PROPOSED ACCOUNTABLE CARE ORGANIZATION REGULATIONS: ANALYSIS AND IMPLICATIONS

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INTRODUCTION AND EXECUTIVE SUMMARY[1]

On April 7, 2011, CMS formally published proposed regulations (an advanced copy was released to the public on March 31, 2011), which would implement the shared savings program ("**SSP**") between Medicare and accountable care organizations ("**ACOs**"), for Medicare fee for service beneficiaries. The proposed ACO regulations have been highly anticipated throughout the health care world, with many providers expecting to create, join, or respond to the advent of ACOs with emotions ranging from enthusiasm to dread. The deadline for submitting comments is 5:00 PM Eastern time on June 6, 2011.

However, the proposed regulations contain a number of significant surprises that have caused many providers to reconsider their Medicare ACO strategy. The proposed regulations would require even greater investments than many providers expected. In addition, the proposed regulations, along with their companion notices on antitrust guidance from the Federal Trade Commission ("**FTC**") and Department of Justice ("**DOJ**") and proposed fraud and abuse waivers from CMS and the Office of the Inspector General ("**OIG**"), contain far fewer protections for Medicare ACOs than the provider community previously anticipated.

CMS has set the bar for participation very high – possibly too high for many providers. In response, it is likely that many public comments will be submitted to the proposed regulations, and CMS will have to determine if it will scale back its requirements when it issues final ACO regulations later this year. If it does not, then many providers may decide to explore ACO alternatives.

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 losses) associated with the care for those assigned beneficiaries.

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

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

- A distinct legal entity;

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

Given the specific structure and governance requirements for ACOs, it may be easiest to use a new, special purpose entity. The ACO must be composed of an "eligible group" of "ACO participants," which essentially includes any Medicare providers or suppliers.[2] However, the ACO must have enough "ACO professionals" (i.e., primary care physicians) to serve at least 5,000 Medicare fee for service beneficiaries. ACO professionals must be exclusive to one ACO, but other ACO participants cannot be required to be exclusive to an ACO and must agree to participate for at least three years.

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

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

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

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

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

- ACO participants and ACO providers/suppliers must make a "meaningful commitment" to the ACO (e.g., invest time, effort or money);
- The ACO must have a physician-directed quality assurance and process improvement program;
- ACO participants must agree to comply with evidence-based clinical guidelines;

[2] The proposed regulations use the phrases "ACO participants" (likely the ACO's founders/owners) and "ACO providers/suppliers" (likely others who contract with the ACO), but do not clearly distinguish between these two categories.

- The ACO must have information technology infrastructure (including EHR – and at least 50% of the ACO's primary care physicians must be "meaningful users" of certified EHR technology)
- The ACO must adopt a compliance plan; and
- The ACO must have a written plan for achieving and distributing shared savings, and improving quality of care.

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

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

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

Shared Savings Based on Three-Year Benchmark. Under the proposed regulations, Medicare would continue 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 proposed regulations would require CMS to develop a benchmark for savings that each ACO must achieve to receive shared savings in each performance year, or else be held liable for losses. The benchmark would be based on per capita expenditures for Medicare 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 would be subject to several adjustments, including for Medicare claims growth and beneficiary health status.

Shared Savings Subject to Several Restrictions. The proposed 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 52.5% under the one-sided model (subject to a maximum sharing cap of 7.5% of the ACO's savings benchmark), and up to 65% under the two-sided model (subject to a maximum sharing cap of 10% of the ACO's benchmark). Each of an ACO's annual shared savings payments (if any) also is subject to a flat 25% withhold in order to offset any losses for which the ACO is responsible during the three-year agreement period. Finally, due to a proposed 6-month claims run-out for purposes of calculating Medicare expenditures, shared savings payments would not be made for at least 18 months after January 1 of the applicable performance year.

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, the details of the proposed SSP indicate that even sophisticated providers with experience in managing care under capitated contracts may find success under the proposed SSP elusive. The following aspects of the proposed SSP may present particular challenges for aspiring ACO participants, providers, and suppliers:

- **Extensive up-front and ongoing participation requirements.** ACOs will require substantial up-front capital, personnel (e.g., a full-time medical director and management staff), and organization (e.g., full-fledged compliance and QAPI programs). Based on findings from the federal Government Accountability Office, CMS estimates that the total average start-up investment and first year operating expenditures for an ACO will total roughly $1.8 million. 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 large capitated IPAs, particularly in states like California, where such organizations are already heavily regulated much like insurance companies.

- **No guaranteed admission to the SSP.** An ACO's initial investment and organization may come to naught if CMS refuses to admit the ACO to the SSP. CMS has not clarified whether an ACO that otherwise meets the SSP requirements will be admitted, but the proposed regulations indicate that CMS will have (and 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 an ACO – 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 proposed approach may diminish an ACO's ability to fully recoup its investment in clinical integration.

- **Significant consequences for underperforming ACOs.** CMS's comments indicate that an ACO that suffers a net loss in the first three-year agreement period will not be permitted to reapply to the SSP. If the projected return on investment horizon for the systemic changes the SSP requires providers to make is greater than three years, or if an ACO is simply the victim of bad luck, this "net loss" restriction could create a substantial disincentive for an ACO to participate in the SSP as presently structured. Given the SSP's strong roots in the Medicare Physician Group Practice ("**PGP**") demonstration project methodology and provider experiences under that program, some data suggest that many organizations may lose money in the first three years under the proposed ACO model. In addition, the use of a historical three-year benchmark may create diminishing returns for ACOs as they become more efficient over time. Thus, while ACOs may offer potential long-term cost savings, the "net loss" restriction under the SSP may create too short a horizon for ACOs to achieve a meaningful return on investment.

- **True downside risk under either of the two models.** Whether in year three under the one-sided model, or in all three years under the two-sided model, an ACO bears substantial risk under the SSP for incurring costs in excess of its benchmark. While CMS proposes to cap an ACO's downside risk to some extent, the SSP as proposed places significant risk on ACOs and their participants, particularly in the absence of limiting downside risk through partial capitation. Such an approach, when combined with retrospective beneficiary assignment and the "net loss" restriction discussed above, may cause providers to think twice about whether their organization can manage care effectively enough on a population basis to ultimately come out ahead under the SSP.

- **Shared savings are subject to many restrictions and delayed payout.** The various qualification thresholds, percentage limitations, withholds, and delayed payout (under the proposed six-month claims run-out) collectively create substantial uncertainty about whether and to what extent shared savings will materialize at all, let alone in sufficient amounts to permit an ACO to recoup its startup and operating costs.

- **Limited antitrust and fraud protections.** While the proposed antitrust guidance may help insulate ACOs from FTC and DOJ enforcement, the guidance does not appear to foreclose private individuals (e.g., physicians excluded from the ACO's network of "ACO professionals") from instituting private causes of action against an ACO or its participants for violation of federal and state antitrust laws.

- **Limited fraud and abuse protections.** The narrow proposed fraud and abuse waivers do not appear to protect many of the financial arrangements an ACO likely would require to acquire start-up capital and to fund operating costs and/or losses, unless those financial relationships are with a physician and meet the applicable requirements of the proposed waivers. In addition, financial arrangements that do not involve distribution of shared savings generally fall outside

the scope of the proposed waivers. As a result, shared-risk, resource pooling, incentive payments, and other financial arrangements an ACO might want to establish internally to promote efficient operation of the ACO generally also would be unprotected.

- **No preemption of state laws.** Finally, nothing in the Joint Notice proposes federal preemption of state laws. Accordingly, state regulatory schemes still apply to ACOs, and ACOs must comply with these laws, such as state self-referral and 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 proposed 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, like California, have strong corporate practice of medicine prohibitions, which heavily restrict the ability of a lay corporation to influence or control the delivery of health care. These prohibitions stand in tension with the goals of the SSP – one of the elements of the SSP is that the ACO implement evidence-based medicine standards and impose those standards on its participants. As a result, notwithstanding the good intentions of the federal program, more restrictive state laws may pose additional obstacles to the formation and operation of ACOs.

