMS	19
Start Date of Agreement	19
Timing/Process for Evaluating Shared Savings.....	20
Data Sharing.....	20
Responsibility for New Program Standards.....	23
Significant Changes During the Agreement Period.....	23
SHARED SAVINGS DETERMINATION AND RELATED MODELS.....	24
Two Available Models.....	25
The Benchmark.....	25
Calculating Expenditures During Contract Period	25
Determining Shared Savings.....	26
Determination of Shared Losses	26
Shared Savings/Losses Overview	27
Option for Interim Payment.....	28
Other Considerations	28
MONITORING AND ENFORCEMENT.....	29
Termination.....	30
Reconsideration/Appeal Rights	30
ADVANCED PAYMENT MODEL	31
APM Eligibility.....	31
APM Selection.....	31
Evaluation Criteria.....	32

Scoring	32
APM Payments	33
Recoupment of Advance Payments	33
FEDERAL ANTITRUST	34
Limited Antitrust Protections.....	34
The ACO Safety Zone	35
Voluntary Expedited Review	36
Sharing of Information Between Agencies.....	36
FINAL FRAUD AND ABUSE WAIVERS FOR ACOs	37
ACO Pre-Participation Waiver	38
Shared Savings Distribution Waiver.....	41
Stark Compliance Waiver	42
Participation Waiver	42
Patient Incentives Waiver	43
Additional Policy Considerations	44
Scope of the Proposed Waivers	44
TAX-EXEMPT ISSUES.....	45
Unrelated Business Income Tax	46
Non-Program Activities of the ACO	46
Tax Issues Relating to Choosing Form of Entity.....	47
STATE LAW ISSUES	47
Corporate Practice of Medicine	48
State Anti-Kickback Laws	48
State Self-Referral Law.....	48
State Antitrust Laws.....	48

State Laws Regulating Health Plans	48
CONCLUSION	49
ADDITIONAL INFORMATION.....	50

INTRODUCTION AND EXECUTIVE SUMMARY¹

On November 2, 2011, CMS formally published final regulations (an advanced copy was released to the public on October 20, 2011), which implement the shared savings program (“SSP”) between Medicare and accountable care organizations (“ACOs”), for Medicare fee for service beneficiaries. The final regulations make substantial changes to the proposed ACO regulations, which were widely viewed as having set the bar too high for providers hoping to form or join in the formation of an ACO, and as not offering enough upside. The final regulations substantially address those shortcomings, in response to numerous public comments seeking changes to the proposed regulations. The regulations become effective on January 3, 2012.

In addition to the final regulations, companion notices were released the same day, providing antitrust guidance from the Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”) and final fraud and abuse waivers from CMS and the Office of the Inspector General (“OIG”). The final antitrust guidance and fraud and abuse waivers also are substantial improvements from the proposed guidance and proposed waivers, which had been widely criticized as containing far fewer protections for Medicare ACOs than the provider community previously anticipated.

ACOs: The Basics

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

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

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

Eligibility. The final regulations set forth specific eligibility requirements to participate in the SSP. An ACO must be:

- A distinct legal entity (this can be an existing entity, if it meets all the requirements);
- Recognized under applicable state, federal or tribal law; and
- Capable of performing all of the ACO functions identified in the rules.

Given the specific structure and governance requirements for ACOs, it may be easiest to use a new, special purpose entity. The ACO must also be composed of an “eligible group” of “ACO participants” defined as:

¹ Portions of this white paper are adapted with permission from P. Deeringer, *ACOs, or Else...Are ACOs a Strategic Imperative for Providers?* (May 2011). Copyright 2011, The Bureau of National Affairs, Inc., 1-800-372-1033, www.bna.com.

- Professionals in group practice;
- Networks of individual practices of professionals;
- Partnerships or joint venture arrangements between hospitals and professionals;
- Hospitals employing professionals;
- Critical Access Hospitals that engage in global billing;
- Rural health clinics (“RHCs”); and
- Federally qualified health centers (“FQHCs”).

Further, the ACO must have enough “ACO professionals” (*i.e.*, primary care physicians) to serve at least 5,000 Medicare fee for service beneficiaries.

Application Process – No Guaranteed Entry. The regulations require those wishing to become an ACO to submit a detailed application to CMS that provides extensive information, including details about how the prospective ACO plans to deliver high-quality care at lower costs for the beneficiaries it serves and how it intends to distribute shared savings. If the application is approved, the ACO must sign a three-year agreement with CMS to participate in the SSP (although the first year is actually slightly longer than a year, starting either April 1, 2012 or July 1, 2012 and ending on December 31, 2013). CMS will not *automatically* accept an applicant to become an ACO into the SSP.

Applicants interested in participating in the SSP must first obtain an ACO ID and submit a non-binding notice of intent (“**NOI**”). While CMS will begin accepting NOI’s on November 9, 2011, an applicant’s NOI must be submitted to CMS no later than January 6, 2012 to be eligible for the April 1, 2012 start date, or February 6, 2012 to be eligible for the July 1, 2012 start date. Applications for the April 1, 2012 start date must also be received no later than January 20, 2012. Applications for the July 1, 2012 start date must be received no later than March 30, 2012.²

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

- Meaningful representation by the ACO participants (or their representatives);
- One or more Medicare beneficiaries who do not have a conflict of interest with the ACO; and
- At least 75% of the governing body must be controlled by ACO participants (versus an outside entity, such as a health plan).
- However, the ACO may seek a waiver of the requirements that the governing body (1) include a Medicare beneficiary and (2) include 75 percent control by ACO participants, if it can justify why it seeks a variance and describe how it will appropriately involve ACO participants and/or Medicare beneficiaries as applicable.

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

Management. The final regulations impose several management requirements on an ACO, including:

² Potential applicants are encouraged to visit the CMS Shared Savings Program Application webpage at https://www.cms.gov/sharedsavingsprogram/37_Application.asp for additional information and instruction.

- ACO participants and ACO providers/suppliers must make a “meaningful commitment” to the ACO (*e.g.*, invest time, effort or money or otherwise commit to complying with the ACO’s processes and be held accountable for meeting the ACO’s performance standards);
- The ACO must have a physician-directed quality assurance/process improvement program;
- ACO participants must agree to comply with evidence-based clinical guidelines;
- The ACO must have information technology infrastructure;
- The ACO must adopt a compliance plan; and
- The ACO must have a written plan for achieving and distributing shared savings, and improving quality of care.

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

Substantial Quality Performance Requirements. In order to qualify for shared savings, an ACO would be required to meet certain CMS-defined quality and continuous improvement goals. The final regulations establish 33 quality performance measures (compared to 65 in the proposed regulations) across four equally-weighted quality domains: (1) patient/care giver experience; (2) care coordination/patient safety, (3) preventive health, and (4) at-risk population/frail elderly health. The ACO will be eligible for shared savings in proportion to its achievement of the quality performance domains, and the ACO will be responsible for complying with changing quality performance requirements over the course of its agreement with CMS. CMS will establish quality performance standards for each measure, including a performance benchmark. For the first performance year, the ACO can meet the quality performance requirements by completely and accurately reporting the specified metrics. In the second year, achievement will be based on measured scores for certain measures and reporting for others, and in the third year, scores will be based on measured scores for all measurements across each domain, with zero points awarded if the ACO falls below the minimum standard, with a sliding scale if it is above the minimum but below the target benchmark.

Downside Risk Under “Track Two.” ACOs have the option of choosing one of two program tracks, one of which requires the ACO to assume downside risk. The first track (the “one-sided model”) allows an ACO to operate on a shared savings-only track without assuming any downside risk. The second track (the “two-sided model”) allows ACOs to share in savings and assume liability for losses, in return for a higher share of any savings it generates.

Shared Savings Based on Three-Year Benchmark. Under the SSP, Medicare continues to pay individual providers and suppliers for specific items and services as it currently does under the fee for service payment systems. In addition, the CMS develops a benchmark for savings that each ACO must achieve to receive shared savings in each performance year. The benchmark is based on per capita expenditures for Medicare fee for service beneficiaries, who would have been assigned to the ACO for the three most recent years (*i.e.*, based on a rolling three-year average). The benchmark

will be subject to several adjustments, including for Medicare claims growth and beneficiary health status.

Shared Savings Subject to Several Restrictions. The regulations include several restrictions on an ACO's ability to qualify and receive shared savings under the SSP. For example, in addition to having to meet the quality performance metrics outlined above, an ACO must achieve a minimum savings threshold to qualify for any portion of the shared savings. In addition, an ACO is subject to a maximum shared savings percentage of up to 50% under the one-sided model (subject to a maximum sharing cap of 10% of the ACO's savings benchmark), and up to 60% under the two-sided model (subject to a maximum sharing cap of 15% of the ACO's benchmark).

Challenges for Providers Under the SSP

The SSP is not a "test field" for providers interested in experimenting with care integration and management strategies on their Medicare fee for service beneficiaries. To the contrary, it is better suited to sophisticated providers with experience in managing care under capitated contracts. Although the final regulations have greatly approved the appeal of the program, there remain important challenges to consider before electing to pursue participation. The following aspects of the SSP may present particular challenges for aspiring ACO participants, providers, and suppliers:

- **Extensive up-front and ongoing participation requirements.** ACOs will require substantial up-front capital, personnel (*e.g.*, a medical director and management staff), and organization (*e.g.*, full-fledged compliance and QAPI programs). CMS estimates that the total average start-up investment and first year operating expenditures for an ACO will total roughly \$1.8 million. In addition, ACOs will be subject to ongoing quality performance reporting requirements, public reporting obligations, and potential CMS audits. Many providers may lack the capital, organization, and discipline to achieve consistent compliance with the SSP's many requirements. One exception to this may be integrated delivery systems that include large multispecialty medical groups or capitated IPAs, particularly in states where such organizations are already heavily regulated much like insurance companies.
- **No guaranteed admission to the SSP.** An ACO's initial investment and organization may come to naught if CMS refuses to admit the ACO to the SSP. CMS has not clarified whether an ACO that otherwise meets the SSP requirements will be admitted, but under the final regulations, CMS will have (and presumably will exercise) discretion over which ACOs it permits to participate in the SSP.
- **Retrospective beneficiary assignment.** CMS appears to be promoting an "all boats rise" approach by combining population-level data reporting with retrospective beneficiary assignment. In addition, CMS estimates that a maximum of five million Medicare fee for service enrollees will be assigned to ACOs – less than 15% of all Medicare fee for service enrollees. Accordingly, an ACO may expend resources managing Medicare fee for service beneficiaries who ultimately are never assigned to it – while overall quality may rise and Medicare program costs may decrease, CMS's approach may diminish an ACO's ability to fully recoup its investment in clinical integration.
- **Shared savings are subject to restrictions and delayed payout.** The various qualification thresholds, percentage limitations, and delayed payout (following a claims run-out) collectively create uncertainty about whether and to what extent shared savings will materialize at all, let alone in sufficient amounts to permit an ACO to recoup its startup and operating costs.

- **Limited antitrust protection.** While the final antitrust guidance may help somewhat to insulate ACOs from FTC and DOJ enforcement, the guidance does not foreclose private individuals (for example, physicians who have been excluded from the ACO’s network of “ACO professionals”) from instituting private causes of action against an ACO or its participants for violation of federal and state antitrust laws.
- **No preemption of state laws.** Finally, nothing in the joint notice from CMS and the OIG suggests any federal preemption of state laws. Accordingly, state regulatory schemes still apply to ACOs, and ACOs must comply with these laws, such as state self-referral and anti-kickback restrictions. Many of these state laws are not the same as their federal counterparts. Thus, an ACO must take into account and comply with these state laws when structuring and operating the ACO, because complying with the waivers for Stark, the anti-kickback statute, or the civil monetary penalty statute will not necessarily mean that the ACO complies with comparable state laws. Similarly, some states have strong corporate practice of medicine prohibitions, which heavily restrict the ability of a lay corporation to influence or control the delivery of health care by physicians. These prohibitions may stand in tension with the goals of the SSP – one of the elements of the SSP is that the ACO implement evidence-based medicine standards and impose those standards on its participants. As a result, notwithstanding the good intentions of the federal program, more restrictive state laws may pose additional obstacles to the formation and operation of ACOs.

ACO Alternatives

Several ACO alternatives exist that may provide levers for providers to drive their organizations’ clinical integration efforts. For example, by January 1, 2013, Medicare will introduce a national payment bundling demonstration that will offer providers opportunities to experiment with ACO-like strategies on specific service lines for certain episodes of care that CMS will specify (*e.g.*, cardiology services, post-acute care). On August 23, 2011 the newly established Center for Medicare and Medicaid Innovations (“**Innovation Center**”), which is tasked with funding additional payment and system delivery models that improve care and lower costs, unveiled four different bundled payment models of its own, and the Innovation Center will doubtless promulgate additional initiatives in the future.³ Also, non-Medicare ACO models have shown promise, although such models must comply with federal and state fraud and abuse laws without any special protections. Moreover, gainsharing and pay-for-performance (“**P4P**”) programs, service line co-management arrangements, and similar programs all remain possible outside the SSP, although such programs must be carefully structured to fit within the current regulatory scheme, which was not designed with these innovative models in mind. Finally, Medicare’s existing demonstration programs in clinical integration (*e.g.*, the Physician Quality Reporting System (“**PQRS**”) and Acute Care Episode (“**ACE**”) programs) may be extended, reopened, or expanded, and such developments may afford providers opportunities to develop their care management skills in a lower-cost, lower-risk environment than the SSP.

³ For further analysis of these bundled payment models, please see “*The Medicare Bundled Payments for Care Improvement Initiative: An Analysis and Its Implications to Potential Participants*,” September 30, 2011, at <http://health-law.com/health-law-advisories/hlb-analysis-medicare-bundled-payment-initiative>.

ORGANIZATION OF AN ACO

The ACO regulations include a number of detailed requirements regarding what types of organizations will be able to qualify to act as an ACO, and who can be a “participant” in an ACO. An ACO must be a legal entity, recognized and authorized under state, federal or tribal law, with its own Taxpayer Identification Number (“TIN”), which is formed by one or more ACO participants. Therefore, a loose, contractual arrangement or informal confederation of separate providers will not be eligible to become an ACO. Instead, the ACO must be an actual, separate legal entity, whether it be a single existing otherwise ACO eligible entity or a new legal entity formed by two ACO participants. The regulations expressly provide that an ACO formed by two or more otherwise eligible ACO participants must be a legal entity separate from its participants.

The regulations require that the legal entity that acts as the ACO be formed for the following purpose:

- Receiving and distributing shared savings;
- Repaying shared losses or other money owed to CMS;
- Establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and
- Being capable of performing the other ACO functions identified in the rules.

The legal entity constituting the ACO must also be legally qualified to do business in each state in which it operates. Thus, for example, a California hospital desiring to form an ACO with Nevada participants, which choose to form a Delaware LLC for purpose of establishing the ACO legal entity, would be required to also register to do business in Nevada, as well as California under the regulations.

Type of Entity

There is substantial flexibility regarding what type of entity may be an ACO, provided the entity is recognized under applicable state, federal or tribal law and is able to obtain a TIN. For example, the ACO could take the form of a corporation (nonprofit or for-profit), a partnership, or a limited liability company (“LLC”). However, some shared governance and state law issues also may have an impact on what type of entity is used. For example, because the regulations require that a Medicare beneficiary serve on the board of the governing body of the ACO, this could prevent a professional medical corporation from being an ACO in certain states, unless the Medicare beneficiary were also a licensed physician. This is because many states provide that only licensed practitioners can serve on the board of directors of a professional medical corporation. Therefore, unless the Medicare beneficiary also happens to be appropriately licensed (*e.g.*, as a physician) to serve on the board of the medical corporation, then that medical corporation would not be able to satisfy the requirement of having a Medicare beneficiary on the board of its governing body, and hence could not qualify as an ACO. However, as discussed in more detail below, the regulations also provide CMS with flexibility to waive certain requirements, where the ACO describes why it seeks to vary the requirements and can explain how it will provide meaningful representation.

