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Ober|Kaler ACO Update

CMS Provides Final Framework for ACO and Shared Savings Program Rules: ACO Participants Get Greater Flexibility

CMS's final regulations (final rule) implementing the Accountable Care Organization (ACO) shared savings program (Shared Savings Program) and the complementary regulations and guidance from CMS/OIG and DOJ/FTC are materially different from the proposed rules. After the proposed rule generated little interest in actually undertaking ACO development, CMS changed the final rule to focus on the themes of flexibility, accountability and innovation. The final rules and guidance provide health care providers with flexibility and, importantly, clear answers and guidance aimed at encouraging the development of ACOs for participation in the Shared Savings Program.

The Affordable Care Act (ACA), signed into law in March 2010, included incentives for the creation of ACOs. Congress established the Shared Savings Program in the ACA to promote accountability of providers to patient populations and to coordinate services under Medicare, as well as to encourage providers to make investments in infrastructure and to design care processes for high-quality, efficient service delivery. Almost a year later on March 31, 2011, several federal agencies (CMS, OIG, DOJ, FTC and IRS) jointly announced the release of proposed rule making and guidance regarding the ACO program. CMS released its much anticipated final rule on October 20, 2011, in time to garner participation before the January 1, 2012 statutory deadline. In addition, CMS and OIG have issued an interim final fraud and abuse waiver rule in an attempt to remove the existing legal impediments in the areas of fraud and abuse. Simultaneously, FTC/DOJ issued

additional antitrust guidance and the IRS clarified its previous guidance to allow for the development of ACOs, providing clarity on such issues as eligibility to participate, governance, legal structure, quality and privacy.

The three goals stressed under the Shared Savings Program are (1) to provide better care to patients with respect to safety, effectiveness, patient-centeredness, timeliness, efficiency and equity; (2) to provide better health for populations through preventive service and education for issues such an substance abuse and physical inactivity; while (3) decreasing the cost of health care and eliminating waste in the system. CMS seeks to move the health care industry towards this patient-centered care approach by adding patients to the governance structure of ACOs, requiring patient satisfaction data and requiring attention to care coordination issues. ACOs will receive shared savings only if they can meet quality standards related to these goals. The final rule emphasizes flexibility with respect to governance and other elements of operations, and CMS allows for a reimbursement track with no down-side risk.

ACOs can take a variety of forms, but all include primary care physicians and other types of providers that provide care to Medicare beneficiaries in a way that will control costs. Achieved savings are shared with the providers and suppliers through the ACO organization when quality metrics are also met. In order to implement the ACA's ACO and Shared Savings Program, CMS's final regulations still provide for a range of issues critical to the development of ACOs, including their organizational structure and governance, internal operations, contracting obligations with CMS, reimbursement systems for ACOs under the Shared Savings Program, and quality reporting and monitoring. The following paper discusses the various provisions of the final rule and other guidance and analyzes the manner in which the changes from the proposed rule to the final rule are designed to encourage more interest in Medicare ACOs.

Eligibility, Governance and Leadership

The final CMS rule provides welcomed flexibility to ACO eligibility, governance and leadership requirements in the hopes of encouraging innovation and participation in the Shared Savings Program. The final rule confirms that ACOs can take a variety of forms, including joint ventures with hospitals, hospitals with employed physicians and physician group practices. An ACO must be a legal entity that is recognized under applicable state law. Under the final rule, CMS expanded its definition of *entity* beyond those entities formed under state law, to also include entities appropriately licensed under federal or tribal law as an ACO. An ACO must be identified by a taxpayer identification number (TIN) and comprised of an eligible group of ACO participants that come together to coordinate and manage care for Medicare beneficiaries. ACO participants are Medicare-enrolled providers or suppliers of services (e.g., hospital or physician group practice). ACOs also include ACO

providers/suppliers that provide services to Medicare beneficiaries, such as nursing homes and other long-term care providers.

Eligibility

The ACA specified certain ACO participants that are eligible to participate in the Shared Savings Program and granted CMS the authority to include other types of ACO participants. Based on comments it received to the proposed rule, CMS continued to expand the list of eligible ACO participants beyond the statutory mandate and those entities identified in the proposed rule. This expansion allows for further innovation in possible ACO models and encourages movement away from the current fee-for-service model with the addition of shared savings incentives. CMS continues to stand by this open approach despite concerns that the inclusion of other providers would not produce the efficiencies CMS was attempting to incentivize providers to create. Under the final rule, ACO participants authorized to form an ACO are:

- ACO professionals in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Critical Access Hospitals (CAH) billing under Method II
- Federally Qualified Health Centers (FQHCs)
- Rural Health Centers (RHCs)

FQHCs and RHCs are included as long they otherwise meet the eligibility requirements specified in the final rule. CMS chose to include FQHCs and RHCs despite concerns raised in the proposed rule regarding their lack of ability to report data needed to assign beneficiaries. CMS included FQHCs and RHCs in part to address the special needs of rural areas and to promote high-quality care for FQHC and RHC beneficiaries. CMS restated its position that a hospital is not required to form an ACO. In addition, CMS expanded the definition of *ACO professional* beyond physicians to include nurse practitioners, physician assistants and clinical nurse specialists. This expansion mirrors the reality that primary care is not always provided just by physicians and, with a potential primary care shortage in our future, other primary care professions will play a larger and important role in primary care.

Legal Structure

The formation of an ACO by ACO participants as required under the final rule is relatively straightforward. Under the slightly more flexible final rule, an ACO must:

- Be a legal entity recognized and authorized to conduct business under applicable state law (e.g., a nonprofit or for-profit corporation, limited liability company, general or limited partnership), or an ACO licensed under federal or tribal law
- Hold a taxpayer identification number (TIN)
- Have a governing body under which the ACO provides meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives
- Be comprised of an eligible group of ACO participants that work together to manage and coordinate care for Medicare beneficiaries

As was the case under the proposed rule, the final rule specifies that the legal entity can be a corporation, partnership, limited liability company, foundation or any other entity permitted by state law. The final rule recognizes that an ACO need not be licensed as an ACO under applicable state law unless state law requires such licensure. In fact, CMS noted in its comments to the final rule that it does not intend to preempt any state law requirement that affects ACO operations. Certain commenters expressed great concern related to compliance with state insurance risk laws. In response, CMS states that the ACO Shared Savings Program is a fee-for-service, not managed care, program and thus, should not implicate those state laws. That being said, those ACOs that opt for Track 2 of the Shared Savings Program, which includes a risk component, should consult state law in their areas of operation.

Existing legal entities that are eligible to be ACOs are permitted to use their existing legal structure as long as they meet other eligibility and governance requirements set forth in the final rule. CMS makes clear in its commentary to the final rule that if a currently existing legal entity adds ACO participants that will remain independent legal entities, then a new legal entity must be created. In CMS's view, the creation of such a new legal entity is necessary to allow newly added ACO participants to have a meaningful voice on the ACO's governing body, and a separate legal entity with such a governing body is essential to accomplish this objective.

Governance

The final rule continues to require that quality be at the center of ACO governance, but provides some relief from the governing body composition requirements discussed under the proposed CMS rule. Under the final rule, the ACO entity must maintain a separate, identifiable governing body (board of directors, board of managers, or the like) with authority to execute the functions of the ACO as required under the ACA and the final rule, including but not limited to, a defined process to promote evidenced-based medicine and patient engagement, report on quality and cost measures and coordinating care. Governing bodies must have the following characteristics:

- *Oversight.* The governing body must have responsibility for oversight and strategic direction for the ACO, holding ACO management accountable for the ACO's activities and mission.
- *Transparency.* The governing body must have a transparent governing process similar to other health care facilities.
- *Fiduciary Duty.* The governing body members have a fiduciary duty to the ACO and must act consistent with that fiduciary duty.
- *Conflict of Interest.* Under the final rule, the ACO now must develop and maintain a conflict of interest policy for the governing body that contains provisions on the disclosure of financial interest of its governing body, the process for such disclosure and appropriate remedial action. This conflict of interest policy must apply to the Medicare beneficiary sitting on the governing body who cannot be an ACO provider/supplier within the ACO's network. CMS acknowledges that each ACO's conflict of interest policy might differ based on the composition of the governing body. CMS directs those who are new to conflict of interest policies to the IRS website. The ACO should check state and federal law before finalizing its conflict of interest policy.
- *Composition and Control.* The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives CMS left ACOs with flexibility in the composition and control of the governing body while balancing its goal of ensuring the ACO is provider-led.