ACO Alternatives

If SSP participation is ultimately unattractive or infeasible, several alternatives exist that may provide levers for providers to drive their organizations' clinical integration efforts. For example, by 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). Further, the newly established Center for Medicare and Medicaid Innovations is tasked with funding additional payment and system delivery models that improve care and lower costs. Additionally, 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.

ORGANIZATION OF AN ACO

The proposed 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. The definition of the term "ACO" provides that the ACO must be a legal entity, recognized and authorized under state law to perform the functions required of an ACO (e.g., the ability to receive and distribute shared savings, repay shared losses, and ensure provider compliance with ACO health care quality criteria and standards), and with its own Taxpayer Identification Number ("**TIN**"). 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.

The definition also requires that the ACO be composed of eligible "ACO participants" that work together to manage and coordinate care for Medicare fee-for-service beneficiaries, and that the ACO have an established mechanism for shared governance that provides all ACO participants with appropriate, proportionate control.

Although the proposed ACO regulations do not expressly require that a new entity be formed to serve as the ACO, in analyzing the requirements of the ACO regulations, it is apparent that the best means to organize an ACO likely would be to form a new special purpose entity to act as the ACO. This is because, as discussed in more detail below, there are a number specific governance requirements that an ACO must satisfy, and it is unclear that an existing entity would be able to (or would desire to) meet these specific requirements. CMS has indicated that existing entities may lack the broad proportionate control necessary for participation as an ACO, and that it might be more difficult for CMS to audit an existing entity that has non-ACO related operations. Finally, CMS has indicated in its commentary that if an existing entity desired the inclusion of new providers and suppliers into an ACO, a new entity would be required. For these reasons, most ACOs will likely be formed as a new entity, established to act as the ACO. If a new distinct entity has already been formed by the participants for operation of the ACO, this should suffice, as the entity can probably meet or be modified to meet all of the applicable requirements of the ACO regulations.

Type of Entity

There is substantial flexibility regarding what type of entity may be an ACO, provided the entity is capable of recognition under applicable state 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 proposed 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 many states, including California. 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.

Similarly, there may be difficulty using a for-profit business corporation as the ACO entity, because a director normally would owe a fiduciary duty to the ACO to maximize returns to the participants. This duty may conflict with the requirement under the proposed ACO regulations that the Medicare beneficiary board member represents the interests of Medicare beneficiaries the ACO serves. Because most state laws (including those in California) provide greater flexibility for limited liability companies, it may be advisable to use an LLC to serve as the ACO, and assign separate duties to the different managers of the LLC. In addition, as part of its response to public comments, perhaps CMS will clarify how the duties of the Medicare beneficiary representative apply, within the context of other duties owed.

ACO Participants

The proposed regulations provide significant flexibility as to who may participate in an ACO, although all ACOs must be anchored by a core group of primary care physicians who have at least 5,000 Medicare fee-for-service beneficiaries, in the aggregate (i.e., not 5,000 per physician), assigned to them. Assuming the ACO is able to meet the 5,000 beneficiary requirement, 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; and
- Other Medicare providers and suppliers that are not professionals or hospitals.

Thus, it appears that any Medicare provider or supplier could participate in an ACO, assuming the ACO has the sufficient core of primary care physicians and the ACO can otherwise satisfy the applicable requirements.

In the CMS commentary to the proposed ACO regulations, CMS went out of its way to indicate that CMS wanted to encourage the participation of rural health clinics ("**RHCs**") and federally qualified health centers ("**FQHCs**") in ACOs. As described in more detail below, CMS is also offering a higher percentage of savings to ACOs that include participation with RHCs and FQHCs.

As mentioned in the introduction, the term "ACO participant" is used throughout the regulations in a manner suggesting that CMS intends the term to mean the owners, investors, and/or founders of the ACO. By contrast, the proposed regulations use the term "ACO providers/suppliers" in a way that suggests that these are merely contractors with the ACO, without ownership or control. Unfortunately, neither term is clearly defined, and thus it is often unclear in the proposed regulations whether particular requirements are intended apply to all the ACO's providers and suppliers, or just the core providers and suppliers that form, own, and/or control the ACO. Hopefully, the final regulations will provide additional clarity in this area, after CMS reviews the comments to the proposed ACO regulations.

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 a governing body. By way of illustration, with a corporation this would likely be the Board of Directors and with a limited liability company it could be a Board of Managers.

Governing Body

The governing body is required to have the following participants: (a) the ACO participants or their designated representatives; and (b) a Medicare beneficiary representative or representatives served by the ACO, who does not (personally, or through a family member) have conflict of interest with

the ACO. The governing board is required to have broad responsibility for the administrative, fiduciary, and clinical operations of the ACO.

At least 75 percent control of the governing body must be held by ACO participants or their representatives. In its commentary, CMS alluded to the fact that remaining 25 percent could include participation from health plans or management companies. This 25 percent would also need to include the Medicare beneficiary representative(s). Importantly, the ACO governing body must be separate from the ACO participants' governing bodies, unless the ACO is made up of one, single participant that meets all of the ACO requirements (e.g., a large IPA with more than 5,000 Medicare fee for service beneficiaries assigned to its primary care physicians).

The proposed ACO regulations require that each ACO participant have proportionate control over decision making. However, the ACO regulations are unclear as to what "proportionate control" means and how it is determined. CMS has indicated that the proportions should be based on capital invested and/or "sweat equity" based on the time or effort of the participants. However, it is unclear how sweat equity should be quantified.

This may raise significant practical issues when an ACO's participants are making disparate contributions to the ACO. For example, institutional ACO participants, such as hospitals, might bring significant capital to the table in forming ACOs, while physicians might devote substantial time and effort. For this reason, it will be very important to have an agreed-upon mechanism for valuing the participants' contributions, and for determining their respective decision-making and control rights. This will also likely impact the Stark, anti-kickback and tax-exempt analysis of the ACO (as discussed in greater detail below in the section titled "PROPOSED FRAUD AND ABUSE WAIVERS FOR ACOS").

Executive Management

The proposed ACO regulations provide some initial guidelines for the executive management of the ACO. For example, the ACO is required to be managed by an executive, officer, manager, or general partner who is overseen by the governing body and has the ability to influence or direct clinical practice to improve efficiency processes and outcomes. The ACO is also required to have a full-time, senior-level medical director who must be present at an assigned ACO location, and who is a board-certified physician in the state in which the ACO operates.

BENEFICIARY ASSIGNMENT

A critically important aspect of the proposed regulations in the manner in which they address the assignment of beneficiaries to an ACO. Surprisingly, CMS has proposed that the assignment of beneficiaries will be made on a retrospective basis, so that the ACO participants will not know who has been assigned to the ACO for a performance year until after the year is over.

The proposed regulations also define what it means to be assigned to an ACO. CMS has opted to preserve the beneficiaries' freedom of choice, so that beneficiaries may obtain services from any provider or practitioner without restriction.

As discussed below, both of these choices have significant implications.

How Beneficiaries Are Assigned to an ACO

The proposed regulations assign beneficiaries to an ACO for a performance year after the completion of the performance year. 42 C.F.R. § 425.6(b). Thus, the ACO and its participating practitioners and providers will not know whether a patient is in the ACO at the time services are furnished.

Beneficiaries are assigned to an ACO based on the provision of primary care services by primary care physicians. CMS identifies all primary care physicians participating in an ACO during a performance year. CMS then determines all beneficiaries who received primary care services during the performance year from the primary care physicians in the ACO, the total allowed charges for primary care services furnished to each such beneficiary, and the total allowed charges for primary care services for each beneficiary for services furnished by each primary care physician participating in the ACO. A beneficiary is assigned to the ACO for a performance year if, for the performance year, the plurality of the total allowed charges for primary care services furnished by primary care physicians were furnished by primary care physicians participating in the ACO.