ACO Participants

There is significant flexibility as to who may participate in an ACO, although every ACO must otherwise meet all of the ACO requirements, unless waived. The ACO regulations provide that the ACO participants may include any and all of the following:

- Professionals in group practice;
- Networks of individual practices of professionals;
- Partnerships or joint venture arrangements between hospitals and professionals;
- Hospitals employing professionals;
- Critical Access Hospitals that engage in global billing;
- Rural health clinics (“**RHCs**”); and
- Federally qualified health centers (“**FQHCs**”).

The regulations further provide that an ACO may include other ACO participants not specifically enumerated in the list above. The law is unclear as to whether such ACO participants must be Medicare providers, as there is an inconsistency between the regulations and its commentary. The commentary indicates that enrollment in the CMS Provider Enrollment, Chain, and Ownership System (“**PECOS**”) system is not required to participate as an ACO participant. In addition, the commentary indicates that non-provider health plans may be authorized to participate in an ACO. However, the regulation that permits participation by non-enumerated ACO participants uses the term “ACO participant”, which is further defined in the regulations. Creating the confusion is the fact that the definition of ACO participant found in the regulations, provides that an “ACO participant” means an individual or group of ACO providers or suppliers, that is identified by a Medicare-enrolled TIN. It is unclear whether the reference to Medicare-enrolled TIN is alluding to the fact that the ACO participant must be a Medicare enrolled provider or that the participant must enroll its TIN in the ACO program with Medicare. Given the flexibility alluded to in the commentary, the intention is likely the latter. Nonetheless, the regulations are unclear in this regard. What is clear is that any Medicare provider or supplier may participate in an ACO, assuming the ACO can otherwise satisfy the applicable requirements for establishing and operating an ACO.

The regulations also allow for most ACO participants to have the opportunity to participate in more than one ACO. The regulations provide that ACO participants will be identified by their TINs, not by NPI numbers. Only the TIN of an ACO participant upon which beneficiary assignment is dependent must be exclusive to one ACO.

The regulations require that all ACO participants demonstrate a meaningful commitment to the mission of the ACO to ensure the ACO’s success. The regulations provide some guidance as to what demonstrates a meaningful commitment. In particular, meaningful commitment may include, for example, a sufficient financial or human investment (such as time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant to achieve the ACO’s mission. A meaningful commitment may also be shown when an ACO participant agrees to comply with and implement the ACO’s processes required and is held accountable for meeting the ACO’s performance standards for each required process. Therefore, commitment can be shown without capital investments by ACO participants, as the regulations allow ACO participant’s commitment to the ACO’s rules to satisfy this requirement. This rule provides a low threshold, which should be easy for ACO participants to satisfy.

GOVERNANCE OF THE ACO

The ACO regulations provide detailed guidance regarding the governance of the ACO. As a threshold issue, the ACO regulations require that the ACO have an identifiable governing body with authority to execute the functions of the ACO. By way of illustration, with a corporation this would likely be the Board of Directors and with a LLC it could be a Board of Managers.

Governing Body

The regulations provide the following regarding the ACO's governing body:

- The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.
- The ACO governing body must include a Medicare beneficiary representative served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with a conflict of interest with the ACO.
- At least 75 percent control of the ACO's governing body must be held by ACO participants.
- The governing body members may serve in a similar or complementary manner for an ACO participant.

Under certain circumstances, the governing body is not required to include a Medicare beneficiary or include 75 percent control by ACO participants, if the ACO describes why it seeks to differ from the requirements (such as corporate practice or state corporate law requirements) and will appropriately involve ACO participants and/or Medicare beneficiaries as applicable.

In addition to the above requirements, there are a number of additional safeguards meant to ensure that the governing body operates the ACO consistent with the goals of the SSP. In particular, the regulations require that members of the governing body have a fiduciary duty to put the ACO's interests before the interests of any one ACO participant or ACO provider/supplier. This could potentially raise difficult conflict of interest, non-competition and fiduciary duty issues between the ACO and its participants, and potential participants should be careful to appropriately analyze their respective agreements and governing documents with this potential issue in mind. The governing body also must have a transparent governing process to ensure that CMS is able to monitor and audit the ACO as appropriate.

Finally, the governing body must also adopt a conflict of interest policy, that:

- Requires disclosure of financial interests;
- Provides a procedure for determining whether a conflict exists; and
- Addresses remedial action for members of the governing body that fail to comply with the policy.

Executive Management

The regulations also provide guidance regarding the executive management and health professional leadership of the ACO. In particular, the regulations require that the ACO have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the SSP and the aims of better care for individuals, better health for populations, and lower growth in expenditures. The ACO's operations must also be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes. Clinical management and oversight must be managed by a senior-level medical director who is a physician with one of its ACO providers/suppliers, who is physically present on a regular basis at any clinic, office, or other location participating in the ACO, and who is a board-certified physician and licensed in a state in which the ACO operates. The commentary clarifies that the medical director

need not be full-time. In addition, the regulations provide flexibility to CMS to waive certain management requirements, providing that CMS retains the right to give consideration to an innovative ACO with a management structure that does not have a manager or medical director meeting all the requirements of the regulations.

BENEFICIARY ASSIGNMENT

The assignment of beneficiaries to ACOs was one of the most controversial aspects of the proposed regulations. Beneficiaries would be assigned to an ACO on a completely retrospective basis. The assignment would occur for each performance year months after the close of that year.

Many commentators objected to this concept of retroactive assignment. One of the problems presented by retroactive assignment is that if an ACO did not know who was included in the ACO until after the close of the performance year, it (and its participating providers) would not know for which patients it should be implementing the ACO practice elements, such as its evidence-based medicine protocols, providing incentives to patients for healthier lifestyles or to comply with drug regimens, or attempting to keep referrals within the ACO network. In addition, it would not know for which patients it should collect and analyze data for the purpose of improving performance with respect to the effectiveness, efficiency, and quality of care. Further, the ACO would be unable to determine whether it was achieving a savings in which it could share or be exposed to a loss. For these reasons, commentators sought to have the assignment of beneficiaries done prospectively.

In the final regulations, however, CMS retained the basic concept of retroactive assignment. The final assignment of beneficiaries for a performance year will still be made after the completion of the year. This means that CMS will be unable to determine an ACO's shared savings or losses until months after the close of a performance year, since shared savings or loss cannot be determined until beneficiary assignment is final for the applicable performance year.

In response to the public comments, CMS included in the final regulations provisions for informing ACOs on an ongoing basis of the beneficiaries who would likely be assigned to them. The final regulations provides that beneficiaries will be assigned "in a preliminary manner" at the beginning of each performance year based on the most recent data available. Beneficiary assignments will be updated quarterly based on the most recent 12 months of data; however, the final assignment of beneficiaries will not be determined until after the completion of the performance year based on data from the performance year.

A principal reason given by CMS for retaining retrospective beneficiary assignment is its desire for ACO networks to apply the same efficient and effective approaches to delivering health care to all Medicare beneficiaries, regardless of whether they are ultimately assigned to the ACO. The notion is that if the ACO is not sure whether a beneficiary its providers are treating will be assigned to the ACO, the ACO's providers will treat all of the beneficiaries under the assumption that they will ultimately be assigned to the ACO, and as a consequence, the Medicare program and all of its beneficiaries will share in whatever benefits are derived from the SSP. CMS did recognize, however, that ACOs had a legitimate interest in understanding on an ongoing basis who would likely be assigned to them, and thus adopted the provisions for quarterly interim assignment data.

The final regulations also retain the approach to beneficiary assignment contained in the proposed regulations in other various key respects. For example, as with the proposed regulations, beneficiary assignment is solely for the purpose of identifying whose care the ACO is responsible for and measuring the performance of the ACO, specifically whether the ACO's performance for a year

has resulted in a shared savings or loss. The beneficiary retains the complete freedom of choice to seek care from any provider or practitioner, regardless of whether the provider or practitioner is an ACO participant. This is consistent with the statutory requirements, in which Congress appears to have made a political judgment that it would not restrict the beneficiaries' freedom of choice.

The inability of ACOs to prevent a beneficiary from going out of network raises concerns as to whether ACOs will truly have the ability to control costs. A key element of most managed care plans is that networks are closed, and the managed care organizations can thereby limit the providers from which enrollees receive services to promote efficient and effective utilization of services. ACOs will not have this benefit and will have to control utilization of services through the relationships the ACO and its providers foster with their patients. It will be critical for ACOs to monitor the frequency with which patients receive services outside the ACO's network, and the ACO and non-ACO providers these patients have seen, so that it can identify and address potential problems as early as possible.

As in the proposed regulations, the determination of whether a Medicare beneficiary is assigned to an ACO is based principally on the primary care services received by the beneficiary from primary care physicians. However, the final regulations contain some modifications to the approach set forth in the proposed regulations to address various comments received by CMS.

The definition of "primary care services" and "primary care physician" are important to understanding the assignment process. Primary care services includes services identified by HCPCS codes 99201 through 99215 (evaluation and management services), HCPCS codes 99304 through 99340, 99341 through 99350 (visits at various facilities, excluding hospitals, and patients' homes), G0402 (welcome to Medicare visit), G0438 and G0439 (annual wellness visits), and revenue center codes 0521, 0522, 0524 and 0525 submitted by FQHCs and RHCs.

CMS rejected requests that visits to hospital inpatients should be included, and also rejected requests to exclude visits to patients in skilled nursing facilities ("SNFs"). CMS viewed the inpatient hospital visits as more unusual and episodic, and not reflecting the physician from whom the patient would generally receive primary care. On the other hand, CMS concluded that SNF patients often reside in SNFs for long periods of time and would receive most of their primary care from the physician or other professional visiting the patient in the SNF, that it was appropriate to view the physician or other professional seeing the patient in the SNF as the patient's principal primary care practitioner.

CMS included the revenue codes for FQHCs and RHCs, so that visits to these facilities could be included in the determination of the physician from whom a beneficiary receives primary care services. CMS noted that RHCs do not report HCPCS codes, and that FQHCs will begin reporting HCPCS codes only in 2011, so that an alternative would be needed to include visits to these facilities. As discussed below, FQHC and RHC visits are now included in the determination of beneficiary assignment. Because of this, ACOs that include FQHCs and RHCs will not get additional shared savings as was the case in the proposed regulations.

Primary care physicians include physicians with a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine, as in the proposed regulations. However, the final definition of primary care physician was expanded to include a physician providing primary care in an FQHC or RHC who is included in an attestation by an ACO so that FQHC and RHC visits may be taken into account in the assignment of beneficiaries.

CMS has continued to exclude from the definition of primary care physician specialists who may frequently act as a patient's primary care physician, such as an OB-GYN or a cardiologist. However, CMS has revised the assignment process to take primary care visits by specialists into account for certain beneficiaries.

CMS has also continued to exclude mid-level practitioners, such as nurse practitioners and physician assistants. Organizations representing mid-level practitioners commented that this does not make sense since in an efficient health care network much primary care is often furnished by mid-level practitioners, and that their use should be encouraged rather than discouraged. CMS responded that the statute generally required CMS to assign beneficiaries based on primary care services furnished by primary care physicians rather than by other professionals, so that its hand were somewhat tied. CMS, however, did add a second step to the assignment process to allow mid-level practitioner services to be reflected in the assignment process.

The final regulations include a two-step process for assigning beneficiaries. Under the first step, CMS identifies all beneficiaries who received at least one primary care service from a primary care physician, either inside or outside of the ACO, during the applicable time period (the most recent 12 months for preliminary prospective assignment and quarterly updates, and the performance year for final assignment). CMS assigns these beneficiaries to an ACO if the beneficiary received the plurality of the beneficiary's primary care services furnished by primary care physicians from primary care physicians who are providers in that ACO. Specifically, CMS assigns the beneficiary to the ACO if the allowed charges for primary care services furnished to the beneficiary by all primary care physicians who are providers in that ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are either ACO providers in any other ACO or not affiliated with any ACO and enrolled in Medicare.

The second step assigns the beneficiaries who received at least one primary care service from an ACO physician, but who did not receive a primary care service furnished by a primary care physician either inside or outside of the ACO during the applicable time period.

The second step takes into account primary care services furnished by all ACO professionals, including specialty physicians and mid-level practitioners. Under the second step, a beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are providers in that ACO are greater than the allowed charges for primary care services furnished by (a) all ACO professional who are ACO providers in any other ACO, and (b) other physicians, nurse practitioners, physician assistants, or clinical nurse specialists who are unaffiliated with an ACO and are enrolled in Medicare.

The final regulations adopt special rules for ACOs that include FQHCs or RHCs. ACOs must identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant or provider. For purposes of assigning beneficiaries to an ACO, CMS treats a service reported on an FQHC/RHC claim as a primary care service if the NPI of a physician included in the attestation is reported on the claim as the attending provider, and the claim includes a HCPCS or revenue center code that meets the definition of a primary care service.

A by-product of CMS' decision to expand the categories of professionals on which beneficiary assignment will be based beyond primary care physicians to include specialty physicians and mid-level practitioners appears to be an expansion of the category of ACO participants that must be exclusive to a single ACO during the term of the ACO agreement. CMS has adopted its proposals to define an ACO operationally as a collection of Medicare TINs, and that ACO

participants on which beneficiary assignment is based would have to be exclusive to a single ACO. This means that any medical group or entity including mid-level practitioners enrolled in Medicare and billing under a single TIN will have to be exclusive to a single ACO. Similarly, a sole practitioner enrolled in Medicare and billing under a single TIN would have to be exclusive to a single ACO with respect to services billed under the sole practitioner's TIN. However, a physician or mid-level practitioner can practice through multiple groups that participate in different ACOs so long as the billings for the services are made using different (*e.g.*, the groups') TINs. If our understanding of the final regulations is correct, specialty groups, like a group of orthopedic specialists, would have to be exclusive to a single ACO. It is unclear whether CMS fully considered the ramifications of this result.

In summary, as with many aspects of the final regulations, CMS was responsive to comments in crafting the final beneficiary assignment provisions and many parties considering ACOs may find the assignment provisions of the final regulations to constitute a significant improvement. However, the final regulations retain the principles of retroactive assignment, and complete beneficiary freedom of choice, and these components of the final regulations may present a substantial challenge for prospective ACOs.

QUALITY REPORTING AND PERFORMANCE

ACOs must satisfy detailed and substantial quality reporting and performance requirements that are established by CMS. Compliance is required in order to receive shared savings. Further, non-compliance can result in sanctions, up to and including contract termination.

Quality Domains and Measures

The regulations divide the quality measures into four domains. They are patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population. The measures are allocated among the domains, although they are not allocated evenly. For example, the care coordination/patient safety domain has seven individual quality measures, while the at-risk population domain has 12 measures.

CMS initially selected 33 measures that it believes demand a high standard of ACO quality, focus on areas of high prevalence in the Medicare population, represent high cost to the program, and align with the measures used in other quality initiatives. Accordingly, the measures emphasize prevention and management of chronic diseases such as heart disease, diabetes, and chronic obstructive pulmonary disease. CMS expects to expand the measures in the future to include areas such as frailty, mental health, substance abuse (including alcohol screening), and caregiver experience. ACOs will be required to comply with measures updates made in future rulemakings as clinical guidelines change.