Continuing under the themes of flexibility, accountability and innovation, CMS revised requirements for the composition of the governing body in the final rule. For example, CMS eliminated its proposal that all ACO participants have appropriate proportionate control over governing body decision making. It was CMS's view, based on comments received, that such a requirement could cause an ACO's governing body to become "unwieldy and lose [its] effectiveness." CMS now requires only that an ACO provide meaningful participation in the composition and control of the ACO's governing body for participants or their designated representatives. Moreover, CMS eliminated its proposed requirement that an ACO participant's representative on the governing body come from within the ACO participant's organization. The final rule adopts the proposed requirement that Medicare beneficiaries served by the ACO have board representation as long as no immediate family member has a conflict of interest with the ACO. CMS declined to expand the requirements of beneficiary participation on the governing body, citing its flexible stance on governance.

As was the case under the proposed rule, the final rule generally requires that ACO participants have no less than 75 percent control of the governing body, leaving the remaining 25 percent for Medicare beneficiaries served by the ACO and, potentially, representatives of entities that are not enrolled in Medicare. The remaining 25 percent of the governing body could provide capital and infrastructure necessary to form an ACO entity and

to administer the programmatic requirements of the Shared Savings Program. CMS continues to believe it is important to allow other non-Medicare enrolled entities, such as health plans and investment companies, to have ownership interests to help fund the infrastructure needed to monitor and report data. It remains CMS's view that the 75 percent requirement will ensure that the ACO remains "provider-driven" so that the ACO stays focused on quality and cost efficiencies.

CMS did provide greater flexibility under the final rule by not imposing any requirement as to the manner in which voting is apportioned within the governing body among the ACO participants. If an ACO applicant seeking to compose its governing body in such a way that does not meet either the 75 percent requirement for ACO participant control, or the requirement regarding beneficiary representation on the governing body, the applicant must describe in its application to CMS's satisfaction the manner in which the proposed structure of the governing body would involve ACO participants in innovative ways in ACO governance and would provide a meaningful opportunity for beneficiaries to participate in the governance of the ACO. CMS also clarified that if a hospital participates in an ACO with its employed physicians, the hospital may retain 100 percent control of the governing body.

CMS explains that such flexibility would potentially:

- allow ACOs that operate in states with restrictions on the corporate practice of medicine to structure beneficiary representation accordingly,
- allow for consumer-driven boards that might have more than 25 percent consumer representation, and
- allow existing entities to explain why they should not be required to configure their board in the manner prescribed if they have other means of addressing the consumer perspective in governance.

In the final rule, CMS reinforces its requirement that ACO participants ensure "meaningful commitment" to the ACO's mission by providing financial or other resources to increase the likelihood of the ACO's success. Such meaningful commitment can be achieved through time and effort as well as financial or human investment.

Examples include:

- *Financial Investment.* Financial investment includes such items such capital contributions for ACO infrastructure information systems, office hardware, computer software, ACO staff, training programs and other ACO operations where the investment provides a stake in the success of the ACO.
- *Human Investment.* Human investment includes serving on the ACO's governing body, serving on committees related to the ACO's evidence-based medical practice or clinical guidelines and other ACO operations such as defining patient engagement, care coordination or quality and cost reporting.

- *Through Agreements.* An ACO participant or provider/supplier achieves and evidences meaningful commitment through its agreement with the ACO to comply with and implement the ACO's required processes and its accountability for meeting the ACO's performance standards.

Leadership

Under the final rule, the basic leadership structure of an ACO remains unchanged. An executive, officer, manager or general partner must manage the ACO operations and the appointment and removal of such manager must be controlled by the governing body. This manager must oversee a leadership team that demonstrates the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes. CMS moved away from its earlier proposed requirement that clinical management and oversight be managed by a "full-time senior-level" state-licensed, board-certified physician medical director who is physically present at the ACO location. Rather, the final rule is more flexible and requires that clinical management and oversight be managed by a senior-level medical director who is one of the ACO's physicians and who is physically present on a regular basis in an established ACO location. This medical director must be a board-certified physician licensed in one of the states in which the ACO operates. Depending on the roles and responsibilities the ACO assigns to the medical director, the ACO may require licensure of the medical director in more than one state.

In addition, the ACO must also have a compliance officer who reports to the governing body and is separate and apart from the ACO's legal counsel. CMS clarifies that the compliance officer may have a legal education but may not serve as the ACO's legal counsel. CMS clarifies that the compliance officer may be an existing compliance officer for an ACO participant. As with most compliance officers, the ACO compliance officer is responsible for implementing a compliance plan. CMS provides flexibility in the ACO's compliance plan development to allow for innovation, although future rule making may provide prescriptive plan development requirements. CMS now requires that the compliance plan of an ACO include:

- Periodic review of the compliance plan for changes in the law
- A reporting mechanism for employees and contractors to report compliance issues
- A mechanism for the ACO to report fraud and abuse issues to federal agencies
- Training beyond just training of the compliance officer

CMS emphasized the need for compliance in light of the potential fraud and abuse issues underlying the sharing of savings among providers under the Shared Savings Program.

In the final rule, CMS eliminated the proposed requirement that ACOs maintain a quality assurance program and process improvement committee to establish quality, cost-effectiveness and process and outcome

improvement standards. Instead, the final rule provides that as part of the ACO's application, it will be required to describe how it will establish and maintain an ongoing quality assurance and improvement program, led by an appropriately qualified health care professional. Finally, in an effort to promote innovative leadership and management structures, ACO applicants will be permitted to describe (and implement if acceptable to CMS) innovative leadership and management structures that do not meet the final rule's requirements for leadership and management structures.

Application and Agreement Provisions

Application

An ACO must complete a detailed application in the form and manner required by the final rule and submit it to CMS for approval before it is able to participate in the Shared Savings Program. As the name suggests, an essential element of an ACO is that it be "accountable" for the services that it provides. Therefore, as a part of the application, an executive with the authority to bind the ACO must certify that the ACO, its ACO participants and its ACO providers/suppliers agree to be accountable for the quality, cost and overall care of the Medicare beneficiaries assigned to the ACO. An ACO must also disclose whether it, its ACO participants or providers/suppliers have participated in the Shared Savings Program previously under the same or different names or whether it/they are related to or have an affiliation with another ACO participating in the Shared Savings Program.

Significant documentation and/or explanation must accompany the application in order to demonstrate that the ACO satisfies the ACO eligibility requirements set forth in the final rule. These include:

- *Documents that describe the relationship between the ACO, ACO participants and ACO providers/suppliers.* CMS expects that these documents will take the form of participation agreements, employment agreements and operating policies or similar documents. These documents should also explain how the shared savings or other financial arrangements the ACO has in place will encourage ACO participants and ACO providers/suppliers to perform in accordance with the quality assurance and improvement program and evidenced-based clinical guidelines of the ACO.
- *Quality Assurance Program.* A description of the quality assurance and improvement program for the ACO. This program must be led by a qualified health professional and include the four defined processes for evidenced based-medicine and other quality of care measures described below.
- *Quality Process.* Documentation that describes how the ACO will implement the defined processes which it is required to have in place to (i) promote evidence-based medicine, (ii) promote beneficiary engagement, (iii) internally report on quality and cost metrics, (iv) coordinate care and (v) adopt a focus on patient-centeredness. This includes a description of the remedial processes and penalties that will

apply if an ACO participant or ACO provider/supplier fails to comply with and implement these processes.

- *Organizational structure.* Documentation of the ACO's organizational structure should include an organizational chart, a list of committees and committee members, how committees are structured and job descriptions for the senior administrative and clinical leaders of the ACO. The final rule requires the inclusion of the job descriptions for the executive in charge of the ACO who reports to the governing body of the ACO and the senior-level medical director.
- *Governing body.* The ACO must provide evidence of meeting the governing body requirements of the final rule. CMS is concerned that the governing body of the ACO be an independent and identifiable body that is comprised of representatives of the ACO participants. As noted elsewhere herein, an existing entity (e.g., a hospital) can apply to become an ACO. However, CMS has made it clear that the members of the governing body of an ACO have a fiduciary duty to the ACO. If the existing board of a hospital were to assume the role of the governing body of an ACO, that board would have conflicting fiduciary duties. Therefore, in order to retain the option that an existing entity can apply to become an ACO, CMS requires that the governing body of the ACO be an independent and identifiable body.
- *Evidence that the ACO participants control at least 75 percent of the governing body.*
- *Evidence that a Medicare beneficiary served by the ACO is a member of the governing body of the ACO and that neither such individual, nor any immediate family member of such individual, has a conflict of interest with the ACO.*
- *A copy of the compliance plan for the ACO.* If a compliance plan has not been completed at the time of application, this requirement can be satisfied by providing documentation describing the plan that will be put in place when the ACO's agreement with CMS becomes effective.