A primary care physician is a physician who is identified with the Medicare program as having a primary care specialty of internal medicine, general practice, family practice, or geriatric medicine. Note that the definition of primary care services excludes physicians in many specialties who furnish primary care services, such OB-GYNs. Primary care services furnished by physicians who are not in one of the designated primary care specialties are not considered when determining the assignment of beneficiaries to an ACO.

Primary care services include evaluation and management service identified by HCPCS codes 99201 through 99215, 99304 through 99340, and 99341 through 99350, the Welcome to Medicare Visit identified by HCPCS code G0402, and the annual wellness visit identified by HCPCS codes G0438 and G0439. Other services furnished by primary care physicians are not taken into account in assigning beneficiaries to ACOs.

CMS's decision to assign beneficiaries on a retrospective basis and the manner in which the assignments will occur have several profound implications and raise various questions.

Because an ACO will not know who is assigned to it until after the performance year, it would likely be prudent for ACO participants to treat all beneficiaries as if they were in the ACO. CMS is clearly aware that this will likely occur, and explains that one of the reasons it has adopted a retrospective approach is so that ACOs and their participants will provide the same level of efficient and quality care to all patients. CMS will thereby realize savings for patients who are ultimately not assigned to the ACO without sharing any portion of those savings with the ACO, essentially obtaining a free ride for the beneficiaries who are not assigned to the ACO.

Retrospective assignment will require ACOs to track the data needed for ACO participants for all beneficiaries. This would include data required to demonstrate compliance with quality performance standards, as well as data supporting the metrics used by the ACO internally to enhance quality and efficiency.

Similarly, ACO participants will likely have to apply the ACO's evidence-based clinical guidelines to all beneficiaries. Additionally, ACOs will develop referral relationships with practitioners and

providers who are not ACO participants, such as physician specialists and post-acute discharge providers, where the participants agree to apply the ACO's clinical guidelines, comply with the ACO's reporting requirements, and otherwise comply with the ACO's policies. ACO participants will likely be encouraged to refer all beneficiaries to these practitioners and providers, because they will not know at the time of the referral whether the beneficiary will be assigned to the ACO. Thus, specialists and post-acute discharge providers will have enhanced incentives to develop relationships with ACOs, as those who do not develop such relationships may lose a proportion of their referrals of Medicare beneficiaries from the ACO participants.

Retrospective assignment may pose a particular problem for a practitioner or provider that is in more than one ACO. As discussed below, in general only primary care physicians will be required to have an exclusive relationship with an ACO. Others, like physician specialists and hospitals, may participate in multiple ACOs. It is unclear which ACO's policies a practitioner or provider that is in multiple ACOs should apply, and to which ACO the practitioner or provider should report data during the year.

Retrospective assignment, combined with the retrospective establishment of the shared saving benchmark as discussed below, will make it extremely difficult for ACOs to evaluate their performance on an ongoing basis during a performance year. An ACO will not be able to determine with any significant degree of precision where it stands in light of its benchmark, whether it is likely to make or lose money for the performance year, and how much any gain or loss is likely to be. This will make contemporaneous financial reporting very difficult, as well as management decisions that are tied to understanding an organization's ongoing financial performance.

CMS's decision to base assignment solely on services furnished by primary care physicians means that services furnished by mid-level primary care practitioners, such as physician assistants and nurse practitioners, will not be taken into account (unless such services are furnished incident to a physician's services and billed under the physician's NPI). This may result in changes to relationships between primary care practitioners and mid-level practitioners so that the services of the mid-level practitioners are furnished in accordance with Medicare's incident-to rules. The exclusion of services furnished by mid-level practitioners that do not meet Medicare's incident-to requirements appears to be inconsistent with a fundamental purpose of ACOs, which is to encourage the efficient provision of care by the appropriate level of practitioner. CMS explains that it believes its hands are tied by the statutory language on this issue.

As noted previously, CMS's definition of primary care physicians excludes many physicians who furnish primary care. CMS recognizes that this definition may create problems, particularly for rural areas in which physician specialists may be the principal providers of primary care and invites comments on this issue. ACOs should take care to ensure that physician specialties are accurately reported to Medicare, so that physicians who are in one of the four primary care specialties are identified correctly. This may require some thought with respect to physicians who practice both in one of the primary care specialties and another specialty.

Operational Identification of an ACO

An issue CMS confronted in connection with beneficiary assignment was how physicians and others would be linked to an ACO. CMS required a methodology for determining which primary care

physicians were part of an ACO in order to assign beneficiaries based on primary care physician services.

CMS has proposed to view an ACO operationally as a collection of Medicare enrolled TINs. ACOs would be required to provide CMS with the TINs of their participants. Thus, a medical group would have a single Medicare enrolled TIN, while a network of independently practicing physicians would have a collection of Medicare enrolled TINs. Beneficiaries will be enrolled in an ACO based on the primary care services furnished by primary care physicians within a TIN of an ACO participant.

CMS proposes that all ACO professionals within a TIN be exclusive to one ACO agreement. This exclusivity applies to primary care physicians, but not to specialists.

ACO participants with TINs upon which beneficiary assignment is not based (that is, participants with TINs that do not include primary care physicians) like hospitals and physician specialty groups, must agree to participate in the ACO for the full three year term of the ACO agreement. However, these entities are not required to be exclusive to an ACO, and must be permitted to join multiple ACOs.

CMS does not directly address what happens when a primary care physician leaves or joins a medical group that participates in an ACO. We believe the services furnished by the physician while he or she is in the medical group would be credited to the ACO, but it would be helpful if CMS were to specifically address this issue.

CMS also does not discuss the purchase or sale of an ACO participant. Where an ACO participant is sold and the buyer has a different TIN than the seller, such as in an asset sale of a medical group or a hospital, may the buyer step into the seller's role and participate in the ACO? A strict reading of CMS's discussion in the proposed rules is that the buyer would not be permitted to participate. This reading of CMS's proposal could destroy an ACO if the ACO's principal primary care physician group was sold in an asset sale.

Finally, CMS does not discuss a specialty group participating in an ACO that adds primary care physicians after an ACO is formed. Prior to adding a primary care physician, the group could not agree to be exclusive to a single ACO. Will the group be required to be exclusive to the ACO after adding the primary care physician?

The Impact to a Beneficiary of Assignment to an ACO

The assignment of a beneficiary to an ACO has no impact on the beneficiary's freedom to choose any Medicare enrolled practitioner or provider. Beneficiaries who seek services from ACO participants, and who are assigned to an ACO, may obtain services from any practitioner or provider enrolled in Medicare. Beneficiary assignment is solely for determining shared savings or loss for a performance year and the beneficiaries for whose care the ACO is accountable. 42 C.F.R. §425.6(a)(2).

Because beneficiary assignments to ACOs are made retrospectively, and do not affect the beneficiary's freedom of choice, the beneficiary is never notified that he or she has been assigned to an ACO. ACO participants, however, are required to post signs in each of their facilities and

provide written notification for beneficiaries about their participation in the SSP. 42 C.F.R. § 425.6(c).

CMS's proposal that beneficiary assignment will not affect freedom of choice limits an ACO's ability to control utilization of services and to direct beneficiaries to practitioners and providers that participate in or are otherwise affiliated or contract with the ACO. The ACO will be accountable for the cost of care for all beneficiaries assigned to it for the purpose of determining shared savings or loss, including Medicare payments to practitioners and providers who have no relationship with the ACO. It appears that ACOs will be able to control utilization primarily through the persuasive efforts of the ACO participants, and, in particular, of the primary care physicians participating in the ACO. This approach places ACOs in an entirely different posture than health plans, which can directly control the use of non-participating providers.

QUALITY REPORTING AND PERFORMANCE

ACOs must satisfy detailed and substantial quality reporting and performance requirements. 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 Performance Standards

The proposed regulations divide the quality measures or performance standards into five domains. These include patient/care giver experience, care coordination, patient safety, preventative health, and at-risk population/frail elderly health. 42 C.F.R. § 425.10(a).

CMS has identified 65 quality measures. These measures are allocated among the domains, although they are not allocated evenly. For example, the patient safety domain has two performance standards, while the at-risk population/frail elderly health domain has 31 performance standards.