For each quality measure, CMS has identified a measure title, a CMS or National Quality Forum ("NQF") measure or standard along with the measure steward responsible for development of the measure criteria, and the method of data submission. For example, the first quality measure is "CAHPS: Getting Timely Care, Appointments, and Information" in the patient/caregiver experience domain. It corresponds to NQF #5 and the measure steward is the Agency for Healthcare Research and Quality ("AHRQ"). The quality data for this measure is submitted through a patient survey. Table 1 to the final rule sets forth the quality measures with this related information.

Some of the quality measures have very specific clinical criteria. An example is quality measure 29, which is in the domain at-risk population – ischemic vascular disease, which has a measure title “Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/dl.” The measures include both process measures (which are usually easy to calculate based on claims and other administrative data) and outcome measures (which provide a better picture of quality of care improvement, but require more effort to report). The measures focus on short-term measurable outcomes. Risk adjustment is included for some of the measures, but is usually limited to age and gender or the exclusion of specific patients, *e.g.*, hospice patients.

Quality Data Reporting

Since ACOs are accountable for all care received by their assigned beneficiary population, care provided by non-ACO providers will be reflected in the quality measures, and claims data will be collected from providers outside of the ACO. However, ACOs submit data on quality measures only for their assigned Medicare beneficiaries.

ACOs must submit data on the quality measures according to methods established by CMS. With respect to the collection of data for the 33 finalized measures, information will be collected by patient survey, taken from claims, calculated from EHR Incentive Program data, and submitted by ACOs and collected via CMS’ Group Practice Reporting Option (“**GPRO**”) web interface (which allows data collection – including clinical information – from electronic medical records, patient registries, and other administrative systems, and from paper records). Regardless of an ACO’s start date, the reporting period for all quality measures will be on the basis of a 12-month, calendar year.

The patient/caregiver experience domain is measured by a standardized patient survey used by all ACOs. CMS selected the Clinician and Group (“**CG**”) version of the Consumer Assessment of Healthcare Providers and Systems (“**CAHPS**”) survey because of its focus on ambulatory care and the SSP’s primary care focus. CMS is considering comments about which CAHPS’ response scale to use and concerns that CAHPS data could include visits outside the reporting periods, and will release detailed instructions about these matters later. Also, because of concerns about consistent administration of the test and reaching non-English speakers, low-income beneficiaries, and disabled beneficiaries, CMS will pay for and administer the survey in 2012 and 2013 using CMS trained and certified vendors. Thereafter, ACOs must select a survey vendor from CMS’ list of certified vendors and pay that vendor to administer the survey and report the results.

ACOs must report data for each quality measure accurately, completely, and timely. If an ACO does not report one or more measures or fails to report completely and accurately on all measures in a domain, CMS sends the ACO a written request to submit the data, correct the data, provide a reasonable explanation for its delay in reporting complete and accurate data, or do any combination of the foregoing. If the ACO fails to do as requested, CMS will terminate the ACO’s contract for failing to report quality measures immediately. An ACO that exhibits a pattern of inaccurate or incomplete reporting of the quality measures may have its ACO contract terminated. A terminated ACO forfeits any of its shared savings. Also, an ACO will not qualify for any shared savings in any year it fails to report fully and completely on the quality measures.

Performance Scores

CMS designates quality performance standards for each quality measure, including a performance benchmark and a minimum attainment level, as well as a point scale for most measures. The performance benchmarks and minimum attainment levels are established using national Medicare

fee-for-service rates, national Medicare Advantage quality measure rates, or a national flat percentage, depending on data availability. The minimum attainment level is set at 30% or the 30th percentile of the applicable benchmark. CMS will publish the benchmarks and minimums before the beginning of each performance year. The minimum attainment level is expected to rise with time.

For the most part, CMS weighs the measures equally at two points for each scored measure. The one exception is that CMS gives double weight to the measure that relates to the use of EHR technology by primary care providers to underscore the importance of health information technology to ACOs.

CMS scores measures individually. However, not every measure within a domain will receive an individual score. For example, the diabetes and coronary artery disease (“CAD”) quality measures are “all or nothing” measures that are composed of several individual measures. These individual measures are part of the composites and are not scored individually. Therefore, the two CAD measures count as one composite score and the five measures of the Optimal Diabetes Care Composite count as one score. Also, six of the seven patient experience survey modules will be scored as one measure (the Health Status/Functional Status module will be scored separately as one measure). Therefore, only 23 of the 33 total quality measures are scored. The total measures for scoring purposes and total points per domain are set forth in Table 4 of the final rule.

The score for a measure is determined based on a sliding scale point system which allows higher levels of quality performance to earn more points, which translates to higher sharing rates. An ACO earns 1.10 point (or 2.2 points for the EHR measure) for attainment at the 30+ percent or percentile level up to the full 2.0 points (or 4 points for the EHR measure) for performance at the 90+ percent or percentile level for a measure. No points are earned for performance below the minimum attainment level for a measure. The diabetes and CAD all or nothing measures receive the full two points if all of the individual criteria are met or no points if one or more of the criteria are not met. The sliding scale point allocation for the various performance levels is set forth in Table 3 of the final rule.

An ACO must report on all measures within a domain. However, in recognition that achieving the quality performance standard on all measures may be difficult, ACOs only have to achieve the quality performance standard on 70% of the measures in each domain. This would allow an ACO to fail some measures and still earn shared savings. However, since the EHR measure is double-weighted for both scoring purposes and for determining poor performance, the preamble to the final rule points out that failure to completely and accurately report the EHR measure would result in missing the 70% cut-off for the care coordination domain. If an ACO does not meet the 70% performance standard in each domain, CMS will place the ACO on a corrective action plan and re-evaluate the ACO the following year. The ACO’s agreement would be terminated if it continues to underperform the next year.

For the first performance year of an ACO’s agreement, the quality performance standard is at the level of full and accurate reporting for all quality measures. In subsequent years, payment based on quality performance is phased in (the ACO must still continue to report on all measures). For example, currently in the second year, 25 measures will be pay for performance and eight will be pay for reporting. In the third year, all except one measure will be pay for performance. Table 1 to the final rule sets forth the pay for performance phase in for each measure.

The Impact of Performance Scores on Shared Savings

An ACO's eligibility to receive shared savings, and the amount of shared savings the ACO may receive, depends in part on the ACO's satisfaction of the quality measures. If an ACO achieves the minimum attainment level for at least one measure in each of the four domains, it is eligible to participate in any realized shared savings if it meets certain provisions for shared savings and losses under subpart G of the regulations. Stated another way, if an ACO scores a zero for an entire domain (*i.e.*, the ACO fails to achieve the minimum attainment level on all measures in a domain), it is not eligible to share in any savings that year. CMS included these requirements to emphasize that all domains are important and to ensure that ACOs do not ignore some domains.

An ACO's overall quality performance score is based on the score of each domain. Each domain is given equal weight in determining the overall quality performance score regardless of the number of measures within the domain. The domain scores are averaged to determine the ACO's performance score and sharing rate.

The total performance score for an ACO is determined as follows. The total points earned for all the measures in each domain are added together and divided by the total points available for that domain to yield a percentage of points earned out of the points available. The four percentages for the domains are added together and divided by four to reflect that the four domains are each weighted at 25%. This percentage is then multiplied against the maximum sharing rate of 50% of the total savings generated by the ACO under the one-sided risk model or 60% under the two-sided risk model.

Audits of Quality Data

CMS has the right to audit and validate quality data reported by an ACO. The ACO is required to provide the auditors with beneficiary medical records information as requested. An audit consists of three phases of medical record review. If CMS elects to conduct an audit, it will abstract a random sample of 30 beneficiaries. In the first step, only eight of the 30 beneficiaries' medical records will be reviewed for "mismatches" between the quality data reported and the medical records provided. If there are no mismatches, the remaining records will not be audited.

If there are mismatches, the second phase of the audit is to review all of the remaining 22 records. A third phase is undertaken if there are mismatches in more than 10% of the records in phase two. If a specific error is identified in phase three, CMS will provide education to the ACO and allow the ACO to correct and resubmit the measure. If, after the third phase, there is a discrepancy greater than 10% between the medical records reviewed and the data reported for any quality measure, the ACO will not be given credit for meeting the quality target for that measure.

ACOs, therefore, must maintain an auditable trail supporting their quality data reporting. Additionally, the ACO must be able to access the medical records of beneficiaries who are assigned to the ACO in order to be able to substantiate the quality reporting. CMS may request documentation from an ACO, ACO participants, or ACO providers/suppliers.

OPERATIONAL REQUIREMENTS:

PROCESSES AND PATIENT-CENTEREDNESS CRITERIA

The final regulations set forth requirements for the ACO's internal processes, which the ACO needs to implement throughout its organization, to ensure that the ACO has an infrastructure in place aimed at continuously improving quality along the spectrum of care. These processes include the internal reporting of quality and costs, promoting evidenced-based care and care coordination, and an organizational focus on patient centeredness.

The regulations do not mandate step-by-step procedures, but rather require the ACO to describe the processes it has developed and implemented, including the means by which each participant and provider/supplier will be held accountable for compliance. An ACO therefore needs tools for monitoring and evaluating participant and provider/supplier performance, and procedures for the different entities to communicate feedback to each other.

Quality Assurance and Improvement Program (“QA Program”)

An ACO's QA Program is headed by a qualified healthcare professional, who does not have to be a physician, although clinical management must be overseen by a senior-level medical director who is a physician. The QA Program must include established performance standards for quality of care and services, cost effectiveness, and process and outcome improvements – all aligned with the quality reporting requirements.

Patient-centeredness is at the heart of the ACO processes, which need to promote patient engagement and include an individualized care program for high-risk patients with multiple-chronic conditions. ACOs can design their QA Program in accordance with the ACO's patient population and practitioners, but the processes must be specific. CMS declined to tell ACOs which diagnoses would need evidence-based medicine guidelines. Instead, each ACO is responsible for determining the diagnoses within its population that have “significant potential” for quality improvement, where the ACO takes into account individual beneficiaries' circumstances.

To engage beneficiaries, processes must address how the ACO will (i) use the beneficiary experience of care survey for the improvement of care, (ii) evaluate and address the health needs of its assigned population, (iii) communicate evidence-based medicine and clinical knowledge to beneficiaries in ways they can understand, (iv) engage beneficiaries in shared decision-making, taking into account the beneficiaries' unique needs, preferences, values and priorities, and (v) provide for beneficiary access and communication, including access to medical records. In addition, the ACO must maintain a partnership with community stakeholders to improve the population's health need, which can be satisfied by a stakeholder organization serving on the ACO's governing body.

Data Collection and Reporting Systems

Information technology (“IT”) is critical to the ACO's operations, and the final regulations reflect this. Although the regulations stop short of mandating that an ACOs and its participants and providers/suppliers maintain electronic health records systems (“EHR”), their adoption of an EHR infrastructure is encouraged: the ACO's quality performance score on adopting EHR is given twice the weight of any other measure. Moreover, the ACO's required processes will be difficult to implement without a sophisticated IT infrastructure, because it is hard to see how else an ACO can

practically track and monitor data and continuously provide feedback and improve the care it provides.

The regulations require an authorized individual, who can legally bind the ACO, to certify program compliance and the “accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge, information and belief.” This certification applies to data and information generated not only by the ACO and those who provide services related to the ACO, but also by the ACO’s participants and providers/suppliers. An individual would most likely be more inclined to make such a certification where the ACO has a reliable and comprehensive means by which to collect quality and cost data across the entire ACO spectrum, compare it to the mandatory quality performance measures, and report the data to CMS and the public.

Plan for Achieving and Distributing Shared Savings

In its application, an ACO must submit a plan that describes the manner in which it will use and distribute its shared savings, although the regulations do not mandate any specific formulae. The regulations require that the written plan show how the use of the shared savings will achieve the SSP’s goals and the “triple aims” of better individual care, better health for populations, and lower growth of expenditures. Accordingly, an ACO applicant will need to have a well-conceived plan for ensuring alignment with the SSP goals before submitting its application to CMS.

Compliance Plan

Each ACO is required to establish a compliance plan that will be operational upon the effective date of the ACO’s agreement with CMS, and to regularly update the plan to reflect changes in the laws. The ACO compliance officer, who cannot also fulfill the role of the ACO legal counsel, will oversee the plan and report directly to the ACO governing body. The compliance plan should contain procedures to address fraud and abuse, including provisions for reporting “probable” violations of the law to law enforcement and reporting mechanisms where an individual suspects problems related to the ACO or violations of the law. The ACO’s compliance efforts can be coordinated with ACO participants, providers and suppliers for better efficiency.

Public Reporting and Transparency

Each ACO must publicly report certain information regarding the ACO in a standardized format that will be specified by CMS. Reportable information will include general information regarding the ACO (such as its name, location and primary contact), ACO organizational information and information regarding the ACO’s shared savings or losses. ACOs must also publicly report results of patient experience of care surveys and other claims-based measures.

Notification to Beneficiaries

ACO participants must also provide notification to beneficiaries of their participation in an ACO. Participants will be required to notify beneficiaries of their ACO participation at the point of care, post signs disclosing their ACO participation at facilities and make standardized written notices available. However, ACOs and their participants will not be required to notify beneficiaries if their participation in the SSP is terminated. The notifications must also meet all of the SSP’s marketing requirements discussed in greater detail below.

Marketing Materials and Activities

Marketing materials and activities by an ACO are heavily regulated. The definition of what constitutes “marketing materials and activities” is quite broad and includes practically any document or activity that the ACO, its providers, participants or others may use to “educate, solicit, notify, or contact” beneficiaries or providers regarding the SSP. For instance, outreach events, web pages, social media (such as Facebook or Twitter) and data sharing opt out letters are all defined as “marketing materials and activities.”

Under the regulations, an ACO must submit the marketing activity or material to CMS for approval. However, an ACO may use or conduct the proposed marketing activity or material without the express approval of CMS after the expiration of an initial 5-day review period that begins on the date of submission. The ACO must also certify compliance with all of the marketing requirements and CMS must not have disapproved the proposed activity or material. Marketing requirements include using available template language developed by CMS, complying with beneficiary inducement requirements and refraining from using marketing material or activities that are materially inaccurate or misleading. Importantly, however, CMS retains discretion to disapprove an ACO’s marketing material or activity at any time, including after the expiration of the initial 5-day review period. ACOs must cease using marketing materials or activities that have been disapproved. Sanctions for failure to comply with the marketing requirement include pre-termination warnings, corrective action plans and termination.

Auditing/Retention of Books and Records

An ACO must agree to grant CMS very broad rights to audit the ACO as well as all of the ACO participants and its providers or suppliers. An ACO must also maintain all books and records and “other evidence” for 10 years from the latter of the last day of the agreement period or from the date of completion of a CMS audit, evaluation or inspection. Even this rather lengthy period is subject to extension for a longer period if CMS determines there is a special need. An ACO may also be required to maintain all books and records for an additional 6 years if there has been a termination, dispute or allegation of fraud or similar fault. The ACO has the ultimate responsibility for these record retention requirements, so if any of an ACO’s participants, providers, or suppliers fail to meet these requirements, then the ACO is held responsible for that failure. Finally, the SSP audit and record retention requirements will not limit or restrict the OIG’s authority to separately audit, investigate, or inspect the ACO or its participants, providers or suppliers.

Analysis of Potential Implications

A sophisticated IT infrastructure to capture all relevant data, accurately and comprehensively, is costly. Without this, an ACO is likely set up for failure. The accuracy of the data is necessary to obtain any shared savings, and CMS has the right to audit an ACO and demand further documentation where data and reporting are incomplete. The submission of inaccurate data could also expose the ACO and the certifying individual to potential False Claims Act liability. Given the potentially grave consequences, those anticipating forming ACOs will want to ensure that all required procedures are functioning in a manner that captures and produces accurate data and produces red flags for fraud and abuse.