Although not required to be a part of the application, CMS has the right to request copies of all documents that form the basis for the organizational and operating structure of the ACO. These documents would include, without limitation, the charter/articles of incorporation and bylaws for a corporation, a partnership or joint venture agreement, an operating agreement for a limited liability company, a management agreement, an asset purchase agreement, and financial and other operating statements.

If an ACO requests a waiver from the governing body or leadership requirements generally applicable to ACOs, then it must include an explanation of why it is seeking a waiver and how it will be able to accomplish the respective goals set forth for the governing body and leadership without meeting those requirements.
An ACO must submit as a part of its application a list of all ACO participants and their Medicare-enrolled TINs. The ACO must also submit a list of the ACO providers/suppliers and their provider identifier (e.g., an NPI number) and also indicate whether the ACO provider/supplier is a primary care physician.

The application must include a description of how the ACO plans to use payments of shared savings and the criteria to be used in distributing the shared savings between ACO participants and ACO providers/suppliers. Further, the ACO must describe how its plan for the use and distribution of shared savings payments will further the specific goals of the Shared Savings Program and the general three-part aim of better care for individuals, better health for populations and lower growth in costs.

An ACO must make an election as a part of its application as to whether it is applying to participate in Track 1 or Track 2 of the Shared Savings Program. An ACO must demonstrate its ability to repay losses for which it may be responsible if it is applying to participate in Track 2 or requesting an interim payment under Track 1. The ability to repay losses or other amounts owed can be demonstrated through the acquisition of reinsurance, a surety bond, escrowing funds, establishing a line of credit or other appropriate mechanism.
CMS eliminated the proposed rule's requirement for an antitrust review as part of the application process. The final rule does not include this significant requirement for the contents of the application. *The treatment of antitrust issues under the final rule are discussed separately in this analysis. For more details, see the Antitrust section.*

Agreement

Agreements with Shared Savings Program applicants approved to participate in the Shared Savings Program for 2012 will have one of the following start dates:

- April 1, 2012 (Term of agreement is 3 years, 9 months; ACO's first performance year is 21 months)
- July 1, 2012 (Term of agreement is 3 years, 6 months; ACO's first performance year is 18 months)

For 2013 and all subsequent years, the start date is January 1 of that year and the term of the agreement is three years.

ACOs will continue to be subject to statutory and regulatory changes with the following exceptions: (i) eligibility requirements concerning structure and governance, (ii) calculation of sharing rate and (iii) beneficiary assignment. However, under the final rule ACOs will be provided the flexibility to voluntarily terminate their agreement without penalty in those instances in which the ACO believes that regulatory standards established during the agreement period will impact its ability to continue to participate in the Shared Savings Program.

The final rule reverses course on whether an ACO can add ACO participants during the term of the agreement. The final rule provides that ACO participants/suppliers may be added and subtracted over the course of the agreement period, provided the ACO notifies CMS of the change within 30 days of the additions/subtractions.

Assignment of Medicare Fee-for-Service Beneficiaries

In order to participate in the Shared Savings Program, an ACO must agree to have at least 5,000 beneficiaries assigned to it during each performance year. Instead of immediately terminating an ACO that fails to maintain this minimum threshold, CMS adopted as final its proposal to issue a warning letter and place the ACO on a corrective action plan if its assigned population falls below 5,000 during an agreement period. The ACO would receive the shared savings available for the year it was placed on the corrective action plan, but if the 5,000 beneficiary threshold is not met by the end of the following year, the ACO will not be eligible for shared savings for that year and CMS will terminate the ACO's participation agreement.

The final rule includes several significant changes from the proposed rule with respect to how beneficiaries are assigned to an ACO. As described in more detail below, CMS finalized a two-step process to assign beneficiaries to an ACO that takes into account not only services provided by primary care physicians, but also primary care services provided by specialists and other nonphysician practitioners (i.e., nurse practitioners, physician assistants, and certified nurse midwives). The adopted methodology also considers primary care services provided by federally qualified health centers (FQHCs) and rural health clinics (RHCs). In addition, CMS abandoned its retrospective approach to the assignment of beneficiaries in favor of an approach to assign beneficiaries prospectively with a retrospective reconciliation of the assignment at the end of a performance year.

Beneficiary Freedom of Choice

CMS again stresses in the final rule that while beneficiaries technically are "assigned" to a particular ACO under the statute, CMS prefers to view the process as "alignment" rather than "assignment" because beneficiaries retain "complete freedom of choice" in the physicians and other practitioners from whom they receive services. As discussed below, however, beneficiaries who receive a plurality of primary care services from an ACO are counted in the shared savings of that ACO. The only way that a beneficiary can "opt out" of an ACO is to receive a plurality of his or her primary care services from a physician who is not participating in an ACO.

Primary Care Services

The assignment of beneficiaries to ACOs based on their utilization of primary care services in accordance with the ACA requires a determination of what services constitute *primary care services*. Under the ACA, CMS is charged with "determining an appropriate method to assign Medicare FFS beneficiaries to an ACO based on

their utilization of primary care services" provided by an ACO physician. CMS finalized its proposal to define *primary care services* based on HCPCS codes for evaluation and management (99201-99215; 99304-99340; and 99341-99350) and codes related to the Welcome to Medicare visit (G0402) and the annual wellness visits (G0438 and G0439). *Primary care services* does not include hospital inpatient evaluation and management codes but does include primary care services when provided in a skilled nursing facility.

Prospective Beneficiary Assignment

One of the more significant changes incorporated into the final rule is CMS's adoption of a prospective approach to the assignment of beneficiaries to an ACO, rather than the retrospective approach set forth in the proposed rule. Under the final rule, ACOs will receive a preliminary list of assigned beneficiaries at the beginning of the performance period that is updated quarterly throughout the performance period. After the end of the performance period, CMS will determine the final assignment of beneficiaries based on the actual treatment data from that year. CMS adopted this hybrid approach of prospective assignment with retrospective reconciliation in response to the overwhelming number of comments received in support of a prospective approach. These commenters argued that the prospective approach was important for beneficiaries to have full knowledge of their inclusion within an ACO in advance and for ACO participants to effectively coordinate care and implement a care management program for its assigned beneficiaries.

"Step-Wise" Approach to Beneficiary Assignment

CMS had proposed to assign beneficiaries to an ACO based upon their receipt of the above-defined *primary care services* provided by a predefined group of primary care physicians. CMS received numerous comments from specialty societies and organizations representing nonphysician practitioners urging CMS to adopt a more expansive approach that considers beneficiaries who turn to specialists or nonphysician practitioners for their primary care. Persuaded by these comments, CMS adopted a "step-wise" approach to assignment of beneficiaries:

(1) Under the first step, CMS identifies beneficiaries who receive at least one physician primary care service from a primary care physician who is a provider/supplier in an ACO. The beneficiary is assigned to the ACO if the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of that ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of other ACOs or who are not affiliated with an ACO. The final rule clarifies that if an individual physician bills for services under more than one TIN, they can be eligible to participate in more than one ACO. It is unclear how often physicians would be billing under more than one TIN.

(2) The second step applies to beneficiaries who have not received any primary care services from a primary care physician either inside or outside of the ACO. The beneficiary will be assigned to an ACO

only if he or she has received at least one primary care service from an ACO physician (regardless of specialty) during the performance year. If this condition is met, the beneficiary will be assigned to the ACO if the allowed charges for primary care services provided by *all* ACO professionals (including specialists and nonphysician practitioners) exceeds the allowed charges for primary care services furnished by any other physician or nonphysician practitioner who is unaffiliated with an ACO.

The approach finalized by CMS is more expansive than the proposal to assign based only on services provided by primary care physicians. While this approach will be more administratively burdensome on the agency, it should result in an increased number of beneficiaries being assigned to ACOs and increase inclusion of specialists and nonphysician practitioners in the coordination of care under the ACO model.