For each quality measure, CMS has identified a measure title and description, a CMS program or National Quality Forum ("**NQF**") measure or standard, a method of data submission, and a measure type. For example, the first quality measure is "Getting Timely Care, Appointments, and Information," which is in the patient/care giver experience domain, corresponds to NQF #5, is submitted through a patient survey, and has a measure type of "patient experience of care." The eighth quality measure is "The rate of readmissions within 30 days of discharge from an acute hospital for assigned ACO beneficiary populations," which is the care coordination domain, has a CMS program measure, is reported based on claims, and has a measure type of "outcome."

Some of the quality measures have very specific clinical criteria. An example is quality measure 36, which is in the domain at-risk population/frail elderly, has a measure title and description of "diabetes mellitus—hemoglobin AIc control (<8%): percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin AIc less than 8.0%," corresponds to NQF #575, has a method of submission using the group practice reporting option data collection tool, and a measure type of "outcome."

The reporting measures are described in Table 1 of the NPRM, which is located at 76 Fed. Reg. 19527, 19571 (Apr. 7, 2011).

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. 42 C.F.R. § 425.10(b). The benchmarks and minimum attainment levels are established using Medicare fee-for-service, Medicare Advantage, or ACO performance data, depending on data availability. CMS proposes to set the minimum attainment level at 30% or the 30th percentile of the relevant data. CMS will publish the benchmarks and minimums before the beginning of each performance year

Two of the quality measures are "all or nothing measures," meaning the ACO scores zero points if it does not attain the benchmark and the maximum points for the measure if the benchmark is attained. The remaining quality measures are scored based on a sliding scale. An ACO that fails to achieve the minimum attainment level receives zero points. An ACO that achieves the benchmark receives the maximum points available for the quality measure, which CMS proposes to be 2 points for each measure. An ACO that achieves a score between the minimum and the benchmark receives a portion of the maximum available points.

For the first performance year, performance is measured by the level of complete and accurate reporting. For subsequent years, performance is measured based on the performance measure scores.

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. 42 C.F.R. § 425.10(d).

An ACO receives a score for each domain. An ACO must submit all measures within a domain to receive any shared savings in order to be considered for shared savings for that domain.

A score is established for each domain based on the score for each measure within the domain. An ACO must attain the minimum attainment score for each measure within a domain to receive a score for that domain. An ACO's overall quality performance score is based on the score of each domain. Each domain is given equal weight in determining an ACO's overall quality performance score regardless of the number of measures within the domain.

If an ACO receives a maximum overall quality score, and meets the other requirements to receive shared savings, the ACO will receive 100% of the shared savings to which it is otherwise entitled. If the ACO receives a score that is less than the maximum, the ACO will receive a portion of the share savings to which it is otherwise entitled, depending upon the percentage of the maximum score achieved.

Audits of Quality Data

CMS may audit the quality data reported by an ACO. 42 C.F.R. § 425.10(d)(3)(iii). The ACO would be required to provide the auditors with beneficiary medical records information as requested.

An audit would consistof three phases of medical record review. 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, will be required to maintain an auditable trail supporting their quality data reporting. Additionally, the ACO will have to have access to the medical records of beneficiaries who are assigned to the ACO in order to be able to substantiate the quality reporting.

Physician Quality Reporting and EHR Technology Reporting

Eligible professionals may receive a Physician Quality Reporting System ("**PQRS**") incentive under the SSP equal to 0.5% of the ACO's eligible professional's total estimated allowed charges under the Medicare physician fee schedule during each calendar year reporting period. To qualify for this incentive, the ACO must submit, on behalf of its eligible professionals, the quality measures determined by CMS. To qualify as a group practice for a PQRS incentive, the eligible professionals within an ACO must report the required quality measures.

At least 50% of an ACO's primary care physicians must be "meaningful users" of certified EHR technology by the start of the second performance year to continue participating in the SSP. CMS proposes to terminate the agreement of any ACO that does not meet this standard.

Implications of Quality Measures

The quality measures are very detailed and comprehensive. It will be imperative for an ACO to develop systems to ensure compliance with the quality measures.

This is likely to require a significant expenditure of time and resources, including the development of an EHR solution involving all ACO participants, as well as other IT applications. All ACO participants, and, in particular, the primary care practitioners, will have to agree to report data on all 65 quality measures, and the ACO will have to implement mechanisms to ensure compliance. This will be no easy task.

OPERATIONAL REQUIREMENTS

The proposed ACO regulations specify numerous processes and procedures aimed at improving quality along the spectrum of care, and reporting data in accordance with the quality of care goals and performance measures. A sophisticated information technology infrastructure is necessary to assure that relevant data is captured and accurately reported. Physicians must lead the ACO's quality assurance program, which must emphasize evidence-based clinical guidelines and provider adherence to performance standards. While certain operational requirements are specified in the proposed regulations, those entities that are contemplating forming an ACO should engage in comprehensive planning that includes the practical aspects of implementing the numerous processes necessary to achieve the ACO goals.

Data Collection and Reporting Systems

Information technology is critical to the ACO's operations, and the proposed regulations reflect that. For example, as noted above, the proposed regulations require that at least 50% of the ACO's

primary care physicians must be "meaningful users" (as defined in the HITECH Act[3]) of certified EHR technology by the start of the ACO's second performance year. If the 50% level is not achieved, the ACO cannot participate in shared savings and CMS can terminate its agreement with the ACO.

However, the EHR capability will be essential to implementing the required processes 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. The quality performance measures span five different domains, from the patient encounter through the coordination of care to the reporting of data (the quality measures are discussed in greater detail above, in the section titled "QUALITY REPORTING AND PERFORMANCE"). While tracking and monitoring the data along the way, the ACO is obligated to provide feedback to each ACO provider/supplier so that continuous improvement occurs.

ACOs that submit the quality measurement data in the manner directed by CMS for each of its eligible professionals for each performance measure are considered "satisfactory reporters" under the proposed regulations. When submitting all of its quality data and other information, an individual in the ACO with the authority to legally bind the ACO must certify the accuracy, completeness, and truthfulness of the information.

Quality Assurance and Improvement Program ("QA Program")

The ACO needs to establish and maintain a physician-directed QA Program. 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. These include evidence-based clinical guidelines and care delivery processes that take into account the circumstances of individual beneficiaries.

The proposed regulations require that a physician-directed committee oversee what the regulations describe as an "on-going action-oriented" QA Program. All of the ACO's providers and suppliers must agree to be held accountable for meeting the performance standards and for investing time, effort, or money in the ACO. The QA Program must include procedures for monitoring and evaluating individual provider/supplier performance and imposing remedial measures, including expulsion from the ACO, for substandard performance. Monitoring and tracking the data is necessary in order to provide feedback to each ACO provider/supplier.

The ACO will need to establish procedures to monitor and evaluate all of the performance standards by which it will be measured. It will need, for example, processes for patient engagement, promoting the coordination of care, identifying and developing individual care plans for targeted patient populations, evaluating the health needs of its assigned population of beneficiaries, and developing care plans that take into account the beneficiary's health and psychological needs and preferences and values.

[3] The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009.

Plan for Achieving and Distributing Shared Savings

The proposed regulations do not mandate the specific manner in which an ACO will achieve and distribute any shared savings and improve the quality of its assigned beneficiaries' care. However, an ACO applicant must submit a written plan describing how it will do so in accordance with the SSP's "triple aim" of better individual care, better health for populations, and lower growth of expenditures. Accordingly, this will have to be carefully analyzed and determined before an aspiring ACO submits its application to CMS.

Compliance Plan

The proposed regulations require every ACO to have a compliance plan, overseen by a compliance officer. The compliance officer would report directly to the ACO governing body (and the compliance officer cannot be the ACO's legal counsel). The compliance plan should contain procedures to address fraud and abuse, such as reporting mechanisms where an individual suspects problems related to the ACO or suspects violations of law. Compliance training for participants and providers is also required.