The tasks of establishing, implementing and documenting all of the processes should not be underestimated. The quality assurance requirements are, in some respects, similar to those imposed upon HMOs. Those who may have participated in an audit or survey conducted by an HMO

regulatory agency can vouch for the administrative burden these types of documentation requirements create. On the other hand, those who have established these sorts of systems will have an easier time building upon that foundation.

ACO applicants also will need to address the disciplinary measures and expulsion of participants and providers/suppliers who fail to meet performance standards. For example, they will need to decide what consequences will follow if and when an ACO provider is expelled from the ACO, and whether there will be fair hearing and/or appeal rights.

The emphasis on patient-centeredness will demand more “customer service” education and engagement tools. An ACO will need to include resources for personnel or software teaching programs, as well as for educating patients regarding procedures, diseases, prevention, health maintenance and so forth, to allow the physician to focus on diagnosing and treating the patient. Moreover, the ACO will need to plan for additional services and infrastructure to facilitate the coordination of care, management of chronic disease conditions, and post-acute care treatment. Those RHCs and FQHCs that have good track records in this area may be excellent partners for an ACO.

AGREEMENT WITH CMS

ACOs must enter into three-year agreements with CMS to participate in the SSP. This section outlines some of the details in the final regulations regarding these agreements, their requirements, and the obligations and benefits for an ACO under the agreement.

Start Date of Agreement

The final regulations provide that: (1) an ACO must enter into a participation agreement with CMS for at least three years; (2) ACO applications must be submitted by a deadline established by CMS; (3) CMS will review applications from eligible organizations and approve or deny the applications accordingly; (4) for applications approved to participate in the SSP for 2012, the start date of the agreement will be either April 1, 2012 (with an initial agreement term of 3 years, 9 months) or July 1, 2012 (with an initial agreement term of 3 years, 6 months); (5) for 2013 and all subsequent years, the start date is January 1 of that year and the term of the agreement is 3 years; and (5) except for agreements starting on April 1, 2012 or July 1, 2012, the performance year will be the calendar year beginning January 1, unless otherwise noted in the agreement. Accordingly, for ACOs with start dates of April 1, 2012 or July 1, 2012, the ACO’s first performance year will be 21 months or 18 months, respectively.

It is unclear how broad the pool of potential applicants will be for whom participation in the SSP is an attractive option. However, the addition of a two mid-2012 start dates may afford greater opportunities for providers to participate in the SSP and to obtain an ultimately longer (up to 3.5 years) initial participation period, particularly given CMS’s attempts to substantially re-work the SSP to make participation more likely (*e.g.*, by removing downside risk under the 1-sided model and increasing the scope of fraud and abuse waivers).

Timing/Process for Evaluating Shared Savings

ACA⁴ is silent as to when the shared savings determination under the SSP should be made. In the proposed regulations, CMS attempted to strike a balance between providing feedback to ACOs on their performance in a timely manner, while at the same time maximizing accuracy in calculating per capita expenditures. CMS considered the relative completion percentages for physician services and Part A services for a three-month run-out (98.5% and 98%, respectively) and a six-month run-out (99.5% and 99%, respectively). In the proposed regulations, CMS proposed using a six-month claims run-out to calculate the benchmark and per capita expenditures for the performance year.

Under the final regulations, CMS has finalized a policy of using three months of claims run-out data, with the application of an “appropriate completion percentage” (developed in coordination with the CMS Office of the Actuary), to calculate the benchmark and per capita expenditures for the performance year. CMS will monitor ACO providers and suppliers for any deliberate delay in submission of claims that would result in an unusual increase in the claims incurred during the performance year, but submitted after the 3-month claims run-out period. CMS will consider such deliberate behavior grounds for termination.

The final regulations reflect CMS’s response to the numerous comments it received in support of a 3-month claims run-out period (and the absence of any comments in support of a 6-month claims run-out). The comments focused on the significant start-up investments ACOs would need to make to provide adequate infrastructure, and suggested that a shorter turnaround period for feedback on both quality metrics and shared savings reconciliation would be less likely to create cash flow distortions and would provide a better opportunity for ACOs to be able to continue to operate.

The impact of the final three-month run-out is that ACOs will not receive any shared savings payments until at least 15 months following the start of the ACO’s agreement with CMS. Providers will need to consider whether a prospective ACO model will be able to accommodate (a) the claims risk providers think may exist under a three-month run-out; and (b) the uncertainty in what kind of “appropriate completion percentage” CMS ultimately will develop.

Data Sharing

ACA is also silent about what data CMS should make available to ACOs about their assigned beneficiary populations to support the ACO in evaluating its performance, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health. In the final regulations, which largely mirror the proposed regulations on the issue of data sharing, CMS recognizes the value of providing ACOs with both aggregate and beneficiary-identifiable data to help ACOs improve the quality of care, improve the health of their beneficiary population, and create efficiencies within their system. CMS relied in particular on its experience with aggregate data-sharing under the Physician Group Practice (“PGP”) demonstration, a Medicare pay for performance program that rewards cost savings and quality improvements in physician practices (with qualifying physician groups receiving 80% of savings).

Under the final regulations, as a general rule, an ACO cannot place unnecessary limits or restrictions on the use or disclosure of individually identifiable health information, and must comply with applicable privacy laws. An ACO must enter into and comply with a Data Use Agreement (“DUA”)

⁴ The Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148.

with CMS, in which the ACO agrees to comply with the HIPAA Privacy Rule and other applicable laws. The ACO must not misuse individually identifiable health information, and if an ACO improperly uses or discloses such information, the ACO could be cut off from eligibility to receive further data from CMS, could be terminated from the SSP, and potentially could be subject to additional sanctions or penalties, such as a misdemeanor and \$5000 fine under the federal Privacy Act.

With that basic foundation in place, under the final regulations, the SSP will provide aggregate-level data to ACOs similar to the data CMS provided to physicians under the PGP demonstration. CMS will provide “aggregate data reports” to the ACO at the start of the agreement period and each quarter thereafter. The annual aggregate data reports will be based on beneficiary claims data used to calculate the ACO’s benchmark; *i.e.*, beneficiaries that would have been assigned to the ACO in any of the three most recent years prior to the agreement period using the ACO participants’ TINs identified at the start of the agreement period. The quarterly aggregate data reports will be based on rolling 12-month data for preliminary prospectively assigned beneficiaries. No beneficiary identifiable information will be provided in either the annual or quarterly aggregate data reports, although CMS will include de-identified claims history for the ACO’s assigned beneficiaries.

The aggregate data reports will include, where available, aggregated metrics and utilization and expenditure data. Aggregated metrics may include breakdown of population into high risk score beneficiaries, beneficiaries with one or more hospitalizations, and chronic disease subpopulations. Utilization data may include the number of patients overall and in each subpopulation with emergency department visits, hospital discharges, physician visits, and their corresponding rate for the assigned population.

The aggregated data reports offer a potential opportunity for ACO participants to obtain additional information about the populations they serve. Armed with these data, ACOs may be better positioned to target care management strategies across their Medicare fee for service population. However, notwithstanding the change in the final regulations to include “preliminary prospectively assigned beneficiaries,” CMS appears to be promoting an “all boats rise” approach by combining aggregate data reports with what ultimately will be retrospective beneficiary assignment. Accordingly, an ACO may expend resources managing Medicare fee for service beneficiaries who ultimately are never assigned to the ACO. While overall quality may rise, CMS’s apparent approach may diminish the ability for an ACO to fully recoup its investment.

CMS also plans to provide the ACO with limited beneficiary identifiable information upon the ACO’s request, either at the beginning of the ACO’s agreement period or at the end of each performance period, for beneficiaries used to generate the ACO’s three-year benchmark (*i.e.*, preliminary prospectively assigned beneficiaries). The beneficiary identifiable information will be limited to a list of beneficiary names, date of birth, sex, and HICN, derived from the assignment algorithm used to generate the three-year benchmark. An ACO may only use these data in furtherance of legitimate ACO “health care operations” (as defined by HIPAA), which include population-based activities to improve health, reduce cost, develop protocols, coordinate care, and manage cases. The ACO must certify that its request for beneficiary identifiable data is the minimum necessary to carry out the ACO’s health care operations, and that the ACO will limit the use of such data to legitimate SSP activities.

To the extent an ACO believes that its preliminary prospectively assigned beneficiaries generally will continue to receive care from the ACO (which CMS assumes often will be the case), this limited

beneficiary identifiable information may aid the ACO in identifying individuals who may benefit from improved care coordination efforts going forward.

In addition, subject to a beneficiary's decision to decline data sharing (described in more detail below), CMS will provide more detailed monthly claims data for preliminary prospectively assigned beneficiaries upon an ACO's request (if certain conditions are satisfied). The more detailed monthly claims data may include a predefined "minimum necessary data set" for Part A, Part B, and Part D claims. The Part A and Part B data set may include, but are not limited to, beneficiary ID, procedure code, gender, diagnosis code, claim ID, from/through dates of service, claim payment type, date of birth and death (if applicable), TIN, and NPI. The Part D data set may include beneficiary ID, prescriber ID, drug service date, drug product service ID, quantity dispensed, days supplied, brand name, generic name, drug strength, TIN, NPI, gross drug cost, and an indication of whether the drug is on the CMS formulary.

Regarding a beneficiary's decision to "decline data sharing," with respect to the more detailed data sharing, the final regulations modified the "opt out" provisions of the proposed regulations in an attempt to lessen the burden on providers. Both the proposed and final regulations provide that the beneficiary must have a "meaningful opportunity" to decline having his or her claims information shared with the ACO. In the proposed rule, CMS noted that to be "meaningful," the opportunity to make the choice about whether the beneficiary's detailed information may be shared must: (1) allow the individual advance notice and time to make a decision; (2) be accompanied by adequate information about the benefits and risks of making the data available for the ACO's proposed uses; (3) not compel consent; and (4) not use the beneficiary's choice to permit his or her information to be shared for discriminatory purposes.

Consistent with CMS's comments concerning "meaningful opportunity," the proposed rule provided that ACO participants must inform the beneficiary in advance of the ACO's data request, and must supply the beneficiary with an opt-out form as part of an office visit to one of the ACO's primary care physicians. CMS received several comments that the office visit requirement would result in a delay in the provision of claims data to ACOs, and may generate unnecessary office visits for the beneficiary population as providers might attempt to schedule needless office visits just to explain the SSP to beneficiaries.

In response to these and other comments, CMS modified the opt-out provisions in the final regulations, which provide that ACOs must notify patients at the point of care that they are participating in an ACO, that they will be requesting PHI data, and that the beneficiary has the right to decline to share this data with the ACO. However, unlike the proposed rule, the final rule also provides a mechanism by which ACOs can notify beneficiaries in advance of the point of care visit (*i.e.*, no office visit is required) using the list of preliminary prospectively assigned patients provided to the ACO at the start of the agreement period and quarterly during the performance year. Beneficiaries have 30 days from the date the ACO provides such notification to respond, and absent an opt-out request from the beneficiary, ACOs will be able to request beneficiary-identifiable data from CMS. The ACO would be responsible for repeating the notification and opportunity to decline sharing information during the next face-to-face encounter with the beneficiary in order to ensure transparency, beneficiary engagement, and meaningful choice. If a beneficiary declines data sharing, the opt out does not apply to the base data set CMS provides for historical beneficiaries, and does not affect other uses of the beneficiary's data (*i.e.*, calculating ACO benchmarks/performance).

CMS noted in the final rule that it plans to compare the outcomes of beneficiaries who decline data sharing with those who do not. CMS's goal may be to protect beneficiaries from discriminatory

treatment based on a refusal to share data. However, to the extent beneficiaries who decline to share data have worse outcomes than beneficiaries who share data, it may be difficult to determine which outcomes were based on discriminatory treatment, versus resulting from the ACO's impaired ability to manage the care of patients who refuse to share their data with the ACO.

Responsibility for New Program Standards

Under the final regulations, an ACO will be subject to all future legal and regulatory changes except for changes to: (1) eligibility requirements concerning the structure and governance of ACOs; (2) calculation of the sharing rate; and (3) beneficiary assignment processes. For example, an ACO would be subject to changes in regulation related to the quality performance standards. Nothing in the SSP would affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under the Medicare fee for service program.

Under the final regulations, if a change in law or regulation requires, or otherwise causes, an ACO to change its processes in a manner that affects the design of its care processes and delivery of care, changes to the quality of care, or changes in planned distribution of shared savings, the ACO will be required to supplement its original application. The supplement must detail how the ACO will respond to the change. If an ACO fails to make the necessary changes to respond, the ACO would be placed on a corrective action plan (“CAP”). If the ACO failed to act upon the CAP in a manner that brought the ACO into compliance within some time specified by CMS, the ACO would be terminated from the SSP. The final regulations added a “safety valve” provision that also permits an ACO to terminate its agreement in instances where SSP statutory and regulatory standards are established during the agreement period which the ACO believes will impact its ability to continue to participate in the SSP.

The ability for CMS to change the rules on an ACO midstream injects an additional layer of uncertainty into SSP participation. As noted elsewhere in this paper, achieving the quality performance targets is a prerequisite to qualifying for shared savings payments. If CMS substantially alters or expands the scope of quality performance standards during the three-year agreement period, such changes could significantly hamper or eliminate an ACO's ability to achieve any meaningful shared savings.

Significant Changes During the Agreement Period

In addition to holding an ACO accountable for external changes during the three-year agreement period, the final regulations impose a process for making an ACO accountable for internal changes, as well.

The final regulations relaxed some restrictions CMS initially proposed on an ACO's ability to alter its original participant structure. Under the final rule, during the three-year agreement period, an ACO may both remove and add ACO participants and ACO providers/suppliers (the proposed rule only permitted an ACO to drop ACO participants). The final rule requires an ACO to notify CMS within 30 days of any such addition or removal.

Similar to the proposed rule, the final rule also requires an ACO to notify CMS within 30 days of any “significant change.” The proposed regulations contained a specific and somewhat convoluted definition of “significant change.” However, the final regulations greatly simplified the definition of “significant change” to occur when an ACO is no longer able to meet the eligibility or program requirements of the SSP. Examples of a “significant change” include the dropping out of a

participant upon which assignment is based; a material change in the ACO's provider/supplier composition; mandated reorganization due to antitrust concerns, and the exclusion or conduct restriction of ACO members.

CMS will review an ACO's notice of a significant change, and four potential outcomes may result. First, CMS may determine that the ACO can continue to operate under its remaining structure. Second, CMS may instead determine that the ACO's structure is so different from the initially approved ACO that it must terminate its agreement and submit a new application to participate in the SSP. Third, CMS may terminate the ACO from the SSP because the remaining structure no longer meets the eligibility criteria for the program (*e.g.*, if the assigned population falls below 5,000 beneficiaries). Finally, CMS and the ACO may mutually decide to terminate the agreement.

SHARED SAVINGS DETERMINATION AND RELATED MODELS

Over time, all ACOs ultimately will be required to bear down-side risk by sharing in losses as well as gains, if the ACO remains in the program beyond the initial agreement term. This approach does not appear to reflect the focus in the statutory scheme on sharing savings with an ACO. However, in recognition of the need for new ACOs, and their participating providers, to learn and ramp up the behaviors and processes needed for an ACO to successfully assume risk, CMS has offered ACOs the option, during only the initial agreement term, to share savings without having to also share losses. However, there does not appear to be any requirement that an ACO continue its participation in the SSP beyond the term of its initial agreement. Accordingly, more cautious participants may wish to initially participate in the one-sided model (discussed in greater detail below), and thereby delay bearing any downside risk of loss.

Further, the requirement that ACOs share in losses has led CMS to require that the ACO provide a mechanism, such as letter of credit, bond or similar arrangement, for assuring the ACO will be able to pay its share of losses or reconciliation payments, if applicable. This aspect of the regulations significantly increases the financial burden and risk on organizations which pursue ACOs.