Plurality of Services

With respect to determining the amount of primary care services provided by an ACO for purposes of beneficiary assignment, CMS finalized its proposal to require that a beneficiary receive only a plurality of primary care services from the ACO, as determined by accumulated allowed charges. CMS rejected suggestions that it adopt a majority approach because requiring that more than 50 percent of primary care services be provided by the ACO would drastically reduce the number of beneficiaries eligible for assignment to the ACO. Moreover, counting charges, rather than number of services, would reduce the likelihood for the need of a "tie breaker" and would assign the beneficiary to the ACO that provided the highest intensity and complexity of primary care services, rather than the ACO that saw the patient the most.

Assignment of Beneficiaries to ACOs that include FQHCs and/or RHCs

In a departure from the proposed rule, the assignment process adopted in the final rule will allow primary care services provided at an FQHC and/or RHC to be considered in the assignment process for an ACO that includes such facilities. Although FQHCs and RHCs predominantly provide primary care services, CMS highlighted the challenges of considering primary care services provided at such facilities in the assignment process in the proposed rule because FQHCs and RHCs submit claims for each encounter based on an all-inclusive rate. Accordingly, FQHC and RHC claims historically did not identify particular HCPCS codes and contain limited information on the practitioner providing services. Under the final rule, however, CMS states that it will utilize a combination of information submitted on the FQHC and/or RHC claims with an attestation submitted by the ACO that identifies all physician NPIs that provide direct primary care services in an FQHC or RHC, to determine whether a beneficiary receives a plurality of services from the ACO.

Quality Monitoring and Reporting

In finalizing the proposed quality data submission and scoring methodologies, CMS made a number of significant changes from the proposed rule that will reduce the reporting burden on providers and, CMS hopes, will encourage providers concerned about the scope and number of quality measures to participate in the program. As discussed more fully below, CMS cut in half the number of quality measures adopted, eliminated the requirement that 50 percent of primary care physicians be "meaningful users" of electronic health records by the second reporting period, and adopted a phased-in approach to pay-for-performance.

Quality of Care Measures

Recognizing that the number and scope of the quality measures in the proposed rule would have created an administrative burden on ACO participants, CMS significantly reduced the number of quality measures to be reported by an ACO during the first performance period. Of the 65 proposed measures, CMS adopted 33 measures for use in calculating the ACO's Quality Performance Standard, which are grouped into four "domains":

- Patient/Caregiver Experience (7 measures)
- Care Coordination/Patient Safety (6 measures)
- Preventative Health (8 measures)
- At-Risk Populations (12 measures)

CMS removed measures that it determined were redundant, operationally complex or burdensome, and retained those measures that it determined would demand a high standard of quality care furnished to beneficiaries who receive services from the ACO. A chart identifying the 33 finalized measures, their assigned domain, method of data submission, and other relevant information can be accessed in a chart available at www.ober.com/files/acoqualitymeasuretable.pdf.

With respect to the final quality-of-care measures, there are several important issues to note:

- CMS finalized the measures for patient/caregiver experience, which will be assessed using the Consumer Assessment of Health Care Providers and Systems (CG-CAHPS) patient surveys. In an effort to standardize administration of the survey and ensure comparable results, CMS will pay for the administration of the survey for all ACOs during 2012 and 2013. After calendar year 2013, an ACO will be required to pay for the survey through a CMS-certified vendor.

- CMS did not adopt its proposal to require that 50 percent of the primary care physicians (PCPs) within an ACO demonstrate Meaningful Use of an electronic health record (EHR) by the beginning of the second year of the shared-saving program. ACOs will, however, be required to report on the percentage of PCPs who successfully qualify for an EHR Incentive Program Payment as part of the quality reporting measure set. CMS wants to encourage EHR adoption as soon as possible and, accordingly, this quality measure will be weighed twice as much as other measures adopted under the shared savings program.
- CMS chose not to adopt the quality measures related to health care acquired conditions (HACs). Responding to numerous concerns submitted by commenters, CMS recognized that not all ACOs will have participating hospitals for which these measures are reported. CMS did not, however, rule out adopting individual HAC measures in the future that would be calculated for an ACO's assigned beneficiaries, regardless of whether an ACO includes a hospital.

CMS adopted final measures with a predominantly ambulatory care focus. While CMS anticipates a "relatively static set of quality measures for the first agreement period," the final rule makes clear that such measures may change during the course of an agreement and ACOs will be required to comply with such changes.

Given that first-year start dates for ACO agreements will begin either in April or July 2012, the first performance period will be 18 or 21 months. ACOs will be eligible for interim payments if they report on quality measures during calendar year 2012 and must report quality measures for calendar year 2013 to qualify for first-performance-period savings.

Data Submission Requirements

Under the ACA, ACOs are required to submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary to evaluate the quality of care furnished by the ACO. As indicated in the chart available at www.ober.com/files/acoqualitymeasuretable.pdf, ACO quality measure data will be collected through three primary methods: (1) claims data; (2) the Group Practice Reporting Option (GPRO) data collection tool utilized under the Physician Quality Reporting System (PQRS) program; and (3) survey instruments.

With respect to patient-level, chart-abstracted quality measures, CMS adopted its proposal to use the GPRO tool. For the GPRO measures, CMS will pre-populate the data collection tool with beneficiaries' demographic and utilization information based on Medicare claims data and ACOs will be required to populate remaining fields. CMS will require submission of data related to a sample of at least 411 beneficiaries for each domain,

unless the pool is less than 411 beneficiaries, in which case data on all assigned beneficiaries must be reported.

Similar to its other quality initiatives, CMS includes a data validation process pursuant to which CMS retains the right to review a random sample of medical records data for each of the measure domains/measure sets. If, at the conclusion of a three-phase audit process, the mismatch between the audited charts and the charts abstracted by the ACO is greater than 10 percent, the ACO will not be given credit for meeting the quality target for any measures for which the mismatch rate exists.

Notably, ACOs that fail to report quality measure data accurately, completely and timely may be subject to termination or other sanctions. CMS, however, has finalized a number of procedural steps that must occur prior to termination, including a written warning, reevaluation, and an opportunity to resubmit data. Nevertheless, ACOs that exhibit a pattern of inaccurate or incomplete reporting may be terminated from the program.

Quality Performance Standard Calculation

For the first performance period an ACO will meet the Quality Performance Standard, and earn either 60 percent (two-sided model) or 50 percent (one-sided model) of the sharable savings, if the ACO completely and accurately reports data on all program measures. For subsequent years, the percent of potential shared savings will vary based on the ACO's performance on the quality measures as compared to established benchmarks, which will be released through sub-regulatory guidance at the start of the second year of the performance period.

In the final rule, CMS announced that it will phase in pay-for-performance under the ACO program during performance years 2 and 3. As indicated in the attached measures chart (see above) in year 1 of the agreement, all 33 measures used for scoring purposes will be pay-for-reporting. In year 2 of the agreement, 8 measures will continue to be pay for reporting, while 25 measures will be pay-for-performance. In year 3 (and 4 if applicable), 32 measures will be pay-for-performance and 1 measure (health status/functional status module) will be pay-for-reporting.

The final rule adopts the "performance score approach" once pay-for-performance begins in years 2 and 3 of the initial agreement period. CMS adopted this approach, which rewards ACOs with better quality with a greater proportion of shared savings, because the agency believes it offers a greater incentive for continuous quality improvement. The steps in determining the performance score are as follows:

(1) Each of the 33 measures is subdivided into the four domains identified above.

(2) *Measure Score:* For each measure, an ACO can achieve a score of up to 2 points, with the exception of the measure of PCPs who Successfully Qualify for an EHR Incentive Program Payment, which is weighted double and worth up to 4 points.
   - Performance equal to or greater than the minimum attainment level (30th percentile) but less than the performance benchmark (90th percentile) will yield points on a sliding scale based on performance ranging from 1.10 to 1.85 points.
   - Performance below the attainment level (30th percentile) will yield zero points, while performance at or above the performance benchmark (90th percentile) will yield 2 points.
   - For seven measures, Measures 22 through 26 (Diabetes Composite) and 32 through 33 (Coronary Artery Disease Composite), CMS has proposed "all or nothing" scoring pursuant to which an ACO will receive all points only if all criteria are met, and zero points if at least one of the criteria are not met.

(3) *Domain Score:* CMS will calculate an aggregate score for all measures for each domain, as well as calculating the percentage of points earned for each domain.