Marketing Materials and Activities

An ACO cannot use any ACO marketing materials and activities until CMS approves them. Once approved, any changes an ACO makes to the marketing materials must also be CMS-approved prior to use. The definition of "marketing materials and activities" is 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, and data sharing opt out letters are all defined as "marketing materials and activities."

Books and Records

An ACO must 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 CMS's determination that a need exists to retain the records for longer, e.g., where fraud is alleged or is reasonably possible, in which case, records must be retained for an additional six years from the date of a final resolution.

Analysis of Potential Implications

An ACO will need a sophisticated information technology infrastructure to capture all relevant data, accurately and comprehensively. Without this, an ACO is likely to set itself up for failure. The accuracy of the data is necessary to obtain any shared savings, and CMS will have 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 all of the necessary procedures are functioning in a manner that captures and produces accurate data.

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 under California state law. Those who may have participated in an audit or survey conducted by the California Department of Managed Health Care can vouch for the administrative burden these types of documentation requirements create. On the other hand, there are some procedures and standards with which California providers will be familiar and that would not create additional processes, e.g., timely access standards.

ACO applicants will need to address the proposed ACO requirement of expulsion of a provider or supplier who does not meet performance standards. For example, they will need to decide what consequences will follow if/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. The ACO plan 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. The ACO will also have 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 maybe excellent partners for an ACO, all the more so because additional compensation is available to ACOs that include RHC and FQHC participants.

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 proposed regulations regarding these agreements, their requirements, and the obligations and benefits for an ACO under the agreement.

Start Date of Agreement

The proposed ACO regulations propose: (1) to adopt the general requirement that ACO applications must be submitted by a deadline established by CMS; (2) that CMS will review and approve applications from eligible organizations prior to the end of the calendar year; (3) that the requisite three-year agreement period will begin on January 1 following approval of an application; and (4) that the ACO's performance periods under the agreement will begin on January 1 each year during the agreement period.

Given the short timeframe for implementing the SSP in the first year of the program (i.e., January 1, 2012), CMS is soliciting comments on alternatives to a January 1 start date. One example CMS provides in the proposed regulations is a single additional start date of July 1, 2012 and to allow the agreement period for ACOs with a July 1 start date to be increased to 3.5 years. Under this example, the first performance year would be defined as 18 months so that all agreement periods would synchronize beginning on January 1 of the following year. CMS has indicated that this additional start date would be available only in 2012, and that for subsequent years, all applications would need to be reviewed and accepted prior to January 1 of the applicable calendar year, and all agreements would be for three years.

CMS has a statutory mandate to roll out the SSP no later than January 1, 2012. If the final regulations are substantially similar to the proposed regulations, the number of potential applicants for whom participation in the SSP is an attractive option may be relatively small, and there may be

fewer still who are prepared to submit a complete application in time to go live on January 1, 2012. However, the addition of a mid-2012 start date may afford greater opportunities for providers to participate in the SSP and to obtain an ultimately longer (3.5 years) initial participation period, particularly if CMS decides to substantially re-work the SSP to make participation more likely (e.g., by reducing barriers to entry and/or increasing the scope of fraud and abuse waivers).

Timing/Process for Evaluating Shared Savings

PPACA[4] 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 proposes using a six-month claims run-out to calculate the benchmark and per capita expenditures for the performance year.

The impact of the proposed six-month run-out is that ACOs will not receive any shared savings payments until at least 18 months following the start of the ACO's agreement with CMS. Depending on (a) what kind of claims risk providers think may exist between a three-month versus a six-month run-out; and (b) how comfortable providers are in relying on CMS to develop an "adjustment factor," providers may want to submit comments to CMS articulating alternative policy options such as a shorter run-out period to accelerate feedback on ACO performance and distribution of shared savings to ACOs.

Data Sharing

PPACA 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 proposed regulations, 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 proposed 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**") 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

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

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 proposed 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 historically assigned beneficiaries used to calculate the ACO's benchmark, which during the first year of the program most likely will be the beneficiaries who would have been assigned to the ACO during the previous twelve months under the ACO beneficiary assignment methodology. The quarterly aggregate data reports will be based on rolling 12-month data for potentially assigned beneficiaries. No beneficiary identifiable information will be provided in either the annual or quarterly aggregate data reports, although CMS will include deidentified claims history for the ACO's assigned beneficiaries.

The aggregate data reports will include, where available, financial performance data, quality metrics, aggregated metrics, and utilization data. Financial performance data may include the number of patients seen, the number of patients assigned, per capita expenditures, risk score, benchmark, total assigned beneficiary expenditures, minimum savings amount, shareable savings, and annual performance payment. Quality metrics may include quality performance scores, including numerator/denominator, rate for each measure, along with the target benchmark for each measure. 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. We note, however, that CMS appears to be promoting an "all boats rise" approach by combining aggregate data reports with 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 ("historically 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 historically assigned beneficiaries generally will continue to receive care from the ACO, the historically assigned beneficiary 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 opt out (described in more detail below), CMS will provide more detailed monthly claims data for potentially 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 beneficiary ID, date of birth, gender, date of death, claim ID, from/through dates of service, provider or supplier ID, and claim payment type. The Part D data set may include beneficiary ID, prescriber ID, drug service date, drug product service ID, quantity dispensed, days supplied, gross drug cost, brand name, generic name, drug strength, and an indication of whether the drug is on the CMS formulary.

With respect to a beneficiary's decision to "opt out" of the more detailed data sharing, the proposed regulations provide that the beneficiary must have a "meaningful opportunity" to opt out. CMS has 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.

Accordingly, in order to comply with the "meaningful opportunity" guidance, 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). If a beneficiary elects to opt out, the opt out does not apply to the base data set for historical beneficiaries, and does not affect other uses of the beneficiary's data (i.e., calculating ACO benchmarks/performance).

Responsibility for New Program Standards

Under the proposed regulations, an ACO will be subject to all 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 proposed 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 CMS has specified, the ACO would be terminated from 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 have a material adverse effect on an ACO's ability to achieve 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, CMS has proposed a process for making an ACO accountable for internal changes, as well.

CMS has placed restrictions on an ACO's ability to alter its original participant structure. During the three-year agreement period, an ACO may remove, but may not add, ACO participants, although an ACO may add or remove ACO providers/suppliers.[5]

CMS also has proposed a requirement that an ACO must provide CMS with 30 days' prior notice to any "significant change." The proposed regulations defines a "significant change" to include deviation from ACO's application (e.g., drop out of an ACO primary care physician, reorganization, change in planned distribution of shared savings); a "material change" (e.g., changes that affect eligibility, sanctions against the ACO); a mandated reorganization due to antitrust concerns; and exclusion or conduct restriction of ACO members.

CMS will review the notice, and five potential outcomes may result. First, CMS may determine that the ACO can continue to operate under its remaining structure. Second, CMS may determine that the ACO must submit a new application to maintain its continued eligibility to participate in the SSP. Third ,CMS may determine that a mandatory antitrust review is required, because the remaining ACO structure has materially changed. Fourth, 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

Perhaps the single most surprising feature of the proposed regulations is a requirement that all ACOs ultimately will be required to bear down-side risk by sharing in losses as well as gains. This approach did not appear to be contemplated by the statutory scheme, which focuses on sharing savings with an ACO.

Further, the requirement that ACOs share in losses has led CMS to propose features would assure the ACO will be able to pay back its share of losses. These include withholds of shared savings

[5] As mentioned above in the section titled "ORGANIZATION OF AN ACO – ACO Participants," the terms "ACO Participant" and "ACO providers/suppliers" are not defined in the proposed regulations so as to be clearly distinguishable categories, thus creating some uncertainty in determining the application of requirements applicable to one category but not the other.

payments to the ACO as well as other devices, such as a bond or letter of credit, to be offered by the ACO. This aspect of the proposed 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.

The ACO will be entitled to share in savings, or be obligated to share in losses, only if the savings or losses exceed an applicable minimum savings or losses. In certain circumstances, once the minimum savings or losses are met, the ACO will then share in the first dollar of savings or losses. In other cases, the ACO will share in losses or savings only above a certain threshold or "deductible" amount.