The shared savings and losses will be calculated annually after the close of each performance year. As a result, the ACO will not know how it is doing until after the end of each year. The calculations of shared savings or losses during each three-year ACO agreement will be measured against a benchmark of expenses for beneficiaries that would have been assigned to the ACO during the most recent three years preceding the commencement of the ACO agreement.

However, because the initial term of ACO agreements will start on April 1 or July 1, 2012, the "first year" of the initial agreement will include 6 or 9 months of 2012 plus all of calendar year 2013, and the total term of the initial agreement will be for 3 years plus 6 or 9 months, as applicable. In light of the extended period for the "first year" of the agreement, CMS will offer ACOs the option of seeking an interim payment after 12 months from the commencement date, subject to reconciliation as of the end of 2013.

The ACO will be entitled to share in savings, or be obligated to share in losses, only if the savings or losses exceed applicable minimum savings or losses. Once the minimum savings or losses are met, the ACO will then share in the first dollar of savings or losses.

Both the shared savings and losses are subject to caps, or ceilings, which vary with the participation model the ACO elects (*i.e.*, the "one-sided" or the "two-sided" model, discussed in more detail below).

Two Available Models

Two models are available to the ACO under the regulations, referred to as the “one-sided model” and the “two-sided model.” Under the one-sided model, the ACO shares in savings, but not losses, throughout the initial agreement period. The one-sided model is available as an option only during the term of the initial agreement.

Alternatively, an ACO may immediately assume downside risk by opting for the two-sided model. As a reward and incentive to the ACO for opting for the two-sided model, and immediately taking downside risk, the ACO is provided more opportunity on the upside, through sharing in a higher percentage of the savings, and certain other benefits.

Regardless of the option elected by ACOs during their initial agreement term, for all subsequent agreement terms all ACOs will be required to participate through the two-sided model and assume the downside risk of losses. Presumably those ACOs which initially participated in the SSP under the one-sided model will have their savings, losses, caps and ceilings adjusted accordingly if they continue to participate in the SSP under their subsequent two-sided model agreements.

The Benchmark

The benchmark against which the ACO’s savings or losses are calculated is based on per capita expenditures for applicable beneficiaries. It is computed by looking at the Medicare fee-for-service beneficiaries who would have been assigned to the ACO under the plurality assignment rule addressed in the regulations for the three years immediately preceding the ACO agreement term, taking into account certain key categories in which the beneficiaries fall (*i.e.*, ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible). Medicare will then determine a per patient amount for Medicare expenditures under Parts A and B for those beneficiaries during the benchmark years. The calculation does not include Medicare Part C (managed care) or Medicare Part D (prescription drugs). In addition, there will be a weighting for the three benchmark years, to emphasize the value of the more recent data, as follows: 10 percent weighting for year one, 30 percent for year two, and 60 percent for year three.

Such per capita benchmark expenditures will be adjusted by (a) the annual growth in national per capita Medicare Part A and Part B, and (b) a health risk factor to reflect the health status of the applicable beneficiaries, which CMS is proposing to base on the CMS-HCC models used in the Medicare Advantage Program.

In addition, CMS will exclude per capita expenditures at the 99th percentile. In other words, outlier patients will be excluded to avoid distortions. Also, CMS will exclude certain expenditures in determining the benchmarks (*i.e.*, expenditures tied to physician quality reporting, electronic prescribing and HITECH incentives for eligible professionals). Also CMS will exclude DSH payments and indirect and graduate medical education payments from benchmark and performance expenditures.

Calculating Expenditures During Contract Period

After each year during the ACO agreement, CMS will look at the actual Medicare Part A and Part B expenditures for the Medicare fee-for-service beneficiaries who are retroactively assigned to the ACO for such performance year. The performance year expenditures will be adjusted for certain beneficiary characteristics, primarily involving demographic characteristics.

However, CMS has decided that, for purposes of comparing actual expenditures under the ACO contract to the benchmark, changes in the health status of assigned ACO beneficiaries during the agreement period will be reflected in the determination of whether the ACO has achieved the benchmark only to a limited extent, due to CMS concerns that those changes could result simply from coding improvements, rather than actual changes in condition. CMS will adjust expenditures in a given performance year to account for changes in severity and case mix for Newly Assigned Beneficiaries for such year. Also, CMS will account for changes in severity and case mix for Continuously Assigned Beneficiaries for the performance year, but only to the extent that population shows a decline in the CMS-HCC prospective risk scores.

For purposes of these adjustments, CMS defines a “Newly Assigned Beneficiary” as a beneficiary assigned to the ACO in the current performance year who was neither assigned to, nor received primary care service from, any of the ACO’s participating providers during the most recent preceding calendar year. CMS defines a “Continuously Assigned Beneficiary” as a beneficiary which is assigned to the ACO in the current performance year but who was assigned to, or received primary care services from, any of the ACO’s participating providers during the most recent preceding calendar year.

As with the benchmark, outlier claims will also be excluded from the calculation of expenditures during the agreement period. The average Medicare per capita expenditures during each year of the ACO agreement term, as so calculated, will then be compared to the benchmark per capita expenditures to determine whether there is a savings or loss for the applicable agreement year.

Determining Shared Savings

In order for the ACO to share in savings, the savings amount must exceed what is being called a “minimum savings rate,” (“MSR”). Under the one-sided model, the MSR is based on a sliding scale, with the MSR decreasing from 3.9 percent to 2 percent as the number of assigned beneficiaries increases from 5,000 to 60,000. Under the two sided model, as one of the benefits in exchange for taking immediate risk, the MSR is a flat 2 percent, regardless of how many beneficiaries the ACO has. Under either the one-sided or two-sided model, once the ACO achieves savings in excess of the applicable MSR, the ACO will share in savings from the first dollar, without any deductible.

The percentage of shared savings an ACO receives, once the MSR is met is determined based on the number of quality performance standards the ACO achieves. In the extreme, if the ACO fails to achieve the minimum level on all measures in a performance domain it will not be eligible to share in any of the savings for that year.

The maximum percentage of savings available to an ACO under the one-sided model, assuming all quality targets are met, is 50 percent, and the maximum percentage of shared savings available to an ACO under the two-sided model is 60 percent.

In any case, however, shared savings are subject to the cap equal to 10 percent of the benchmark for the one-sided model, and 15 percent of the benchmark for the two-sided model.

Determination of Shared Losses

The required sharing of losses, of downside risk, by the ACO is a feature that was generally unexpected when the proposed regulations were unveiled. This approach may have been in lieu of incorporation of any “partial capitation” or similar risk component, as would have been expressly

permitted under ACA. Instead, this shared loss approach, which survived the final regulations (albeit in a somewhat less restrictive form, because it will be voluntary), will require ACOs that ultimately participate in the two-sided model to bear downside risk by sharing in the “losses” resulting from expenditures in the applicable ACO agreement year which are higher than the benchmarks established by CMS.

As noted above, loss sharing begins immediately if the ACO elects to participate under the two-sided model. If, however, the ACO elects to initially participate under the one-sided model, it will be required to share in losses beginning only after the end of the term of the initial ACO agreement, for all subsequent ACO agreements.

There is also a minimum loss rate (“MLR”) which must be hit before an ACO under the two-sided model is required to participate in losses. The ACO is responsible for losses only if the per capita expenditures exceed the benchmark by at least 2 percent. However, once the MLR threshold is reached, the ACO is responsible for sharing in losses from the first dollar. In other words, there is no deductible applicable to the shared losses.

The percentage of losses which the ACO must share is set as the inverse of the shared savings rate percentage applicable to the ACO. For example, if an ACO is at a 60 percent level for shared savings, such ACO would share in losses at the rate of 40 percent. However, the ACO’s shared loss rate cannot exceed 60 percent, even if the shared savings rate is less than 40 percent.

In addition, the shared losses will also be subject to caps of 5 percent, 7.5 percent, and 10 percent of the benchmark for each of the three years of the agreement, respectively.

The following chart summarizes, in table format, the key shared savings and loss components, as addressed in the preceding discussion, reflective of data in the Federal Register.

Shared Savings/Losses Overview		
Design Element	One-Sided Model	Two-Sided Model
Maximum Sharing Rate	50 percent	60 percent
Quality Scoring	Sharing rate up to 50 percent based on quality performance	Sharing rate up to 60 percent based on quality performance
Minimum Savings Rate	Varies by population, from 3.9% to 2%	Flat 2 percent regardless of size
Minimum Loss Rate	Not Applicable	Flat 2 percent regardless of size
Maximum Sharing Cap	Payment capped at 10 percent of ACO’s benchmark	Payments capped at 15 percent of ACO’s benchmark
Shared Savings	Savings shared once MSR is exceeded from first dollar of savings, up to 50 percent maximum	Savings shared once MSR is exceeded from first dollar of savings, up to 60 percent

Shared Savings/Losses Overview		
Design Element	One-Sided Model	Two-Sided Model
Shared Losses	None	First dollar shared losses once the minimum loss rate is exceeded. Final loss sharing rate will be inverse of final savings sharing rate but will not exceed 60% Cap on the amount of losses to be shared phased in over three years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the caps would not be shared.

Option for Interim Payment

In light of the extend 18-21 month term of the “first year” of the ACO agreement, CMS is granting ACOs the option of seeking an interim payment, based on the first twelve months of agreement. Such option must be exercised as part of the ACO’s original application. For ACOs electing to receive an interim payment, calculations of shared losses or shared savings will be reconciled as of the end of CY 2013. These reconciliation amounts will reflect aggregate calculations for the “stub” period in 2012 plus the full CY 2013, taking to account the overlap of the interim 12 month period and CY 2013 period. If the reconciliation determines that the ACO was overpaid through the interim payment, the ACO will be required to repay to CMS the amount of such overpayment within 90 days after receipt of notice from CMS that such amount is due.

However, as a condition to receiving the interim payment, the ACO must, in the initial application, establish and provide proof of a self-executing mechanism for ensuring it will be able to pay back any overpayment.

Other Considerations

There are other points of concern and consideration relative to the establishment and calculation of shared savings and losses which we believe are worth noting. One concern relates to the long-term viability of the ACO model based on the concept of ratcheting down expenses for benchmark purposes. As noted, the benchmarks are based on a trailing three years. Therefore, in the initial three-year ACO agreement, the benchmark is based on the three years preceding that agreement. In the second ACO agreement, as the regulations are currently written, the benchmark would be based on per capita expenditures for beneficiaries assigned to the ACO for the three preceding years, which would be the three years under the first ACO agreement. Presumably, during those initial, preceding three years, the ACO would have provided care as efficiently as possible and reduced any excess expenses.

Accordingly, the benchmark against which savings or losses will be calculated for the second ACO agreement would then be based on a reduced level of expenditures, making it that much harder for the ACO to achieve any savings and realize any benefits during the term of the second agreement. For similar reason, the ACO will face greater risk that it will be unable to operate as efficiently in the second agreement as it did during the initial agreement and, therefore, will have to share in losses. We believe that this problem creates significant concerns over the long-term viability of the ACO program as a whole.

Another somewhat surprising and challenging feature is the requirement that the ACOs devise a mechanism to ensure CMS that the ACO will be able to pay its share of any losses or, if applicable, repayment of any excess funds received as part of an interim payment, as noted above. CMS has elected not to establish, in these regulations, an express right to withhold funds from any shared savings payments to apply to later shared losses, or to carry forward any unpaid ACO share of losses to offset against future shared savings payments. However, CMS will require that ACOs establish, and provide proof of, a “self-executing” method for paying any shared losses (or overpayment due upon reconciliation after an interim payment). Although the regulations do not definitively establish how this requirement may be met, examples include mechanisms such as reinsurance, bonds, lines of credit, escrowed funds or other similar readily available fund to pay for potential losses. The regulations require such self-executing method to ensure payment equal to at least one percent of per capita expenditures for all of the ACO’s assigned beneficiaries, based on data from the most recently available year.

This security requirement would apply to two-sided plans, and one-sided plans in which the ACO opts to receive an interim payment, from day one, and must be addressed in the ACO’s application. In addition, the ACO must describe how the ACO’s liability for sharing in losses will be shared among the ACO participants and participating providers.

Finally, even if ACOs are successful in achieving efficiencies and savings, their ability to share in the benefits from such savings will still be dependent on the ACO’s ability to meet detailed quality targets, as addressed above. While many ACOs, particularly those with strong managed care experience, may feel they have effective tools to manage expenses and efficiencies, it may be much harder to develop and implement the tools needed for achieving the quality targets.

MONITORING AND ENFORCEMENT

As discussed throughout this white paper, there is a tremendous amount of information that the ACO will be required to submit to CMS, including a detailed initial application describing the ACO applicant, its ACO participants, its ACO providers/suppliers, how the ACO will be governed and operated, how it will achieve cost savings, monitor quality, and distribute the savings that are achieved. There are also substantial ongoing quality performance reporting requirements relative to the ACO’s quality of care, outcomes, patient satisfaction, etc. CMS, in turn, has indicated in the regulations that it intends to monitor the information that the ACO submits to it, as well as other information on the ACO and its performance. CMS will be using many of the monitoring tools that it is currently using to monitor providers and suppliers, such as analyzing data reported to it, conducting site visits, investigating beneficiary (and other) complaints, and conducting audits, all of which monitoring activities are intended to ensure that the ACO is operating properly within the regulatory framework.

In particular, CMS will be focused on a couple of priority areas. First among these is the potential that an ACO might be engaging in avoidance of “at-risk” beneficiaries (*i.e.*, those beneficiaries whose Medicare costs are likely to be the highest). There is significant concern that an ACO might try to avoid Medicare beneficiaries whose care is likely to be greatest because they have chronic, expensive conditions, or are very sick or elderly or otherwise at risk, and/or that the ACO might try to shed these beneficiaries and discourage them from continuing to see their primary care physician within the ACO, in an effort to shift their costs off the ACO’s budget.

CMS intends to actively monitor ACOs for this. If CMS determines that an ACO is avoiding “at risk” beneficiaries, then the ACO will be required to submit a corrective action plan, and will not be

entitled to any shared savings while the corrective action plan is in place. If the conduct continues despite the corrective action plan, then the ACO will be terminated from the SSP.

CMS intends to be vigilant about compliance with quality performance standards. In the first year, the ACO is required only to accurately report quality data, and does not need to meet the minimum quality performance thresholds. In year two, if the ACO fails to meet certain minimum thresholds for one or more quality of the four “quality domains,” then the ACO will be issued a warning, and will be subject to reevaluation the subsequent year. The ACO will be terminated if there is a continued failure to meet the minimum quality standards.

The ACO can also get in trouble if it does not report data that is required to be reported, and does not have a “reasonable explanation” for that failure. The failure to report the required quality performance data could subject the ACO to termination from the SSP.

All of the ACO’s activities will be potentially subject to monitoring, and if the ACO fails to continue to meet all the ACO eligibility requirements, or its activities are inconsistent with applicable regulatory requirements, then the ACO would be subject to various penalties up to and including termination.

Termination

Prior to terminating an ACO that has breached the applicable regulatory or contractual requirements, CMS may, in its sole discretion, choose to issue a warning notice, request a corrective action plan or place the ACO on a special monitoring plan (naturally, CMS retains discretion to immediately terminate the ACO, if warranted). If the ACO does not remedy the problem after the applicable warning notice has been issued, or pursuant to any corrective action plan or special monitoring plan, then CMS may terminate the ACO from continued participation in the SSP. The potential grounds for termination include breach of the ACO’s agreement with CMS, failure to satisfy the ACO requirements, breaches of other laws by the ACO, etc. If an ACO is terminated, it can reapply later, but only after the end of the original three-year contract term has ended.