(4) *Overall ACO Performance Score:* Stating its belief that all adopted domains are of equal importance, CMS is finalizing its proposal to weigh all domains equally. Accordingly, CMS will average all domain scores for the ACO to calculate the overall quality score to determine the ACO's final sharing rate.

Despite receiving comments suggesting that benchmarks should be established based on comparisons with other ACOs, rather than data collected under the Medicare Advantage (MA) or other fee-for-service (FFS) programs, CMS finalized its proposal to establish national benchmarks using a national sample of Medicare FFS claims data, MA quality data or a flat percentage if such data are not available. Some commenters had urged that comparison of ACO quality data with MA data was improper as MA patients are locked in to receiving care from MA providers. CMS plans to adopt benchmarks through subregulatory guidance.

Providing some leniency in the final rule, CMS decided not to adopt the requirement that an ACO must meet the minimum attainment level on each measure of a domain in order to earn shared savings. Instead, ACOs must achieve the minimum attainment level on 70 percent of the measures in each the four domains. If an ACO fails to meet this 70 percent threshold, it will be placed on a corrective action plan and would not be eligible to earn any shared savings.

Incorporation of the Physician Quality Reporting System

CMS adopted its proposal to incorporate reporting requirements and payments related to the PQRS into the Shared Savings Program for "eligible professionals" (EPs) (i.e., physicians, nurse practitioners, physical or occupational therapists, etc.) that participate in the ACO. EPs may *only* participate in the PQRS incentive as a

group practice under their ACO participant TIN. Accordingly, an ACO, on behalf of its EPs, must satisfactorily submit quality data on the GPRO quality measures under the Shared Savings Program, for an EP to qualify for the PQRS incentive, which is equal to 0.5 percent of the ACO's eligible professionals' total estimated Medicare Part B PFS-allowed charges for covered professional services furnished for the first reporting period. In contrast to the proposed rule, CMS will not require that ACOs meet all other requirements for shared savings payment to qualify for the PQRS incentive payment.

In summary, it is apparent that CMS received the message that the number and scope of the quality requirements set forth in the proposed rule would have deterred a number of potential ACO providers from participating in the Shared Savings Program. ACOs will require a significant amount of infrastructure and coordination between their physicians and other suppliers to ensure complete and accurate reporting of quality data and will need to focus resources on the improvement of quality throughout the ACO to ensure eligibility to share in achieved savings. To the extent that an ACO does not completely and accurately report its quality data, or does not demonstrate continued quality performance in relation to the benchmarks, the ACO will not reap the benefits of participation in the Shared Savings Program no matter how much savings the ACO achieves.

Shared Savings and Losses

Selection of Shared Savings/Losses Model

Although CMS finalized its proposal to offer ACOs a choice of two shared savings tracks, the final rule includes important changes to the shared savings models. In a significant departure from the proposed rule, the one-sided model has been amended so that it will be a shared-savings-only model for the duration of the ACO's first agreement period. In making this change, CMS acknowledged comments suggesting that ACOs that are new to the accountable care model—particularly small, rural, safety net, and physician-only ACOs—would benefit from additional time under the one-sided model before being required to accept downside risk.

ACOs electing to participate under Track Two will be under the two-sided model for the duration of their first agreement period. All ACOs are required to participate in the two-sided model in agreement periods subsequent to the initial enrollment period. This approach reflects CMS's belief that models that expose ACOs to the risk of financial loss are more likely to induce meaningful systematic change. Recognizing that it may take some ACOs longer than the initial agreement period to achieve shared savings, CMS modified its

proposal to allow continued participation in the Shared Savings Program by ACOs that experience a net loss during their first agreement period.

Shared Savings and Losses Determination

Overview of Shared Savings and Losses Determination

An ACO is eligible to receive payment of shared savings only if "the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark..." To determine and appropriately share savings with ACOs, therefore, CMS must make several determinations as part of the shared savings methodology.

In response to a deluge of comments suggesting that CMS needed to make the Shared Savings Program more attractive to encourage broad participation by providers and suppliers, CMS revised several of its proposals to make the program more financially rewarding for ACOs. The preamble to the regulations contains a chart that summarizes many of the key changes. See www.ober.com/files/CMS-ACO-Summary-Chart.pdf.

Establishing the Benchmark

In order to implement the Shared Savings Program, CMS was first required to establish an expenditure benchmark. Citing the constraints imposed by the statutory language, CMS finalized its proposal for establishing the benchmark without substantial change. An ACO's initial benchmark will be based on the Parts A and B fee-for-service (FFS) expenditures of beneficiaries who would have been assigned to the ACO in any of the three years prior to the start of an ACO's agreement period using the ACO participants' TINs identified at the start of the agreement period. However, CMS noted that it plans to revisit the benchmarking methodology in future rulemaking once it gains more experience with benchmarking based on an ACO's actual assigned population, as in the Pioneer Model.

CMS adopts a categorical approach to establishing the benchmark. Specifically, historical benchmark expenditures will be calculated for cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries. Further, CMS will truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark year and performance year. This approach—as opposed to truncating at the 95th percentile—gives ACOs a greater incentive to coordinate care and services for high-cost beneficiaries. Finally, the benchmark will be reset at the start of each agreement period.

Adjusting the Benchmark and Actual Expenditures

Adjusting Benchmark and Performance Year Average Per Capita Expenditures for Beneficiary Characteristics. In the proposed rule, CMS considered three options for risk-adjusting the initial benchmark: patient demographic factors, patient demographic factors in combination with diagnostic information, and the Medicare Advantage "new enrollee" demographic risk adjustment model. The final rule adopts the CMS-HCC prospective risk-adjustment model used under the Medicare Advantage program. According to CMS, this approach best accounts for variation in case complexity and severity, and thus most accurately predicts health care expenditures.

The final rule also modifies CMS's initial proposal so that ACO benchmarks will better reflect the risk associated with their assigned beneficiaries. Specifically, CMS will annually update an ACO's CMS-HCC prospective risk scores for newly assigned beneficiaries to adjust for changes in severity and case mix in this population. CMS will also recalculate the ACO's CMS-HCC prospective risk scores for continuously assigned beneficiaries each year.

Technical Adjustments to the Benchmark. The ACA requires that the shared savings benchmark be adjusted for beneficiary characteristics and such other factors as HHS deems appropriate. In an effort to capture all relevant Medicare costs in an ACO's benchmark, CMS will take into account payments made from the Medicare Trust Fund for Parts A and B services, including payments made under a demonstration, pilot or time-limited program, when computing average per capita Medicare expenditures for an ACO during both the benchmark period and performance years.

Geographic and Other Payment Adjustments. In the proposed rule, CMS considered whether to include or exclude a myriad of payments from ACO benchmark and performance year expenditures. The treatment of Medicare FFS payment adjustments can affect an ACO's ability to realize savings. For example, if an ACO fails to receive a particular incentive payment during the benchmark year, but subsequently receives the incentive during a performance year, then performance year expenditures will appear to be inflated.

The final rule includes all Parts A and B expenditures—with the exception of IME and DSH payments—in the calculation of the benchmark and performance year expenditures. CMS does not believe that the inclusion of these payments, such as geographic payment adjustments, will result in a significant incentive to steer patients away from particular hospitals or providers because ACOs will be compared to their own historical expenditure benchmark as updated. It is important to note, however, that payments falling outside of Part A and B claims will be excluded from calculations of benchmark and performance year expenditures (e.g., DGME payments, PQRS, eRx, and EHR incentive payments).

Trending Forward Prior Year's Experience to Obtain Initial Benchmark. Because the statute requires the use of historical expenditures to estimate a benchmark for each ACO, the per capita costs for each year must be trended forward to current year dollars to obtain the benchmark for the first agreement period. The final rule trends forward the most recent three years of per-beneficiary expenditures using growth rates in per-beneficiary expenditures for Parts A and B services. A national growth rate in Medicare Parts A and B expenditures will be used for FFS beneficiaries to trend forward.

To account for variation in costs between different populations of Medicare beneficiaries, CMS will trend forward benchmark expenditures and update the benchmark for the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries. This will enable CMS to provide a more complete and accurate benchmark for ACOs since it will capture the proportion of ACO assigned patients in each category.

Updating the Benchmark During the Agreement Period

The benchmark will be updated during the agreement period by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program. Using the same update for all ACOs will provide a relatively higher expenditure benchmark for low-growth/low-spending ACOs and a relatively lower benchmark for high-growth/high-spending ACOs. CMS notes that this should incentivize providers in higher cost areas to bring spending in line with national averages.