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 proposed regulations, referred to as the "one-sided model" and the "two-sided model." Under the one-sided model, the ACO shares in savings throughout the agreement period, but is responsible for losses, (i.e. sharing in the failure to achieve benchmark efficiencies) only in the third year 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.

Once the ACO is in the position of assuming risk under the one-sided model (i.e. in year three), it is treated essentially the same as under the two-sided model.

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 proposed regulations for the three years immediately preceding the ACO agreement term. 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).

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, 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.

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). CMS, however, will not make adjustments for such items as Medicare DSH payments, indirect and graduate medical education payments, and changes to the wage index.

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 contract period will be excluded from the determination of whether the ACO has achieved the benchmark, due to CMS concerns that those changes could result simply from coding improvements, rather than actual changes in condition.

As with the benchmark, outlier claims will also be excluded from the calculation of expenditures during the contract period. The average Medicare per capita expenditures during each year of the ACO contract 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 contract 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-side model, the MSR is based on a sliding scale, with the MSR decreasing from 3.9 percent and two 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 the one-sided model, once the ACO achieves savings in excess of the applicable MSR, the ACO will share in savings in excess of 2 percent. In other words, for the one-sided model, even after the requisite MSR is met, there is still a "deductible" for which the ACO does not share in savings. Alternatively, under the two-sided model, if the ACO savings exceed the MSR, the ACO shares in the savings from the first dollar, without any deductible.

The percentage of shared savings an ACO receives, once the MSR is met and the deductible (if applicable) is applied, is determined based on the number of quality performance standards the ACO achieves. In the extreme, if the ACO failed to pass any quality performance standards, the ACO would share in none of the savings.

The maximum percentage of savings available to an ACO under the one-sided model, assuming all quality targets are met, is 52.5 percent, which includes a 50 percent "base" sharing rate, plus an additional 2.5 percent if the ACO includes the requisite involvement by a Rural Health Center ("**RHC**") or a Federally Qualified Health Center ("**FQHC**") as an ACO provider.

The maximum percentage of shared savings available to an ACO under the two-sided model is 65%, which includes a 60 percent base rate plus an additional 5 percent if the ACO includes the requisite involvement by a RHC or a FQHC.

In any case, however, shared savings are subject to the cap equal to 7.5 percent of the benchmark for the one-sided model, and 10 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. This approach may have been in lieu of incorporation of any "partial capitation" or similar risk component, as would have been permitted under the statute. Instead, this shared loss approach will require ACOs ultimately to participate in downside risk by sharing in the "losses" resulting from expenditures in the applicable ACO contract 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 have to share in losses beginning only in the third year. In any case, after the initial ACO contract, all ACOs will have to participate in downside risk under the two-sided model.

There is also a minimum loss rate which must be hit before the ACO 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 minimum loss rate 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.

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 contract, respectively. For an ACO participating under the one-sided model, the cap applicable during the third year, when it first assumes downside risk, will be set at 5 percent of the benchmark.

The following chart summarizes, in table format, the key shared savings and loss components, as addressed in the preceding discussion, and is largely taken directly from the Federal Register.

Shared Savings/Losses Overview

Design Element	One-Sided Model (performance years 1 & 2)	Two-Sided Model
Maximum Sharing Rate	52.5 percent	65 percent
Quality Scoring	Sharing rate up to 50 percent based on quality performance	Sharing rate up to 60 percent based on quality performance
FQHC/RHC Participation Services	Up to 2.5 percentage points	Up to 5 percentage points
Minimum Savings Rate	Varies by population	Flat 2 percent regardless of size
Minimum Loss Rate	None	Flat 2 percent regardless of size
Maximum Sharing Cap	Payment capped at 7.5 percent of ACO's benchmark	Payments capped at 10 percent of ACO's benchmark
Shared Savings	Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2 percent threshold; up to 52.5 percent of net savings up to cap.	Savings shared once MSR is exceeded; up to 65 percent of gross savings up to cap

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 contract 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 contract. 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.

If unaddressed in the final regulation we believe that this problem will call into question the long-term viability of the ACO program as a whole.

Another somewhat surprising and challenging feature is the proposed requirement that the ACOs devise a mechanism to ensure CMS that the ACO will be able to pay its share of any losses. CMS can look at the 25 percent withholds from any prior shared savings payments to apply to later shared losses. In addition, however, CMS will require that ACOs provide a "self-executing" method for paying any shared losses. 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 propose requiring 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 one-sided plans as well as two-sided plans from day one, even though an ACO under a one-sided plan isn't going to be responsible for losses until the third year of the initial agreement.

Additionally, CMS will have the right to carry forward any unpaid losses if the ACO is does not make the loss repayment, and to offset unpaid losses from one year against future shared savings payments.

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 proposed 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. The proposed regulations indicate that CMS will use many of the monitoring tools that are currently in use, such as using and analyzing data reported to it, conducting site visits, investigating beneficiary (and other) complaints, and conducting audits, which 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 appears to be 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 proposes to be very vigilant about, e.g., 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 the minimum thresholds for one or more quality of the five "quality domains," then, under the proposed regulations, 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 is 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 under the proposed regulations.

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. If the ACO does not remedy the problem after that, 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. The other consequence of an ACO being terminated before the three-year term in the agreement has ended is that the ACO forfeits the 25% withhold of shared savings that the ACO earned previously, which CMS holds to offset potential payments the ACO owes to CMS.

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.[6] This list of CMS decisions that are not

[6] The six (6) 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. In addition, CMS proposes that the determination by an antitrust agency to challenge an ACO will not be subject to review.

subject to review is actually directly from PPACA, so it presumably was not something that CMS viewed as discretionary when preparing the proposed 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 that the decision by CMS was wrong. 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.

Auditing/Record Retention

Under the proposed regulations, CMS would require ACOs to agree to grant CMS very broad rights to audit the ACO as well as all of the ACO participants and the ACO's providers or suppliers. CMS also proposes to require ACOs to maintain books and records for at least ten years, which can be extended for another six years, on 30 days' notice from CMS, if there has been a termination or a dispute or some type of allegation of fraud or a similar fault by the ACO or any of its participants or contracted entities.

In addition, the proposed regulations provide that 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.

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.

Limited Antitrust Protections

The proposed regulations were accompanied by a proposed Statement of Antitrust Enforcement Policy Regarding ACOs to be issued by the FTC and the DOJ (the "**Policy Statement**"). The proposed antitrust guidance provides a "safety zone" for ACOs (based on the market share of the ACO participants), "danger zones" in which certain ACOs are at risk, and a middle ground in which ACOs are not within a safety zone but are not definitely at risk and can operate, although the ACO may want to seek an advisory opinion to ensure that it is operating in a manner acceptable to the FTC/DOJ.

Hospitals and ambulatory surgery centers ("**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. The proposed antitrust guidance does not preclude private rights of action against an ACO for alleged antitrust violations event if the ACO is within a safety zone.

The Policy Statement applies to health care collaborations among otherwise independent providers and provider groups formed after March 23, 2010 (the date of enactment of PPACA) that seek to participate as ACOs in Medicare. It would create a new antitrust "safety zone" for qualifying ACOs.

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 operating in the commercial market would require agreement among otherwise competing providers on pricing, and perhaps market allocation – agreements that typically raise antitrust concerns.

The FTC and the DOJ have issued prior antitrust enforcement policy statements. These laid 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. Collaborations falling outside a safety zone are not necessarily illegal; 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 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 New Safety Zone

The Policy Statement would create a new safety zone for ACOs that meet the CMS eligibility criteria to participate in the SSP. ACOs within the safety zone would have no obligation to contact the antitrust agencies. ACOs falling outside the safety zone would not be presumptively unlawful. In certain cases they would be required to submit to antitrust review by the FTC and DOJ. Those falling outside the safety zone but not triggering the mandatory review requirement would have the option of requesting 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 Policy Statement would create a new safety zone for ACOs where independent ACO participants providing the same service have a combined share of 30% or less of each common service in each participant's Primary Service Area ("**PSA**"). The PSA is 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 indentified 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 would first define the PSA of each of the surgeons. It would then determine whether two or more of them provided services in any of the PSAs. If two or more of the surgeons provided services to patients in the same PSA, the ACO would 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 would make available aggregate fee-for-service allowed charges by service and zip code.