Reconsideration/Appeal Rights

There are a number of specific determinations affecting an ACO that are not subject to any type of reconsideration, appeal or review of any type whatsoever. The six CMS decisions that are not subject to review are: (1) specification of ACO quality and performance standards, (2) assessment of quality of care furnished by an ACO, (3) assignment of beneficiaries, (4) calculation of shared savings due to ACO, (5) the percent of shared savings available to an ACO and any limits on same, and (6) the termination of an ACO for failure to meet quality standards. This list of CMS decisions that are not subject to review is actually directly from ACA, so it presumably was not something that CMS viewed as discretionary when preparing the regulations.

On the other hand, if the initial submission to CMS to participate in the ACO program is denied and the applicant is not awarded a three-year contract, that decision can be appealed. Likewise, a termination based on something other than the ACO’s quality can also be appealed.

However, the reconsideration review process is not especially robust. First, the ACO must request review within 15 days of the adverse decision that the ACO wishes to have reviewed, so there is very little time to respond. Also, the review process is relatively informal. The request for review is heard by a “reconsideration official.” In this informal hearing, the burden of proof, of course, is on

the ACO to demonstrate with “convincing evidence” that the initial decision by CMS was inconsistent with the regulations or the applicable statutory authority. Then, the decision by the reconsideration official can be appealed to CMS. At that point, CMS’s decision, after reviewing the reconsideration official’s recommendation, is final and binding.

ADVANCED PAYMENT MODEL

The Innovation Center was established under ACA to test innovative payment and service delivery models in an effort to reduce Medicare costs while preserving and hopefully enhancing the quality of care delivered to Medicare beneficiaries. The Innovation Center is testing and sponsoring various models to determine which may be effective in meeting these goals. Among the models the Innovation Center is sponsoring is the Advance Payment Model (“APM”).

The Innovation Center is using the APM as a complement to the SSP to test whether pre-paying a portion of the future shared savings that certain ACOs may receive will result in increased participation in the SSP; and further, testing whether increasing participation in ACOs may also increase the amount of improvement in care to beneficiaries and the speed at which ACOs can implement such improved care, thereby resulting in Medicare savings.

The thrust of the APM is to assist certain ACOs and their participants that do not have access to sufficient capital to acquire new infrastructure (*e.g.*, invest in data warehouses to generate patient registries) or increase or improve existing infrastructure (*e.g.*, add nurse, care coordinators to expand care management services) necessary for ACOs to meet the criteria and achieve the goals for receiving SSP payments.

The Innovation Center has committed up to \$170 million for the APM with 60% available for eligible ACOs with SSP agreements beginning April 2012, and 40% available for eligible ACOs with SSP agreements beginning July 2012. If there is unused initial period funding, it will be rolled over to the second period.

APM Eligibility

Only two (2) types of ACOs participating in the SSP are eligible to participate in the APM: (1) ACOs with no inpatient facilities and that have less than \$50 million in total annual revenue (*i.e.*, physician-only ACOs), and (2) ACOs with inpatient facilities that are either critical access hospitals (CAHs) or low-volume rural hospitals and that have less than \$80 million in total annual revenue. Specifically excluded as ineligible for the APM are ACOs co-owned with health plans even if they fall within one of the foregoing two types of ACOs.

Eligible ACOs must first be accepted by SSP to be eligible for APM (existing SSP participants that entered program during a prior application period are not eligible for the APM). Applicant ACOs for the APM must apply for the SSP first and then complete the APM applications. The Innovation Center has indicated that it will accept applications in late fall 2011. Information on the timing and form of application will be available at the Innovation Center website, innovations.cms.gov. CMS will review eligibility for SSP applicants and APM applicants concurrently.

APM Selection

Eligible ACOs will be selected for the APM based on a scoring system with criteria that favor those ACOs: (1) with the least access to capital, (2) that serve rural populations, and (3) that serve a

significant Medicaid population. In addition, they will be evaluated on the “Spend Plan” required to be submitted by applicant ACOs that outlines how the ACO intends to utilize and expend the advance payments received through the APM. The APM scoring criteria (described further below) include (a) total revenue of the ACO, (b) the extent or percentage of Medicaid beneficiaries served by the ACO, (c) the rural location of the ACO (in a nonmetropolitan county or in a code 4-10 rural urban commuting area (RUCA)⁵), and (d) the quality of the Spend Plan.

Evaluation Criteria

The evaluation criteria for the Spend Plan will be graded as “unacceptable,” “acceptable,” “good,” or “exceptional.” However, the Innovation Center has not articulated the manner in which the foregoing grades will be determined. A Spend Plan submitted by an ACO must include the following information:

- *Procurements, activities, hiring* – describe in detail the cost estimates, type and number of staff (including estimated salaries, benefits, etc.);
- *Feasible timeframe* – describe the timeframe in which the ACO will implement the foregoing within the initial 18 months of entering into the APM agreement;
- *Compelling rationales* – describe the way each of the procurements, activities, and hiring plans will support care management, financial management, and other essential ACO functions;
- *Investment effectiveness* – explain and describe the way investment of the APM payments will build upon existing infrastructure and experience in care coordination, information management, community partners coordination, and other essential ACO functions;
- *ACO investment in infrastructure* – describe and provide documentation supporting, and level of, the ACO’s own investment in infrastructure; and
- *Strength* – describe the overall strength of plan and business case for the APM making an investment in the ACO through the advance payments.

Scoring

Physician-only ACOs will be scored on the other criteria using the following metrics:

<u>Total revenue</u>	\$30-\$50 million – 4 points \$15-\$30 million – 6 points < \$15 million – 10 points
<u>Medicaid Reliance</u> (Percentage of Medicaid Patients)	< 5% – 0 points 6-10% – 2 points > 10% – 4 points
<u>Rural Location</u>	< 65% in nonmetropolitan counties or in RUCA – 0 points 65-85% in nonmetropolitan counties or in RUCA – 2 points > 85% in nonmetropolitan counties or in RUCA – 4 points

⁵ Please see the websites for the USDA’s Economic Research Service and the Health Resources & Services Administration for definitions and determination of criteria for such counties and RUCAs.

<u>Spend Plan Quality</u>	Acceptable – 0 points
	Good – 4 points
	Exceptional – 8 points

ACOs with CAHs or low-volume rural hospital will be scored on the other criteria using the following metrics:

<u>Total revenue</u>	\$60-\$80 million – 4 points
	\$45-\$60 million – 6 points
	< \$45 million – 10 points
<u>Medicaid Reliance</u> (Percentage of Medicaid Patients)	< 5% – 0 points
	6-10% – 2 points
	> 10% – 4 points
<u>Rural Location</u>	< 65% in nonmetropolitan counties or in RUCA – 0 points
	65-85% in nonmetropolitan counties or in RUCA – 2 points
	> 85% in nonmetropolitan counties or in RUCA – 4 points
<u>Spend Plan Quality</u>	Acceptable – 0 points
	Good – 4 points
	Exceptional – 8 points

APM Payments

If selected, ACOs will begin to receive advance payments at the beginning of the first performance period and ending upon settlement of the SSP savings amount which is scheduled to occur in June, 2014.

There are three (3) types of payments that will be made to selected ACOs: (1) an upfront, fixed payment, under which each ACO will receive a \$250,000 payment in the first month of the SSP, (2) an upfront variable payment, under which each ACO will receive a payment in the first month of the SSP that is equal to the number of its preliminary, prospective assigned beneficiaries multiplied by \$36, and (3) a monthly payment varying based on the size of the ACO, under which each ACO will receive a monthly payment equal to the number of its preliminary, prospective assigned beneficiaries multiplied by \$8. As an example: If an ACO begins participation in April, 2012 with 13,000 assigned beneficiaries it would receive \$718,000 in upfront payments [$\$250,000 + (\$36 \times 13,000)$] and another \$2,808,000 in monthly payments [$\$8 \times 13,000 \times 27$] for a total of \$3,526,000 over the 27-month period.

Recoupment of Advance Payments

If an ACO does not have sufficient savings upon settlement to fully repay advance payments in mid-2014, CMS will recoup the balance from earned shared savings in the subsequent two (2) years of the SSP agreement, and additional years thereafter if the ACO, if any, chooses to enter a second agreement period.

If an ACO does not earn sufficient shared savings in the first agreement period to fully repay advance payments and the ACO does not enter a second agreement period, CMS will not pursue full recoupment of remaining advance payment balance (*i.e.*, CMS will not pursue amounts in excess of ACO's total earned shared savings under the SSP).

However, CMS will pursue full recoupment of advance payments from any ACO that does not complete the full, initial agreement period of the SSP, and CMS will terminate an APM agreement and recoup all advance payments from any ACO that expends funds in a manner inconsistent with the approved Spend Plan. All ACOs receiving advance payments will be required to file periodic reports documenting their use of funds.

FEDERAL ANTITRUST

Antitrust risk is a major concern for ACO development as most ACOs will involve competitors. The Federal Trade Commission (“**FTC**”) and the Department of Justice (“**DOJ**”), the federal antitrust authorities, have expressed particular concern with ACOs being used for the commercial market and competitors collaborating on prices through the ACO. Accordingly, ACO developers will have to engage in potentially complex and costly antitrust analysis, which could serve as another significant hurdle or bar to those potential participants without access to significant resources, which could serve as another significant barrier to potential participants, especially those without access to significant resources.

Limited Antitrust Protections

The final regulations were accompanied by a final policy statement jointly issued by the FTC and the DOJ (“**Antitrust Agencies**”), entitled the Statement of Antitrust Enforcement Policy Regarding the Accountable Care Organizations Participating in the Medicare Shared Savings Program (the “**Policy Statement**”). The antitrust guidance provides a “safety zone” for ACOs (based on the market share of the ACO participants). An ACO that is outside of the safety zone may still request a review by the Antitrust Agencies to ensure it is operating in a manner acceptable to the agencies. Mandatory review by the Antitrust Agencies before participating in the SSP is not required.

Hospitals and ambulatory surgery centers (“**ASCs**”) must not be required or agree to be exclusive to any ACO, irrespective of their market share, although this does not mean that a hospital or ASC must participate in more than one ACO. Importantly, the antitrust guidance does not preclude private rights of action against an ACO for alleged antitrust violations even if the ACO is within a safety zone, and so the risk of a private challenge to an ACO will always be present.

The final regulations and Policy Statement apply to health care collaborations among otherwise independent providers and provider groups that seek to participate as ACOs in Medicare, regardless of their date of formation. The final regulations and Policy Statement, however, do not apply to mergers or single, fully integrated entities.

The Policy Statement recognizes that providers are more likely to form ACOs if they can also use the ACOs for commercially insured patients. However, ACOs that operate in the commercial market will require agreement among otherwise competing providers on pricing, and perhaps market allocation – agreements that typically raise antitrust concerns.

The Antitrust Agencies have issued prior antitrust enforcement policy statements. These statements identified the ground rules for financial and clinical integration as a basis for collaboration, and created several “safety zones,” within which the agencies will not ordinarily challenge a collaborative venture. However, collaborations that fall outside a safety zone are not necessarily illegal; instead, the agencies will apply a “rule of reason” or balancing test if the providers are financially or clinically integrated and the agreement on price is reasonably necessary to accomplish the pro-competitive benefits of the integration. Using this approach, the FTC has previously

declined to challenge several clinical integration programs on the ground that they had the potential to improve the quality and cost-effectiveness of care, and that agreement on price was necessary to this end. However, there is no bright-line test for clinical integration.

The Policy Statement acknowledges that ACOs meeting CMS criteria to participate in the SSP are reasonably likely to be bona fide arrangements intended to improve quality and reduce costs. Therefore, the Antitrust Agencies will apply the “rule of reason” or balancing test to all ACOs that meet CMS criteria and participate in the SSP. The Policy Statement also recognizes that providers would benefit from further additional antitrust guidance, and establishes the safety zone and the option of expedited review in response.

The ACO Safety Zone

The Policy Statement creates a new safety zone for ACOs that meet the CMS eligibility criteria to participate in the SSP. Barring extraordinary circumstances, however, the Antitrust Agencies will not challenge ACOs that fall within the safety zone. ACOs that fall outside the safety zone would not be presumptively unlawful, and will have the option to request review; otherwise, they would be subject to enforcement action if the FTC or the DOJ determined that their formation or conduct was anti-competitive. The Policy Statement provides examples of anticompetitive conduct, and states that an ACO that avoids these types of conduct is highly unlikely to present competitive concerns.

The new safety zone applies to ACOs where independent ACO participants that provide the same service have a combined market share of 30% or less of each common service in each participant’s Primary Service Area (“**PSA**”). The PSA is defined as the lowest number of contiguous zip codes from which the participant draws at least 75% of its patients for the service. To fit within the safety zone, hospitals, ambulatory surgery centers and dominant providers must be non-exclusive to the ACO, regardless of market share. A dominant provider is a participant with a greater than 50% share in its PSA of any service that no other participant provides within the PSA (if another participant also provides the service within the PSA, the 30% limit would apply).

Significantly, the market share analysis is on a service-specific basis. For physicians, the service is based on the specialty identified by the Medicare Specialty Code (“**MSC**”). For hospital inpatient services, the service is based on the Major Diagnostic Condition (“**MDC**”).

For example, suppose that an ACO has three orthopedic surgeons. To determine whether it meets the safety zone, it must first define the PSA of each of the surgeons. It must then determine whether two or more of them provide services in any of the PSAs. If two or more of the surgeons provided services to patients in the same PSA, the ACO must then calculate its participants’ share of orthopedic surgery in each such PSA as a percentage of total allowed charges for orthopedic surgery for all Medicare beneficiaries in the PSA. To aid this calculation, CMS has provided the available aggregate fee-for-service allowed charges by service and zip code on its website.

The ACO will have to perform this analysis for the PSA for each of its participants in which two or more of its participants provide a common service. If the aggregate shares are 30% or less, and hospitals, ASCs and dominant providers are not exclusive to the ACO, it falls within the safety zone. In addition, an ACO with a dominant provider may not restrict the ability of a commercial payer to deal with other ACOs or provider networks.

It appears likely that ACOs that include as participants two or more hospitals providing services in the same PSA will not satisfy the 30% limit to be within the safety zone. Further, since ACOs will

need to assess the PSA on a service-specific basis, calculating the relevant PSA shares could be complex and costly.

Finally, there is an exception to the 30% safety zone limit for ACOs operating in rural counties, as defined by the Census Bureau. These ACOs may include rural hospitals and one physician per specialty per county on a non-exclusive basis, even if the inclusion of the hospital or physician causes the ACO's share of a common service in a PSA to exceed 30%.

Voluntary Expedited Review

All ACOs that were formed after March 23, 2010 may seek a voluntary expedited review. The Antitrust Agencies promise review within 90 days of submission of the required documentation. The reviewing agency will advise the ACO either that it has no present intent to challenge the ACO, or that it is likely to challenge the ACO. A no-action letter may be conditioned on the ACO's addressing concerns raised by the agency. CMS strongly encourages an ACO to seek an expedited review if there is any uncertainty as to its legality.

The Policy Statement also provides guidelines on conduct, which if avoided, will make an enforcement action unlikely. These types of conduct include:

- Preventing or discouraging commercial payers from directing or incentivizing patients to choose other providers;
- Tying sales to the payer's purchase of services from non-ACO participants (and vice versa) – for example, a hospital system's requiring a payer to contract with all of the system's hospitals in order to participate in an ACO to which a single hospital belongs;
- Requiring providers (other than primary care physicians) to be exclusive to the ACO;
- Restricting availability to payers of cost, quality, efficiency and performance data;
- Sharing competitively sensitive price or other data that could be used to set prices or terms of service outside the ACO.