Determining Shared Savings

Minimum Savings Rate. An ACO is eligible to share in savings only if it achieves savings in excess of the minimum savings rate (MSR). In the proposed rule, CMS expressed its desire to set the MSR in such a way that the ACO's performance and shared savings are a result of its interventions, not normal variations in expenditures based upon the number of Medicare FFS beneficiaries assigned to the ACO.

One-sided model. The final rule uses a sliding scale based on the size of the ACO's assigned population to establish the MSR for ACOs participating under the one-sided model. Varying the MSR based on the size of the ACO will permit groups of solo and small practices to participate in the Shared Savings Program. For an ACO with between 5,000 and 5,999 beneficiaries, for example, the MSR would be between 3.6 percent and 3.9 percent, depending on the number of assigned beneficiaries. At the other extreme, an ACO with over 60,000 beneficiaries would have an MSR of 2.0 percent.

Two-sided model. A flat 2.0 percent MSR will be applied to all ACOs participating under the two-sided model. CMS observed that the greater predictability of a fixed MSR was more

likely to attract organizations to participate under this model in light of the potential for shared loss.

Quality Performance Sharing Rate. ACOs with savings in excess of the MSR are eligible to share in up to 50 percent of total savings under the one-sided model, and up to 60 percent of total savings under the two-sided model. CMS declined to accept comments urging it to increase the sharing rates based on quality performance.

Additional Shared Savings Payments. Under the proposed rule, ACOs would have been eligible to receive higher sharing rates for including FQHCs and RHCs as ACO participants. The incentive was designed to promote care coordination and the use of FQHCs and RHCs since these entities were not permitted to participate in the Shared Savings Program independently. CMS abandoned the proposed incentive in the final rule, however, having determined a statutorily satisfactory way of assigning beneficiaries to an ACO on the basis of services furnished by these entities.

Net Sharing Rate. In a significant departure from the proposed rule, the final rule will allow ACOs under the one-sided model to share in first dollar savings once savings meet or exceed the MSR. Consistent with the proposed rule, ACOs under the two-sided model will also be eligible to share in first dollar savings once savings meet or exceed the MSR. CMS elected to permit ACOs to share in first dollar savings, as opposed to only those savings in excess of the MSR or some other threshold, based on comments persuading CMS that a higher threshold could deter participation in the program. The approach adopted maximizes the reward that ACOs can realize, and should ensure that ACOs receive needed capital.

Performance Payment Limits. In welcome news for potential ACO participants, the final rule increases the proposed payment limits. The maximum performance payment ACOs under the one-sided model can receive is 10 percent of benchmark expenditures. ACOs under the two-sided model can receive a performance payment of up to 15 percent of the ACO's updated benchmark. CMS increased the payment limits to encourage participation in the program and to ensure that ACOs receive capital to invest in achieving the program's goals.

Calculating Sharing in Losses

The shared losses methodology will mirror the shared savings methodology. It will consist of a formula for calculating shared losses based on the final sharing rate, use of a minimum loss rate to protect against losses resulting from random variation, and a loss-sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay.

Minimum Loss Rate. The final rule applies a minimum loss rate (MLR) to ACOs participating in the two-sided model. To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must exceed its updated benchmark costs for the year by at least 2 percent. Once losses meet or exceed the MLR, an ACO would be responsible for paying the percentage of excess expenditures, on a first dollar basis, up to the proposed annual limit on shared losses.

Shared Loss Rate. The shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures that exceed the updated benchmark will be determined based on the inverse of its final sharing rate based on quality performance (i.e., 1 minus the shared savings rate). However, the final rule makes an important change to the shared loss rate: whereas the shared loss rate was bounded at 100 percent in the proposed rule, the final rule imposes a cap of 60 percent on shared losses. CMS observed that the approach under the proposed rule could deter ACO participation in the two-sided model.

Limits on Shared Losses

To provide a greater incentive for organizations to participate in the Shared Savings Program under the two-sided model, limits on shared losses will be phased in over the agreement period. Shared losses will be limited to 5 percent of the benchmark in the first performance year, 7.5 percent in the second year, and 10 percent in the third year.

Ensuring ACO Repayment of Shared Losses

CMS states that it is critical to the viability of the Shared Savings Program that ACOs entering the two-sided model be capable of repaying CMS for costs that exceed their benchmark. CMS gives ACOs flexibility to specify their preferred method for repaying potential losses, and how that would apply to ACO participants and ACO providers/suppliers. CMS will determine the adequacy of each ACO's repayment mechanism prior to the start of each year. Under the final rule, the repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of total per capita Medicare Parts A and B fee-for-service expenditures for assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark.

CMS received several comments to the proposed rule which suggested that the repayment proposal would be too burdensome. Although CMS did retain the repayment proposal in the final rule, two significant changes are worth mentioning. First, to the extent that an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, CMS will not carry forward unpaid losses into subsequent performance years and agreement periods. Second, CMS eliminated the proposed requirement for a 25

percent withhold of shared savings as a means to ensure that ACOs could repay any future shared losses. These changes make participation in an ACO significantly more appealing than it was under the provisions of the proposed rule.

Timing of Repayment

ACOs must make payment in full to CMS for any shared losses within 90 days of receipt of notification of the shared losses to avoid interest. This is a significant increase from the 30-day period originally proposed.

Withholding Performance Payments

CMS originally proposed withholding 25 percent of any shared savings earned by an ACO to offset potential future losses. In response to comments suggesting that the proposed withhold would adversely affect participation and/or restrict necessary capital, the final rule eliminates the 25 percent withhold requirement.

Determining First-year Performance

ACOs can begin participating in the Shared Savings Program on either April 1 or July 1, 2012. CMS has outlined a methodology for determining shared savings and losses for the first performance year, which will be either 21 months or 18 months depending on the start date.

Interim Payment Calculation. In the first performance year, ACOs will have the option to elect an interim payment based on the first 12 months of participation and a final reconciliation at the end of the performance year. However, ACOs that opt for interim payment under either the one-sided or two-sided model will be required to assure CMS of their ability to repay any monies determined to be owed at the year-end reconciliation. Thus, ACOs under the one-sided model that opt for interim payment will be required to meet the same requirement as all ACOs participating under the two-sided model: demonstrating an adequate repayment mechanism to repay any overpayment of shared savings.

First Year Reconciliation. The reconciliation for the first performance year will occur at the conclusion of CY 2013. Due to the overlap between the ACO's first 12 months of performance and the beginning of CY 2013, CMS provides a detailed overview of how it will aggregate performance year expenditures and update the benchmark for the overlapping timeframes.

EHRs, Data Sharing and HIPAA Privacy Compliance: Key Components of Successful ACOs

ACOs must be accountable for HIPAA-compliant data sharing, as well as spur innovation needed by ACOs through the adoption of electronic health records. In some ways, the final rule's provisions relating to data sharing do not depart significantly from the proposed rule and provide a more consistent model with the current HIPAA Privacy Rule. In contrast, EHRs are no longer a prerequisite to eligibility for the ACO program in the final rule. Instead, an EHR is a highly scored quality measurement and may be needed for quality reporting itself.

Data Sharing

In the final rule, CMS finds financial and quality data pivotal to the success of an ACO. Data related to patients will assist ACOs with accountability for the quality and cost of care. That being said, the sharing of data will implicate the Privacy and Security Rule along with the relevant provisions of the ACO final rule. Data exchanged between an ACO, its participants, its providers/suppliers and CMS fall into three categories:

- Aggregated data reports from CMS
- Data reporting to CMS by the ACO
- Data independently identified and produced by the ACO to improve patient outcomes

Each of these categories of data sharing creates its own unique privacy and security challenges.

Sharing Aggregated Data

Under the first category, CMS will provide the ACO "aggregate reports" derived from beneficiary claims data at the start of the agreement period and then quarterly during the term of the agreement between CMS and the ACO. Despite comments for the need for "real time" data to promote quality outcomes, CMS stated that data would only be ready once it was submitted and then processed, causing a delay between the provision of services and a claim being processed. In addition, the need to aggregate the claims data made it "impossible" for real time data submission.