The ACO would have to perform this analysis for the PSA of each of its participants in which two or more of its participants provided a common service. If the aggregate shares were 30% or less, and hospitals, ASCs and dominant providers were not exclusive to the ACO, it would meet the safety zone, and would not require antitrust review. 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, and will often exceed the 50% threshold discussed below which leads to mandatory review. Accordingly, we would expect many ACOs will have only one hospital participant, or only one hospital participant furnishing services in the same service area.

There is an exception to 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%.

ACOs Outside the Safety Zone

If the share of two or more participants in any common service provided by the ACO in any PSA exceeds 50%, the ACO would be required to submit to review by the FTC and DOJ. The 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. For an ACO that meets the 50% mandatory review threshold, a no-action letter is required for enrollment in the Medicare ACO program.

If the share of two or more participants in any common service provided by the ACO in any PSA exceeded 30% but not 50%, the ACO would be outside the safety zone, but not required to obtain agency review. It could, however, obtain that review voluntarily to obtain comfort that the FTC and DOJ would not take enforcement action. The Policy Statement also provides guidelines on conduct the avoidance of which will make 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 the all 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.

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. And by limiting the availability of the safety zone to ACOs formed after the enactment of PPACA, the Policy Statement would exclude established provider networks. 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.

PROPOSED FRAUD AND ABUSE WAIVERS FOR ACOS

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 Office of the Inspector General ("**OIG**")[7] proposes waivers of three fraud and abuse laws as applied to ACOs: (1) the federal physician self-referral law ("**Stark**")[8]; (2) the federal anti-kickback law ("**AKS**")[9]; and (3) the federal civil monetary penalty law ("**CMP**") prohibiting hospital payments to physicians to reduce or limit services to Medicare or Medicaid beneficiaries.[10]

The Joint Notice solicits public comments (within 60 days) on the three proposed waivers, additional or different waivers that CMS and OIG should consider with respect to the SSP, and input from stakeholders on other related considerations. The Joint Notice indicates that final waivers likely will be issued concurrently with CMS's publication of the final ACO regulations.

The proposed waivers apply to three specific circumstances. The table below illustrates these three scenarios and which waivers would apply to each scenario:

Scenario	**Stark**	**AKS**	**CMP**
Distribution of shared savings within the ACO (e.g., to ACO participants or ACO providers/suppliers)	X	X	X

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

[8] 42 U.S.C. § 1395nn(a).

[9] 42 U.S.C. § 1320a-7b(b)(1) and (2).

[10] 42 U.S.C. § 1320a-7a(b)(1) and (2).

Distribution of shared savings outside the ACO (e.g., to non-contracted providers or suppliers)	X	X	
Financial relationships necessary for and directly related to the ACO's participation in the SSP		X	X

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.

The proposed waivers are very narrow. Importantly, the proposed waivers would not apply to any other provisions of federal or state law, including state fraud and abuse laws. So, ACOs would be 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 proposed waivers generally only apply to ***distribution of shared savings*** and certain financial relationships with physicians. All other financial arrangements are not covered by the waiver, and would need to comply with existing laws. The very narrow nature of the proposed waivers may create obstacles to implementation of ACOs under both federal and state laws.

Proposed Stark Law Waiver

The proposed Stark law waiver would waive application of the Stark law to distributions of shared savings received by an ACO from CMS under the SSP: (1) to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the ACO earned the shared savings; or (2) for activities "necessary for and directly related to" the ACO's participation in and operations under the SSP. The waiver would apply to distributions of shared savings, even if the distributions occurred after the expiration of the ACO's agreement with CMS. Any other types of financial relationships among or between the parties must meet an existing Stark exception.

CMS and OIG indicated in the Joint Notice that the proposed Stark waiver is not intended to protect distributions of shared savings dollars to referring physicians outside of the ACO, unless those referring physicians are being compensated (using shared savings) for activities necessary for and directly related to the ACO's participation in and operations under the SSP. "Other financial relationships with referring physicians outside the ACO would need to meet an existing [Stark law] exception ...."

Proposed AKS Waiver

The proposed AKS waiver would waive application of the AKS in two scenarios. First, the proposed waiver would apply to distributions of shared savings (both within and outside the ACO) that meet the requirements of the proposed Stark law waiver. Financial arrangements outside the ACO that do not meet the proposed waiver criteria must otherwise comply with the AKS.

Second, the proposed waiver would also apply to any financial relationship within the ACO (i.e., between or among the ACO, its ACO participants, and its ACO providers/suppliers) "necessary for

and directly related to" the ACO's participation in and operations under the SSP that implicates the Stark law and fully complies with a Stark exception. Unlike the proposed waivers that apply to distributions of shared savings (which apply after the expiration of the ACO's agreement with CMS), the second proposed AKS waiver scenario applies only during the term of the ACO's agreement with CMS.

Interestingly, the second scenario under the proposed AKS waiver is narrow and does not protect any non-physician financial relationships, because that second scenario presupposes a Stark relationship (i.e., a physician financial relationship), whereas, the AKS potentially applies to a much broader set of relationships. In addition, while the Stark law and the AKS are different statutes, most of the time if a relationship meets a Stark exception, risk under the AKS is likely to be low.

Proposed CMP Waiver

The proposed CMP waiver would waive application of the CMP with respect to two scenarios. First, the proposed waiver would protect distribution of shared savings received by the ACO from CMS under the SSP, where the hospital makes distributions to a physician, and (1) payments are not made knowingly to induce physician to reduce or limit ***medically necessary*** items or services; and (2) both the hospital and the physician are ACO participants or ACO providers/suppliers, or were during the year in which the ACO earned the shared savings. As with the other waivers of shared savings distributions, this first proposed waiver would apply even if distribution occurs after the expiration of the ACO's agreement with CMS. This first proposed CMP waiver is very narrow; the only concession CMS has made is to add the modifier "medically necessary," because the CMP statute does not explicitly distinguish between medically necessary items and services and other items and services, and OIG has interpreted the CMP statute so broadly that even if a payment were narrowly tailored to induce a physician only to avoid providing unnecessary care, OIG still would be likely to assert that the payment constituted a CMP violation.

Second, the proposed waiver would protect any financial relationship within the ACO "necessary for and directly related to" the ACO's participation in and operations under the SSP that implicates the Stark law and fully complies with a Stark exception.

Scope of the Proposed Waivers

The scope of the proposed waivers is surprisingly narrow. With limited exceptions, the waivers apply only to distributions of shared savings, or to financial relationships with physicians within the ACO. The limited scope of the proposed waivers raises several issues providers contemplating participation in an ACO should consider.

First, the limited scope of the waivers may create challenges in structuring and financing the ACO in its early stages. Distributions of shared savings will not occur for at least 18 months after the start date of the ACO's agreement with CMS, due to the currently-proposed six-month claims run-out period. Consequently, all of the financial relationships required to address the ACO's (likely substantial) up-front investment costs, infrastructure development, and ongoing operating expenses, would be outside of the scope of the proposed waivers and so would have to comply with generally applicable federal fraud and abuse laws, in addition to state laws (which are not subject to any waiver or federal preemption under the SSP). Accordingly, the proposed waivers are unlikely 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, unless those financial relationships are with a physician and meet existing exceptions. In addition, financial arrangements that do not involve distribution of shared savings generally fall outside the scope of the proposed waivers. As a result, shared-risk, resource pooling, incentive payments, and other financial arrangements an ACO might want to establish internally to promote efficient operation of the ACO generally also would be unprotected.