Sharing of Information Between Agencies

CMS will provide the Antitrust Agencies with data and information to help them assess the competitive effects of all ACOs. Such information will include all of the SSP applications for ACOs formed after March 23, 2010 and the aggregate claims data regarding allowed charges and fee-for-service payments for all ACOs accepted into the SSP. The Antitrust Agencies will use this information, together with their traditional enforcement tools, to take whatever action they deem appropriate.

The Policy Statement provides for the first time something in the nature of a bright-line test for clinical integration. A challenge of clinical integration has always been the intensely factual nature of the analysis – the approving advisory opinion that the FTC issued to TriState Health Partner, Inc. in 2009, for example, contained 37 pages of discussion. On the other hand, the participant-by-participant market-share analysis that the Policy Statement would require of ACOs to determine whether they meet the new test appears daunting. Moreover, the Policy Statement would provide no direct protection against antitrust challenges by payers or competing providers that believed an ACO

was acting anti-competitively, and the Antitrust Agencies have stated that they will “vigilantly monitor” complaints about an ACO’s formation or conduct. Lastly, if an ACO’s PSA shares are significantly higher than 30%, it may be prudent to seek a voluntary expedited review. However, given the short time to get an ACO up and running for the initial year, and the fact that the voluntary review program is new, it is yet to be seen whether the Antitrust Agencies will be able to respond to all the inquiries they receive within the 90 day timeframe.

FINAL FRAUD AND ABUSE WAIVERS FOR ACOs

The final fraud and abuse waivers for ACOs are one of the areas that underwent the most pronounced change between the proposed and final regulations. ACA authorizes the HHS Secretary to waive certain fraud and abuse laws to enable implementation of ACOs. Accordingly, the April 7, 2011 joint notice (“**Joint Notice**”) from CMS and the OIG⁶ proposed waivers of three fraud and abuse laws as applied to ACOs: (1) the federal physician self-referral law (“**Stark**”)⁷; (2) the federal anti-kickback law (“**AKS**”)⁸; and (3) the federal civil monetary penalty law (“**Gainsharing CMP**”) prohibiting hospital payments to physicians to reduce or limit services to Medicare or Medicaid beneficiaries.⁹ These proposed waivers were narrow and applied to two basic types of relationships: distributions of shared savings, and financial relationships “necessary for and directly related to” the ACO’s participation in the SSP.

In the Joint Notice, CMS and OIG requested comments on potential additional waiver issues, including start-up costs, costs of ongoing operations, beneficiary inducements, financial arrangements other than distributions of shared savings, and interactions with other non-SSP shared savings programs. CMS and OIG received numerous comments requesting broader protection of ACO activities, and also requesting clarification of various terms, such as “necessary for and directly related to.”

CMS and OIG responded to comments by issuing an interim final rule, which became effective November 2, 2011 with a public comment period that runs until 5:00 p.m. Eastern time on January 3, 2012 (the “**IFR**”) that sets forth final fraud and abuse waivers for ACOs that are broader, simpler in scope, and that contain relaxed criteria for meeting their requirements. In all, the IFR establishes five separate fraud and abuse waivers, including the proposed shared savings distribution and Stark compliance waivers with minor modifications, as well as three new waivers, including a waiver of the federal prohibition on offering incentives (inducements) to Medicare beneficiaries that might influence the items or services the beneficiary orders (the “**Beneficiary Inducements CMP**”).¹⁰ The 5 fraud and abuse waivers established by the IFR are:

- Start-up waiver (new)
- Shared savings distribution waiver

⁶ 76 Fed. Reg. 19655-19660 (Apr. 7, 2011).

⁷ 42 U.S.C. § 1395nn(a).

⁸ 42 U.S.C. § 1320a-7b(b).

⁹ 42 U.S.C. § 1320a-7a(b)(1) and (2).

¹⁰ 42 U.S.C. § 1320a-7a(a)(5).

- Stark compliance waiver
- ACO participation waiver (new)
- Patient incentives waiver (new)

As a threshold requirement, to qualify for the waivers, the ACO and its participants, providers and suppliers must comply with the three-year agreement with CMS, the ACO statute, and the implementing ACO regulations.

While the final waivers are broader than the proposed waivers, like the proposed waivers, they do not apply to any other provisions of federal or state law, including state fraud and abuse laws. Accordingly, ACOs are still responsible for complying with applicable state laws, including state self-referral and anti-kickback restrictions, to the extent they are different from the federal laws. In addition, the final waivers generally only apply to financial relationships in connection with the SSP. All other financial arrangements, such as non-SSP shared savings arrangements, are not covered by the waivers and would need to comply with existing federal and state laws. The waivers will be applied uniformly, and are self-implementing (*i.e.*, they do not require special application to CMS or OIG). Further, the waivers will not be codified in the Code of Federal Regulations.

The IFR notes that the start-up and participation waivers were added to address the majority of ACO-related arrangements, as these waivers cover arrangements both within and outside the ACO. The IFR solicits comments about whether CMS and OIG should exclude outside party arrangements altogether from the scope of the waivers, or, alternatively, whether CMS and OIG should impose conditions to the participation waiver for outside party arrangements (*e.g.*, commercial reasonableness, fair market value requirements, or a ban on exclusive arrangements).

ACO Pre-Participation Waiver

The final “ACO pre-participation waiver” (*i.e.*, the “start-up waiver”) is new from the Joint Notice and is the most complicated of the final waivers. The start-up waiver waives Stark, the AKS, and the Gainsharing CMP with respect to financial arrangements that pre-date the ACO’s participation agreement with CMS.

The IFR provides a non-exhaustive list of fourteen examples of “start-up arrangements” that might qualify for the start-up waiver:

- Infrastructure creation and provision;
- Network development and management, including the configuration of a correct ambulatory network and the restructuring of existing providers and suppliers to provide efficient care;
- Care coordination mechanisms, including care coordination processes across multiple organizations;
- Clinical management systems;
- Quality improvement mechanisms (*e.g.*, mechanisms to improve patient experience);
- Creation of governance and management structures;
- Care utilization management (*e.g.*, chronic disease management, creation of care protocols, patient education);
- Creation of incentives for performance-based payment systems and the transition from fee-for-service payment system to one of shared risk of losses;

- Hiring of new staff (*e.g.*, care coordinators, quality leadership, IT support)
- Information Technology (*e.g.*, EHR systems, data reporting systems)
- Consultant and other professional support (*e.g.*, market analysis for antitrust review, legal services, financial and accounting services);
- Organization and staff training costs;
- Incentives to attract primary care physicians;
- Capital investments including loans, capital contributions, grants and withholds.

Assuming an arrangement is a “start-up arrangement,” it must meet the following six requirements to qualify for waiver from Stark, AKS and the Gainsharing CMP:

- **Good-faith intent:** the arrangement must be undertaken by a party or parties acting with good-faith intent to develop an ACO that will participate in the SSP starting in a particular year and to submit a completed application to participate in the SSP for that year;
- **Diligent steps:** the parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year, including taking diligent steps to meet the SSP requirements concerning ACO governance, leadership, and management;
- **Reasonably related to SSP purposes:** the ACO’s governing body has made and duly authorized a bona fide determination, consistent with a duty to the ACO that is equivalent to the duty owed by ACO governing body members, that the arrangement is “reasonably related” to the “purposes of the SSP”;¹¹
- **Contemporaneous documentation:** the party or parties to the arrangement must maintain contemporaneous documentation of the arrangement, authorization, and the diligent steps;
- **Public disclosure:** the description of the arrangement must be publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary (although such disclosure shall not include the financial or economic terms of the arrangement);
- **Statement of reasons if no application submitted:** if the ACO does not submit an application for a participation agreement by the last available application due date for the target year, the ACO must submit a statement on or before that date, in a form and manner to be determined by the Secretary, describing the reasons it was unable to submit an application.

The parties to a start-up arrangement must include an ACO or one or more ACO participants eligible to form an ACO. The parties cannot include drug or device manufacturers (because they are not Medicare-enrolled providers/suppliers), and cannot include durable medical equipment or home

¹¹ The term “purposes of the SSP” is defined to include promoting accountability for the quality, cost, and overall care for a Medicare patient population described in the SSP; managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and encouraging investment in infrastructure, redesigned care processes for high quality, and efficient services delivery for patients, including Medicare beneficiaries.

health suppliers (because CMS and OIG view them as having historically “posed a heightened risk of program abuse”).

The IFR provides several additional examples of purposes that CMS and OIG consider “reasonably related” to the purposes of the SSP:

- Promoting evidence-based medicine and patient engagement
- Meeting requirements for quality and cost reporting
- Coordinating care
- Meeting SSP clinical integration requirements
- Meeting SSP quality performance requirements
- Evaluating health needs of assigned beneficiaries
- Communicating clinical knowledge and evidence-based medicine to beneficiaries
- Developing standards for beneficiary access and communication

An arrangement need only be reasonably related to one enumerated purpose to qualify for the waiver. The IFR notes, however, that arrangements with similar purposes but unrelated to the SSP (e.g., arrangements solely relating to commercial ACOs) are not eligible for the waiver, although arrangements that involve care for non-Medicare patients and Medicare beneficiaries would be eligible for the waiver. The IFR solicits comments on whether CMS should further define “reasonably related.”

The IFR also provides guidance about what type of documentation of start-up arrangements they will expect, and for how long they expect such documentation to be maintained.

- The documentation of the arrangement must be retained for at least 10 years following completion of the arrangement or, in the case of diligent steps, must be retained for at least 10 years following date ACO submits its application or the date the ACO submits its statement of reasons for failing to submit an application.
- The description of the arrangement must include all parties to the arrangement; the date of the arrangement; the purpose(s) of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.
- The documentation of the authorization should reflect the date and manner of the governing body’s authorization of the arrangement, and should include the basis for the determination by the ACO’s governing body that the arrangement is reasonably related to the purposes of the SSP. The IFR does not specify the manner in which the ACO governing body must make the determination or authorize the arrangement, although the ACO must have a meaningful conflicts of interest policy in place.
- The description of the diligent steps taken to develop an ACO should include the timing of actions undertaken and the manner in which the actions relate to the development of an ACO that would be eligible for a participation agreement.

The IFR also provides interim guidance regarding the public disclosure of the arrangement. Pending the Secretary’s official guidance on public disclosure of start-up arrangements (which the final Joint Notice notes is not expected to be onerous), parties to a start-up arrangement should disclose the

arrangement within 60 days of the start of the arrangement by posting the disclosure on the public website belonging to the ACO or the individual/entity forming the ACO. The disclosure should contain the name of the ACO or the individual/entity forming the ACO, and other identifying info sufficient to allow individuals conducting an electronic Internet search using a widely available search engine to readily locate the website.

For arrangements that meet all of the preceding conditions, the start-up waiver period will start on November 2, 2011 for target year 2012, and one year preceding the application due date for later target years. The waiver period will end on either: (1) the ACO's participation agreement start date (if the ACO's application is submitted and accepted); (2) the date of the denial notice from CMS (if the application is denied), unless the arrangement qualified for the waiver before the denial was issued, in which case the waiver period would end 6 months after the date of the denial notice; or (3) the earlier of the application due date for the target year or the date the ACO submits its statement of reasons for failing to submit an application, although an extension of this period is available if the ACO can demonstrate a likelihood of successfully developing an SSP-eligible ACO by the next available application due date.

The Secretary will establish procedures in guidance for the waiver extension process. The determination of whether to grant waiver extension will be in sole discretion of Secretary and will not be reviewable. An ACO may use the start-up waiver, including any extensions, only once.

Shared Savings Distribution Waiver

The IFR adopts the proposed shared savings distribution waiver with minor modifications. The shared savings distribution waiver waives Stark, the AKS, and the Gainsharing CMP with respect to distributions or use of shared savings the ACO earns, subject to five conditions:

- The ACO has entered into a participation agreement and remains in good standing under that agreement;
- The ACO earned the shared savings pursuant to the SSP;
- The ACO earned the shared savings during the term of its participation agreement (even if actual distribution occurs after the agreement has expired);
- The shared savings are either (1) distributed to or among the ACO's participants, providers/suppliers, or individuals and entities that were participants or providers/suppliers during the year in which the ACO earned the shared savings, or (2) used for activities that are reasonably related to the purposes of the SSP; and
- Payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.

The waiver permits distributions of shared savings within the ACO in any form or manner, including "downstream" distributions or uses of shared savings funds between or among ACO members. The waiver also permits ACOs to use shared savings in arrangements with outside parties, provided the arrangement meets the "reasonably related" test (simplified from the proposed "necessary for and directly related to" standard in the proposed waiver). The waiver will not protect distributions of shared savings to referring physicians outside the ACO unless they meet the reasonably related test

or were ACO participants or providers/suppliers during year in which the ACO earned the shared savings.

With respect to the fifth condition for the shared savings distribution waiver, which prohibits payments to reduce or limit medically necessary care, the waiver permits the ACO to incentivize the provision of alternate and appropriate medically necessary care consistent with the purposes of the SSP. For example, the provision of coordinated outpatient care rather than inpatient services, or the use of evidence-based protocols for medically necessary care. The IFR notes that “medically necessary” will be interpreted consistent with Medicare program rules and accepted standards of practice.

Stark Compliance Waiver

The IFR adopts the proposed Stark compliance waiver with minor modifications. The Stark compliance waiver waives the AKS and the Gainsharing CMP with respect to any financial relationship between or among the ACO, its participants, and its providers/suppliers, which implicates Stark, subject to three conditions:

- The ACO has entered into a participation agreement and remains in good standing under that agreement;
- The financial relationship is reasonably related to the purposes of the SSP; and
- The financial relationship fully complies with a Stark exception.

Similar to the final shared savings distribution waiver, the final Stark compliance waiver replaces the “necessary for and directly related to” standard with the simpler “reasonably related” standard.

Assuming the above conditions are met, the waiver begins on the ACO’s participation agreement start date, and ends on the earlier of the expiration (including any renewals) or voluntary termination of the participation agreement. This means that the final Stark compliance waiver would not protect distributions or use of shared savings following the expiration or termination of the ACO’s participation agreement. CMS has solicited comments regarding the possible addition of a “tail” period (*e.g.*, 3-12 months) after expiration or termination of the ACO’s participation agreement.

Participation Waiver

The ACO participation waiver is new from the Joint Notice, and waives Stark, the AKS, and the Gainsharing CMP with respect to any arrangement of an ACO, one or more of its ACO participations or providers/suppliers, or a combination thereof, subject to five conditions:

- The ACO has entered into a participation agreement and remains in good standing under that agreement;
- The ACO meets the SSP requirements concerning ACO governance, leadership, and management;
- The ACO’s governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the SSP;

- Contemporaneous documentation (same requirements as the start-up waiver, except no “diligent steps”);
- Public disclosure (same as the start-up waiver).

Because the participation waiver protects the activities of an ACO and its constituent parts, the source of the funds under arrangements that qualify for the participation waiver is irrelevant. Accordingly, this waiver arguably could protect arrangements downstream of commercial ACOs, such as arrangements between hospitals and physician groups.

Assuming the arrangement qualifies for the participation waiver, the waiver starts on the participation agreement start date and ends 6 months following the expiration (including any renewals) or voluntary termination of the participation agreement. However, if CMS terminates the participation agreement, the waiver period will end on the date of the termination notice.