CMS acknowledges that the need for aggregated data still exists because Medicare beneficiaries will be free to seek services both inside and outside the ACO. ACO data alone may not be enough for ACOs to track treatment patterns and ensure high-quality treatment plans for their patients. CMS recognizes the difficulties ACOs would face in securing a list of services performed outside the ACO. As such, CMS proposed providing aggregated data reports to provide certain identifying information, which CMS settled on in the final rule. CMS

modified its original proposal to provide information such as names, birth dates and sex each quarter based on the most recent 12 months of data. Once a beneficiary is no longer treated by the ACO, the ACO should not request data on that beneficiary.

Opting Out. In the proposed rule, CMS allowed beneficiaries to opt out or decline to be included in such reports. While stating that it has the authority to eliminate opt-out provisions, CMS declined this option in the final rule. CMS also declined to require beneficiary permission before sharing data (opt in) since this approach requires burdensome paperwork tracking beneficiary decisions. Forms and an explanation of the opt-out must also be made available to the beneficiary at the beneficiary's first primary care service with an ACO participant, along with other notifications, such as notification of the primary care doctor's participation in the ACO. The physician's office will provide beneficiaries with a form, which will include a method, such as a phone number or email address, to request that their data not be shared.

The ACO must care for the beneficiary even if he or she opts out of data sharing. CMS views the data sharing discussion between the ACO and the beneficiary as an opportunity for the ACO to engage in "true patient-centered care." ACOs may provide advance notification prior to a primary care service visit of their participation in the ACO and the option to opt out of data sharing. Thirty days after providing such notification, the ACO may request beneficiary-identifiable data from CMS, but still must engage the beneficiary in the data sharing discussion at the beneficiary's first primary care visit. The notification to opt out may be received by CMS or the ACO. The final rule notes that data protected under the federal Confidentiality of Alcohol and Drug Abuse Regulations will not be provided, but does not specifically exclude any other sensitive information. ACOs should also check state laws, which may provide greater protection than HIPAA.

De-identified Information. Consistent with the requirements that ACOs seek innovative and compliant ways to improve quality for patients and patient populations, CMS will provide ACOs aggregated data consistent with the Privacy Rule. CMS will aggregate data or "de-identify" the data as defined in the Privacy Rule. Data that has been de-identified falls outside the scope of the privacy protections and individual rights of HIPAA. Interestingly, neither the proposed nor the final rule deal with the alternative option for de-identification set out in the Privacy Rule. Most de-identification occurs through compliance with a "safe harbor" specified in the Privacy Rule which requires the removal or masking of direct and indirect identifiers specifically listed in the Privacy Rule.

Some comments to the proposed rule expressed concern that CMS failed to provide certain critical data elements. The Privacy Rule also provides an alternative means to de-identification allowing "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and

methods" to use statistical methods of de-identification. This statistical method arguably offers the opportunity to provide more beneficiary-specific information that might be of use to the ACO for the contemplated purpose of modeling the ACO's assigned beneficiary population. For example, this method may provide more specific age and zip-code or geocode information that must be removed or masked for de-identification under the Privacy Rule's other method for de-identification. CMS also included identifiable data for limited purposes to address concerns on the need for data for quality improvement purposes.

Beneficiary-Identifiable Data. Under the final rule, ACOs now have access to information regarding preliminary prospective assigned beneficiaries—who might use the ACOs' services. As such, an ACO now may request identifiable beneficiary data to evaluate itself and its ACO participants and suppliers/providers. This data, which may be requested as often as once per month, may include beneficiaries assigned to the ACO as well as beneficiaries who received primary care services from the ACO but may not necessarily be assigned to the ACO. CMS made these reports optional based on the varying desire and resources of ACOs to receive this level of data. Beneficiaries, however, still can opt out of the opportunity to data share.

The ACO must enter into a Data Use Agreement (DUA) with CMS before receiving identifiable beneficiary data. The DUA is tied, under the Privacy Rule, to the release of a "limited data set" for research and certain other purposes. In this DUA, the ACO must certify that the claims data is its own patients and is the minimum data necessary for the ACO to conduct its health care operations. A parallel provision applies to ACO business associates. The "minimum necessary" standard is a key to the Privacy Rule and, under the HITECH Act, the Secretary is required to provide "guidance" with respect to the minimum necessary standard, although such guidance has not yet been provided. There seems to be some room for negotiation in the minimum necessary provisions of the final rule. First, the scope of activities specified in the relevant sections of the definition of *health care operations* is broader than the specific provisions used by CMS in the final rule. Second, response to comments in the final rule indicate that this data can be expanded upon a showing by the ACO that additional data is necessary to perform the ACO's functions.

The ACO also must certify that the information will be used to develop processes and engage in appropriate activities related to care coordination and improvement that are applied uniformly to all beneficiaries receiving primary care services at the ACO, and will not be used to limit or restrict care for those beneficiaries. CMS points out that misuse of this information will subject the ACO to penalties, including termination from the Shared Savings Program. The DUA does not authorize the data recipient to use or further disclose the information in a manner that would violate the requirements of the Privacy Rule, if done by the covered entity. The ACO must use appropriate safeguards to prevent use or disclosure of the information other than as

provided for by the DUA and recipients must report to the covered entity any use or disclosure of the information not provided for by its DUA of which the recipient becomes aware.

Reporting of Data to CMS

As part of the ACO quality reporting requirements, the ACO must submit data in a form and manner set out by CMS. Various reporting tools exist, such as eRx and *Hospital Compare*; however some commenters found it confusing and expensive to have so many different methods for reporting data. In the final rule, CMS decided to provide a CMS-specific data collection tool for certain measures (i.e., web interface). ACOs will report through a GPRO web interface that was used in physician demonstrations and is pre-populated with beneficiary data. Some GPRO measures, such as compliance with eRX or EHR incentives, are attestations rather than data submission. CMS reserves the right to validate such data submitted by the ACO. CMS welcomes comments on the proposed data submission requirements, as well as the methods for submission, such as limiting measures to claims-based or survey-based reporting only. Data submission guidelines will come in the form of subregulatory guidance.

Sharing of Data Among ACO Participants

Finally, under the third category, the ACO creates its own reports which it shares with its ACO participants and suppliers/providers in an effort to best evaluate the health care needs of its patients. CMS finds this last category an important and much needed skill for each ACO to develop, especially as it serves its own unique patient population. An ACO may be composted of several different entities, such as a hospital and an independent physician group, that must share data related to the ACO's beneficiaries to meet the goals of providing high quality care. An ACO and its participants may not use or disclose data in a manner in which a HIPAA covered entity could not use or disclose.

The sharing of individually identifiable beneficiary information depends on a long-standing provision of the Privacy Rule that permits covered entities to share *protected health information* (PHI) with other covered entities (but not with health care providers that are not covered entities) for specified *health care operations* activities of the recipient. This sharing of PHI is permitted so long as each covered entity has or has had a relationship with the individual and the information pertains to that relationship. For example, *health care operations* includes conducting quality assessment and improvement activities such as coordination of care. *Health care operations* also includes the evaluating practitioners' performance necessary to monitor, educate, train and supervise practitioners whose quality performance does not meet the ACO's standards.

Electronic Health Records

The proposed rule required specific levels of EHR use, but in the final rule, EHR is now a quality measure. The quality measure requires ACOs to report the percentage of primary care providers who successfully qualify for an EHR Incentive Program payment. This measure has a double weight compared to other quality measures, and CMS strongly endorses the adoption of EHRs to report data, increase quality and coordinate care across care settings. CMS addressed a comment regarding reporting to state agencies to assist in identification and care for high risk population with a recognition of its importance as an objective in the EHR Incentive Program. For example, eligible professionals could share immunization data with state health agencies. This information may also be shared with state health agencies through health information exchanges (HIE), but CMS declined to require such reporting as part of the final rule.

Fraud and Abuse Waivers for ACOs Participating in Medicare's Shared Savings Program

Background

The ACA authorizes the Department of Health and Human Services to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Program. On October 20, 2011, concurrently with the issuance by CMS of the final Shared Savings Program rule, CMS and OIG jointly issued a interim final rule with comment period (the "rule") describing five separate fraud and abuse waivers that may be used by entities participating in the Shared Savings Program (including the Advanced Payment Initiative). Under the rule entities participating in the Shared Savings Program that meet a waiver need not be concerned with the Stark self-referral law, the anti-kickback law, the civil money penalty provision related to payments to physicians by hospitals for reducing or limiting care (often referred to as the gainsharing CMP), and certain applications of the civil money penalty for inducements to beneficiaries.