Second, as noted above, the proposed waivers cover only ACOs under the SSP. Accordingly, private payor shared-savings distribution programs are not protected and must comply with generally applicable federal and state laws.

Third, mandating referrals within the ACO is not protected, unless the requirement can comply with generally applicable federal and state laws (e.g., the limited Stark exception for conditioning a physician's compensation for personal services on the physician's referrals to particular provider, practitioner or supplier, *see* 42 C.F.R. § 411.354(d)(4)).

Fourth, the Joint Notice has not proposed a waiver of the federal statute that prohibits inducements to beneficiaries. Such a waiver, had it been proposed, could potentially have permitted ACOs to implement mechanisms to provide financial incentives to potentially assigned ACO beneficiaries to remain within the ACO and prevent beneficiary "leakage."

Finally, nothing in the Joint Notice proposes federal preemption of state laws. Accordingly, state regulatory schemes still apply to ACOs, and ACOs must comply with these laws. For example, many states, including California, have anti-kickback statutes or self-referral prohibitions that are not the same as 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, like California, have strong corporate practice of medicine prohibitions, which heavily restrict the ability of a lay corporation to influence or control the delivery of health care. These prohibitions stand in tension with the goals of the SSP; 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.

Additional Proposed Waivers

The Joint Notice indicates that the proposed waivers would apply uniformly to all ACOs, ACO participants, and ACO providers/suppliers participating in SSP. The Joint Notice requests comments on the scope of the proposed waivers, the timing of waivers, and ten additional topics related to potential waivers. The ten "additional waiver" topics include several areas on which providers may wish to submit comments, including topics related to the problem areas identified above. These ten topics include:

- **Arrangements related to establishing the ACO** (e.g., formation/startup costs; implementing governance/administration requirements; building technological and administrative capacity, including training activities).

- **Non-shared savings arrangements among ACO members** (i.e., related to ongoing operations of the ACO).

- **Non-shared savings arrangements with individuals or entities outside the ACO.**

- **Distributions of shared savings or similar payments received from private payors.**

- **Other financial arrangements for which a waiver would be necessary** (i.e., why no current exception/safe harbor would apply, any applicable safeguards that should apply).

- **Duration of waivers** (e.g., only during ACO's agreement with CMS versus extending beyond expiration of ACO's agreement with CMS).

- **Additional safeguards** necessary to protect federal health care programs.

- **Scope of the proposed waivers** (e.g., comments on the "necessary for and directly related to" standard).

- **Unique features of two-sided risk model** (e.g., relative risk of over- or under-utilization under the downside risk feature of two-sided model; whether different waivers necessary where ACO participants, providers/suppliers are individually at risk for cost overages).

- **Use of existing exception / safe harbor for EHR arrangements** (i.e., whether CMS needs to waive Stark and the AKS for ACO arrangements that meet existing exception/safe harbor for EHR arrangements, but that are expected to occur after 2013 sunset date).

- **Waiver of beneficiary inducement prohibition** (i.e., circumstances under which Secretary should waive the prohibition in connection with SSP; arrangements that require protection and how they advance the goals of the SSP; necessary conditions/safeguards).

- **Timing of final waivers** (i.e., issued contemporaneously with, in advance of, or soon after Final Rule regarding the SSP).

Unfortunately, the narrow proposed fraud and abuse waivers do not protect many of the financial arrangements an ACO likely would require to acquire start-up capital, to fund operating costs and/or losses, and to reward desired behavior during the first 18 months of operations (i.e., before shared savings may be payable by CMS), because they protect only financial arrangements that involve ***distribution of shared savings***. As a result, start-up costs, working capital contributions, shared-risk and incentive payments, and other financial arrangements an ACO might want to establish using funding sources other than the shared savings payments from CMS, would be unprotected.

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 initial commentary as to its proposed treatment of ACOs that are participating in the ACO program.[11]

In its notice, 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 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.

- 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.

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[11] IRS Notice 2011-20.

As discussed above with respect to proportionate control (see "GOVERNANCE OF THE ACO – Governing Body"), 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. Likewise, the requirement that payments for services be consistent with fair market value may also be challenging, 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 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 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.

CALIFORNIA STATE LAW ISSUES

The formation of ACOs under the proposed regulations raises many difficult state law issues. Neither the ACO statutory provisions, the proposed regulations, the antitrust guidance, nor the fraud and abuse waiver guidance pre-empts state law. ACOs which comply with the proposed regulations, fall within the antitrust safety zone, 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, including California.

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

Corporate Practice of Medicine

California law contains a very strong prohibition on the corporate practice of medicine. This doctrine prohibits lay entities from practicing medicine, with limited exceptions. The prohibition may 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. In particular, any ACO that includes hospitals as an owner will almost certainly be a lay entity that is prohibited from practicing medicine.

ACOs will be required to engage in activities which may be characterized as practicing medicine. For example, an ACO is required to utilize evidence-based medicine. The adoption of clinical guidelines, and the imposition of such guidelines on physicians participating in an ACO, at least arguably, exerts a level of control over a physician's clinical judgment and therefore constitutes the practice of medicine.

Unlike health plans that are licensed under the Knox-Keene Act, there is no exception from California's corporate practice of medicine prohibition for ACOs as ACOs will not be licensed health plans. ACOs in California will have to be carefully structured to avoid violating the corporate practice prohibition. It is not obvious that an ACO can simultaneously comply with the corporate practice prohibition and the proposed ACO regulations.

California Anti-Kickback Laws

California law (Business and Professions Code § 650, Health and Safety Code § 445) prohibits payments for patient referrals. As discussed above, the waiver of the federal anti-kickback statute is somewhat narrow and applies only to distributions of the shared savings or other activities necessary for the ACO that comply with a Stark exception.

However, an approach to distributing the shared savings or other ACO relationships that are within the federal waiver may still violate California's anti-kickback statutes. For example, distribution of the shared savings to physicians as an inducement for the physicians to make referrals to a particular

entity could violate state law. Thus, ACO arrangements must be analyzed for compliance with California's anti-kickback statutes regardless of whether they satisfy a federal waiver.

California's Self-Referral Law

California's Physician Ownership and Referral Act **("PORA")** prohibits referrals by physicians for certain services to entities in which the physicians have a financial interest. There is a broad exception under PORA for referrals to health facilities, like hospitals, and entities owned by health facilities. However, it is possible that an ACO structure could create a financial interest of a physician in an entity furnishing services subject to PORA that is not a health facility or owned by a health facility, such as a freestanding imaging center. Compliance with a Stark waiver or exception does not ensure compliance with PORA.

California Antitrust Laws

California law includes antitrust laws that are similar to federal antitrust laws, such as the Cartwright Act. Satisfaction of a federal safety zone, or a favorable FTC or DOJ letter, does not provide immunity from a violation of California's antitrust laws. However, it does reduce the likelihood of a state antitrust enforcement action.

The Knox-Keene Act

The Knox-Keene Act requires that a health care service plan obtains a license to operate and complies with a detailed regulatory scheme. There was concern prior to the promulgation of the proposed regulations that California ACOs would have to obtain a Knox-Keene license. However, the Department of Managed Health Care has indicated that an ACO under the proposed regulations would not require a Knox-Keene license because it would not receive pre-paid capitated payments in return for the provision of health care services. This situation could have been different if CMS had included a partial capitation option in the proposed regulations.

CONCLUSIONS

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

The proposed regulations will likely generate substantial comments from would-be ACO participants and their consultants and advisors. Given the political stakes associated with the success of the SSP, it remains unclear to what degree CMS will substantially revise the shape of the program in the Final Rule. We would advise providers to review the Final Rule to see whether CMS adequately addresses the current barriers outlined in the proposed regulations in a way that makes participation more attractive.

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

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

However, regardless of whether a provider participates in an ACO, the elements of the proposed SSP offer a window into the probable future shape of the Medicare program. For example, the proposed regulations specifically mention telehealth, remote patient monitoring, and electronic records as "modern technologies" that CMS 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.

If you have questions, or would like additional information, please contact one of the following members of HLB's ACO Task Force:

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