Patient Incentives Waiver

The IFR adopts a new “patient incentives waiver” that waives the AKS and the Beneficiary Inducements CMP with respect to items or services provided by an ACO or its participants or providers/suppliers, to any Medicare beneficiary (not limited to an ACO’s assigned beneficiaries) for free or below fair market value, subject to four conditions:

- The ACO has entered into a participation agreement and remains in good standing under that agreement;
- A “reasonable connection” exists between the items or services provided and the beneficiary’s medical care (*e.g.*, waiver would cover blood pressure cuffs for hypertensive patients, but not beauty products or theater tickets);
- The items or services provided are in-kind (*i.e.*, no direct financial or monetary incentives, such as waiving or reducing patient co-pays or deductibles); and
- The items or services are preventive care, or advance one or more of a specified set of clinical goals, including adherence to a treatment regime, drug regime, or follow-up care plan, or management of a chronic disease or condition.

Assuming the above conditions are met, the waiver begins on the ACO’s participation agreement start date, and ends on the earlier of the expiration (including any renewals) or voluntary termination of the participation agreement. Beneficiaries may keep items they have received before the agreement expiration or termination, and also may receive the remainder of any services initiated before expiration or termination. For example, a post-surgical patient receiving free home visits to coordinate in-home care during the recovery period could receive home visits for the entire recovery period, even if the ACO’s participation agreement terminated halfway through the recovery period.

The IFR notes that the waiver does not protect the provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries or to the ACO, ACO participants, or ACO providers/suppliers. Thus, the waiver would cover an ACO, ACO participant, or ACO providers/supplier that provides beneficiaries with items or services that they have received from manufacturers at discounted rates, but would not cover the upstream discount arrangement between the manufacturer and the ACO, ACO participant, or ACO provider/supplier.

The IFR also notes that even in the absence of the patient incentives waiver, some beneficiary incentives may meet an existing exception to Beneficiary Inducements CMP for promotion of delivery of preventive care.

The patient incentives waiver could potentially permit ACOs to implement mechanisms to provide financial incentives to preliminary prospectively assigned ACO beneficiaries to remain within the ACO and prevent beneficiary “leakage.”

Additional Policy Considerations

In the IFR, CMS and OIG noted that they intend to “closely monitor” ACOs during 2012 and through June 2013, and that they plan to narrow the waivers in the future, unless the Secretary determines that the final waivers established in the IFR adequately protect the Medicare program and beneficiaries from fraud and abuse. Any subsequent modifications to the waivers would apply prospectively, and the IFR solicits comments regarding narrower waivers and additional categories of arrangements that require waiver protection.

Thus, notwithstanding the much more expansive waivers established under the IFR as compared with the Joint Notice, CMS and OIG’s comments indicate the potential for decreased flexibility under the fraud and abuse waivers in the future. As noted above in the discussion regarding regulatory changes during an ACO’s agreement period, narrower fraud and abuse waivers could force an ACO to restructure its arrangements, or possibly withdraw from the SSP altogether. Such uncertainty may create disincentives for providers to participate in the SSP, at least until OIG and CMS issue definitive guidance about the ultimate shape the “final” waivers will take.

Scope of the Proposed Waivers

The scope of the final waivers is much broader than the surprisingly narrow waivers initially proposed under the Joint Notice. CMS and OIG appear to have taken comments from providers seriously in broadening the scope of the waivers to include necessary ACO-related activities such as start-up arrangements, and to protect arrangements beyond the mere distribution of shared savings to ACO participants and ACO providers/suppliers. The expanded scope of the waivers appears to encompass most financial arrangements that ACO participants might wish to construct to allocate or require reimbursement for up-front costs and/or operating losses, such as shared-risk, resource pooling, incentive payments, and other financial arrangements an ACO might want to establish internally to promote efficient operation of the ACO.

While the final waivers are broader than the proposed waivers, the final waivers still generally cover only ACOs under the SSP and related arrangements. Accordingly, private payer shared-savings distribution programs generally will not be protected and must comply with generally applicable federal and state laws. In addition, while the final waivers set forth in the IFR do apply to the APM (because this model is merely an alternative payment mechanism under the SSP), the final waivers do not apply to other programs that the Innovation Center administers, such as the Pioneer ACO program or the Bundled Payments for Care Improvement program. The ACA contains separate fraud and abuse waiver authority for Innovation Center programs, and the IFR indicates that guidance on these waivers will be issued “shortly.”

Finally, as in the Joint Notice, nothing in the IFR preempts state laws or other federal laws not specifically mentioned in the IFR (such as federal tax and antitrust laws). Accordingly, state regulatory schemes still apply to ACOs, and ACOs must comply with these laws. For example,

many states separately have anti-kickback statutes or self-referral prohibitions that are similar but not identical to Stark or the AKS. Thus, an ACO must take into account and comply with these state laws when structuring and operating the ACO, because complying with the proposed waivers for Stark, the AKS, or the CMP statute will not necessarily mean that the ACO complies with comparable state laws. Similarly, some states have strong corporate practice of medicine prohibitions, which heavily restrict the ability of a lay corporation to influence or control the delivery of health care. These prohibitions may stand in tension with the goals of the SSP; because one of the elements of an ACO is that the ACO implement evidence-based medicine standards and impose those standards on its participants. As a result, notwithstanding the good intentions of the federal program, more restrictive state laws may pose additional obstacles to the formation and operation of ACOs.

TAX-EXEMPT ISSUES

ACOs raise a number of issues for tax-exempt hospitals. For example, tax-exempt hospitals will want to know that ACO participation will not result in private inurement, more than incidental private benefit or unrelated business income, all of which can result in adverse consequences for a tax-exempt hospital. Fortunately, the IRS has provided some commentary as to its proposed treatment of ACOs that are participating in the ACO program.¹²

In its guidance, the IRS acknowledged that many tax-exempt hospitals and potentially other tax-exempt entities (such as community clinics or medical foundations) would be participating in ACOs in conjunction with “insiders” of such tax-exempt entities. Relationships between “insiders” and tax-exempt entities are subject to additional scrutiny and regulation to prevent private inurement and non-incidental private benefit. This is particularly relevant in the ACO context for tax-exempt hospitals, as physicians who are medical staff leaders or otherwise affiliated with the participating hospital may be deemed to be “insiders” of the hospital, and would be logical ACO partners.

Thankfully, the IRS has indicated that if the ACO is properly structured it should not result in private inurement or non-incidental private benefit. Although the IRS generally indicated that it will review ACO arrangements on a case-by-case basis, based on all the facts and circumstances, the IRS also explained that a tax-exempt organization’s participation in an ACO will not generally result in private inurement or non-incidental private benefit if the following conditions are satisfied:

- The terms of the tax-exempt organization’s participation in the ACO (including its share of profits or losses and expenses) 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 ACO program.
- The tax-exempt organization’s share of economic benefits derived from the ACO (including its share of profits) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO.

¹² IRS Notice 2011-20; IRS Fact Sheet FS 2011-11.

- The ownership interest received by the tax-exempt organization in the ACO is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations, and distributions are made in proportion to such ownership interest.
- The tax-exempt organization's share of the ACO's losses do not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.
- All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

The provisions addressing sharing of profits and losses and capital contributions may raise challenges where a tax-exempt hospital has provided the bulk of the up-front of capital for the ACO, but ACO primary care physicians are generating the bulk of the savings through their ongoing efforts. However the IRS has provided some guidance, which sheds some light on how the IRS will likely evaluate these factors. In particular, the IRS has indicated that it will take into account all contributions made by the charitable organization and other ACO participants to the ACO, in whatever form (cash, property, services), and all economic benefits received by ACO participants (including shares of ACO payments and any ownership interests) in determining whether ownership interests and allocation of ACO payments are appropriately apportioned.

Similarly, the requirement that payments for services be consistent with fair market value may also raise unique challenges, as questions arise as to whether fair market value is more appropriately determined by the hours of time expended by physicians boosting quality and controlling costs, or by the dollars of cost savings those efforts actually yield, which result in shared savings paid to the ACO. In many circumstances, these requirements regarding fair returns on capital invested and fair payments for services provided may require protracted negotiations between tax-exempt hospitals and their physician partners, and may provide practical impediments to constructing and operating a successful ACO.

Unrelated Business Income Tax

The IRS also addressed whether a tax-exempt organization's portion of the bonus payments received by virtue of its participation in an ACO would be subject to unrelated business income tax. Unrelated business income generally results when the activities generating the income are not "substantially related" to the performance of the tax-exempt organization's charitable purposes. The IRS indicated in its guidance that ACO participation by a tax-exempt entity could be structured to avoid unrelated business income, assuming that private inurement and private benefit are not present, and provided the ACO meets all of the eligibility requirements established by CMS for participation in the ACO program. In such cases, any payments received by the tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government (by reducing Medicare program costs), which has been previously recognized by the IRS on the rationale that Medicare is the burden of the federal government.

Non-Program Activities of the ACO

The IRS's guidance was limited to participation in the ACO program and does not extend to protect outside activities (such as entering into and operating under shared savings arrangements with private health insurance payers). The IRS indicated that these types of activities are unlikely to

lessen the burdens of government and that negotiation with private health insurers on behalf of unrelated parties is generally not a charitable activity, regardless of whether such an agreement involves a program aimed at achieving cost savings in health care delivery. The IRS, however, recognized that there are certain non-program activities that may further or be substantially related to an exempt purpose of a tax-exempt organization. By way of example, the IRS indicated that an ACO participating in shared savings arrangements with Medicaid may further the charitable purpose of relieving the poor or underprivileged.

Given this lack of clarity regarding the treatment of ACOs in the private payer context, tax-exempt hospitals may wish to structure their ACOs in such a way so that they would be unlikely to result in private inurement, non-incidental private benefit and unrelated business income, regardless of the IRS guidance. In order to achieve this, tax-exempt hospitals should follow the general guidance regarding other joint ventures, which involve insiders, such as ancillary service ventures, ambulatory surgery centers, and other joint ventures. Thus, tax-exempt hospitals should strongly consider maintaining majority control of the governance of and profit participation of the ACOs, as well as ensuring that the organizational documents of the ACOs provide for covenants that are consistent with the tax-exempt hospitals' charitable purposes.

Tax Issues Relating to Choosing Form of Entity

Tax issues may also arise based on the type of entity that is used to form an ACO with multiple participants. For example, an ACO structured as a corporation for federal tax purposes will be treated as a separate taxable (unless exempt) entity from its participants. By contrast, if an ACO is structured as a partnership for federal tax purposes (including LLCs electing partnership tax treatment), its activities will generally be attributed to its partners. Therefore, if a tax-exempt hospital is participating in an ACO that is formed as an LLC with partnership tax election, the LLCs actions will be attributed to the tax-exempt hospital owner. The IRS has indicated that participation in the ACO program will generally further charitable purposes. Therefore, if the LLC limits its activities to the SSP, there will not be risk to the tax-exempt hospital owner. However, if the LLC attends to activities beyond the SSP, the tax-exempt hospital will need to evaluate those activities to determine whether they are consistent with its charitable purposes or, if not, whether they will be more than an insubstantial part of the tax-exempt hospital's activities. In addition, the tax-exempt hospital would be wise to ensure that they have majority control of the governance of the LLC, if it will engage in any activities beyond the SSP.

The ACO itself may also be a tax-exempt entity. However, an entity that is treated as a partnership or disregarded for tax purposes will not be eligible to qualify for tax-exempt recognition. Note, if the ACO is formed as a tax-exempt entity, that should be considered, there may be additional restrictions on the distribution of shared savings to the ACO participants.

STATE LAW ISSUES

The formation of ACOs under the final regulations raise many difficult state law issues. As discussed above, neither the ACO statutory provisions, the regulations, the antitrust guidance, nor the fraud and abuse waiver guidance pre-empts state law. ACOs which comply with the regulations, fall within the antitrust safety zone or obtain a favorable FTC or DOJ letter, and would not violate the federal fraud and abuse laws in view of the available waivers, may nevertheless violate state law. We perceive this as a major flaw in the ACO scheme; one which could be an obstacle to the development of ACOs in many states.

We discuss briefly several of the important state law issues below.

Corporate Practice of Medicine

Many states, such as California, Texas and New York have enacted laws with a very strong prohibition on the corporate practice of medicine. This doctrine prohibits lay entities from practicing medicine, with limited exceptions. The prohibition can potentially be violated where a lay entity exerts an impermissible level of control over a physician's medical judgment, or where a lay entity profits directly from a physician's practice of his or her professions.

We anticipate that most ACOs will be lay entities, and therefore, it will be important for ACO participants located in states with strong corporate practice prohibitions to appropriately structure their ACOs in accordance with applicable state law requirements.

State Anti-Kickback Laws

Many states have enacted laws that, separate and independent of the AKS, prohibit payments for patient referrals. An approach to distributing the shared savings or other ACO relationships that are within the federal waiver may still violate a state's anti-kickback statute(s), depending on the specific state involved. For example, any distribution of the shared savings to physicians that could be viewed as an inducement for the physicians to make referrals to a particular entity could violate state law. Thus, in many cases, ACO arrangements must be analyzed for compliance with applicable state anti-kickback statutes regardless of whether they satisfy a federal waiver.

State Self-Referral Law

Many states have also enacted laws that prohibit referrals by physicians for certain services to entities in which the physicians have a financial interest. As with the corporate practice and anti-kickback laws discussed above, potential applicants should be mindful of applicable state self-referral requirements and structure their ACO arrangements accordingly. Compliance with a Stark waiver or exception might not ensure compliance with the applicable state self-referral law, depending on the state.

State Antitrust Laws

Many states have enacted their own antitrust laws that are similar to federal antitrust laws. Satisfaction of a federal safety zone, or a favorable FTC or DOJ letter, does not necessarily provide immunity from a violation of a state's antitrust laws, and ACO applicants may need to consider their state antitrust laws as part of their planning and feasibility analysis.

State Laws Regulating Health Plans

Many states have regulations that require a health plan, HMO or any entity that accepts risk for the provision of health care to obtain a license to operate and comply with a detailed regulatory scheme. Thus, depending on the state, an ACO could find itself subject to regulation as an HMO. ACO participants in states that have laws regulating health plans, HMOs and the like should consider inquiring with their applicable state licensing agency regarding that agency's position with respect to the licensing of ACOs, and also ensure that their arrangements are appropriately structured to comply with the state's applicable licensing laws.

CONCLUSION

ACOs are the most recent development in the ongoing convergence of reimbursement and quality under the Medicare program. Despite being a “permanent” program, the SSP, as currently structured, is presumably a transitional play by CMS. ACOs are one of several strategies CMS is employing that indicate a broader shift toward a risk-based reimbursement model under the Medicare program with an emphasis on care integration and quality performance measures. Other examples include incentive programs like the PGP, Acute Care Episode (“ACE”), value-based purchasing, and national payment bundling demonstrations, and reimbursement penalties for hospital-acquired conditions (“HACs”).

Given the short ramp-up period for ACOs to meet the initial implementation dates of April 1, 2012, or July 1, 2012, providers may want to consider waiting for some period after the commencement of the SSP before making a final decision about whether to take on the risk of becoming an ACO participant.

Although the final regulations on Medicare ACOs look much better than the proposed regulations, the universe of providers for whom participation under the SSP is attractive – or even feasible – may still be relatively small. Accordingly, providers should view ACOs as one of a number of potential strategies available to help drive their organizational efforts to further clinical integration. Whether and to what extent participating in an ACO makes sense will depend on a variety of market-specific factors. In the final analysis, many providers may determine that it is either too costly or too uncertain a proposition to participate in an ACO.

However, regardless of whether a provider participates in an ACO, the elements of the SSP offer a window into the probable future shape of the Medicare program. For example, CMS has specifically mentioned telehealth, remote patient monitoring, and electronic records as “modern technologies” that it expects ACOs to implement “to continually reinvent care in the modern age.” Thus, even for those who decide not to participate in the SSP, finding opportunities to strengthen an organization’s competencies in clinical integration, patient-centeredness, and care management should pay dividends as Medicare’s payment model ultimately moves in a direction that demands such skills to succeed.

ADDITIONAL INFORMATION

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