The rule does not include specific regulatory language. Rather, it describes the scope and criteria of each of the potential waivers and seeks additional public input regarding certain aspects of the waivers, including whether there should be greater specificity in the waivers themselves. Public comments are due sixty days after publication in the federal register, which will be approximately November 2, 2011.

The rule creates waivers that are far broader than the initial waivers contained in the notice with comment period (Notice) issued April 7, 2011 (76 Fed. Reg. 19655). This rule shows that OIG and CMS seriously considered input from commenters that criticized the proposed rule as not expansive enough to foster

development of ACOs under the Shared Savings Program. However, it is also clear that the agencies intend to ensure that ACO arrangements do not abuse federal program patients or funds. ACOs taking advantage of the waivers must meet stringent waiver criteria, as well as program integrity safeguards found in the Shared Savings Program rule itself. On balance, the waivers encompass most, if not all, arrangements necessary for the development and execution of ACOs under the Shared Savings Program through waivers that are specifically intended to promote "flexibility, adaptability and innovation." These same themes are seen in the Shared Savings Program final rule.

As explained in greater detail below, the rule contains two waivers that were initially proposed along with three new waivers. The waivers were also reorganized by the type of arrangement protected, rather than by the type of law that is waived. The waivers are for:

- ACO pre-participation (new)
- ACO participation (new)
- Shared savings distributions (modified)
- Compliance with the physician self-referral law (modified)
- Patient incentive waiver for beneficiary inducements to encourage preventive care and compliance with treatment regimens (new)

While more than one waiver may apply, parties are only required to meet the criteria for one waiver. In addition, the rule clarifies that failure to meet one of the proposed waivers under the anti-kickback statute does not mean that the arrangement is necessarily illegal. In addition, the agencies note that other Stark exceptions and anti-kickback safe harbors may protect certain aspects of ACO arrangements. Further, the rule specifically notes that the ACO pre-participation and ACO participation waivers are likely to encompass many of the arrangements undertaken by ACOs. However, it appears that CMS and OIG did not want to be seen as limiting the waivers previously proposed, so the rule maintains those as well.

The waivers apply uniformly to ACOs, ACO participants, and ACO providers/suppliers (as defined in the Shared Savings Program). The waivers are intended to be self-implementing and parties do not apply for individualized determinations of the waiver authority. Notably, CMS and OIG do not intend to codify the waivers in the Code of Federal Regulations. The rule states that due to the fact that the waivers cover multiple legal authorities and to ensure consistency over time, the text of the waivers will be made available on the CMS and OIG websites and is included in the rule. CMS and OIG have specifically requested comments with respect to this approach.

The Five Waivers

General Terms Applying to All Waivers

The rule specifies that the terms ACO, ACO participant and ACO provider/supplier as used throughout the waivers have the meaning ascribed to those terms in the Shared Savings Program. With respect to the ACO pre-participation waiver, the terms refer to the individuals and entities in the Shared Savings Program definition as if those individuals and entities had an ACO participation agreement with CMS, except for the fact that the ACO had not yet submitted the required materials for application into the Shared Savings Program.

The various waivers contained in the rule often use the term "reasonably related to the purposes of the Shared Savings Program." In an attempt to be less proscriptive, the agencies changed the proposed language which had been, "necessary for and directly related to ACO purposes." The rule defines "purposes of the Shared Savings Program" as one or more of the following:

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

Section V of the rule provides additional guidance with respect to the meaning of the purposes, including patient engagement, meeting quality reporting requirements, coordinating clinical care, etc. Importantly, purposes that include both Medicare and non-Medicare patients will qualify for the waiver.

It is worth noting that while the various waivers require contemporaneous documentation and an audit trail that is maintained for at least ten years, there is no requirement for a written and signed agreement. The rule notes that such an agreement is a best documentation practice, but is not required. Further, unlike most Stark exceptions and anti-kickback safe harbors, there is no requirement that the arrangements are fair market value or have been assessed to be commercially reasonable. Presumably, CMS and OIG recognized from comments that those ideas are not necessarily applicable when developing health care systems that promote cost effectiveness and efficiency and are successful based on positive clinical outcomes and shared savings. However, the agencies have requested comments as to whether such elements should be included in the final waivers.

ACO Pre-Participation Waiver

The ACO pre-participation waiver applies to the Stark self-referral law, the anti-kickback statute and the Gainsharing CMP. It provides an expansive waiver from these laws with respect to start-up arrangements that pre-date an ACO's participation in the Shared Savings Program as long as six requirements are met. Section V of the rule provides an illustrative but extensive list of start-up arrangements including everything from staffing to capital loans to information technology to incentives to attract primary care physicians. The waiver protects both those arrangements among ACO participants and ACO providers/suppliers as well as outside parties, although the agencies are seeking comments as to whether the waiver should be limited to exclude outside parties. The rule states that an ACO pre-participation waiver may only be used one time by an ACO. It appears that this does not limit the ACO to a single pre-participation arrangement, but rather, an ACO may only claim a single one year period (plus any extension granted) during which it can claim the ACO pre-participation waiver.

If all of the requirements of the ACO pre-participation waiver are met, the waiver would start as of the publication date of the rule for 2012 or, in future years, one year preceding the Shared Savings Program application due date. The waiver ends either (i) on the application date (for those entities that submit an application), at which point the ACO participation waiver would apply; (ii) on the date of the denial notice (for ACOs whose Shared Savings Program application is denied), although if the arrangement fully qualified for the pre-participation waiver, the waiver extends for six months after the denial date; (iii) the earlier of the application due date or the date the ACO submits a statement of reasons for failing to submit an application (for ACOs that do not submit an application).

There is a process for ACOs to apply for an extension if the ACO can demonstrate that the ACO would be able to participate by the next application due date. The Secretary will have sole discretion to approve or deny such an extension and will be developing further guidance with respect to procedures for requesting an extension.

The criteria for the ACO pre-participation waiver are as follows:

- The parties must have a good faith intent to develop an ACO to participate in the Shared Savings Program and submit an application for that year. The parties must include the ACO and at least one ACO participant. The parties to the arrangement may not include drug and device manufacturers, distributors, durable medical equipment (DME) suppliers, or home health suppliers;
- The parties must be taking diligent steps to develop an ACO that would be eligible for the Shared Savings Program, including meeting the ACO governance, leadership and management requirements;

- The ACO's governing body must make a "bona fide" determination that the arrangement is reasonably related to the purposes of the Shared Savings Program;
- The previous three criteria must be contemporaneously documented. All of the documentation must be maintained by the ACO for ten years following the date the ACO submits its application or the date it submits its reasons for not submitting an application. The documentation is required to be presented upon request from the Secretary of HHS. The documentation must include the following at a minimum:
    - A description of the arrangement, including the parties to the arrangement; date; purpose; items, services, goods, facilities covered by the arrangement; and the financial terms.
    - The date and manner of the governing body's authorization, including the basis for the determination that is reasonably related to the purposes of the Shared Savings Program.
    - A description of the diligent steps taken by the ACO to make it eligible for the Shared Savings Program.
- The description of the arrangement must be publicly disclosed as required by the Secretary (to be determined in future guidance), except that the financial terms need not be disclosed; and
- If an ACO does not submit an application by the last available application due date, the ACO must submit a statement to the Secretary describing why it was not able to submit an application (the manner and form to be determined in future guidance).

According to the rule, arrangements with drug and device manufacturers and distributors are carved out of this waiver as they are not Medicare enrolled suppliers and providers. Home health agencies and DME providers are excluded according to the agencies because they have historically posed a greater risk of program abuse.

While the text of the waiver makes clear that the Secretary will issue further guidance on the public disclosure of pre-participation (as well as participation) waivers, Section V of the rule specifically states that until that guidance is provided, ACOs must post on a website belonging to the ACO or an individual or entity forming the ACO, information about the arrangements to which they are applying the waiver. Such information must be posted "within sixty days of the arrangement" and must be labeled as an arrangement for which waiver protection is sought.

ACO Participation Waiver

The ACO participation waiver applies to the Physician Self-Referral Law, the anti-kickback statute and the Gainsharing CMP. The ACO participation waiver is a blanket waiver that appears to cover all aspects of an arrangement between an ACO, one or more ACO participants or ACO providers/suppliers or any combination. The waiver begins at the beginning of the participation agreement under the Shared Savings Program and ends six months after the earlier of the expiration of the participation agreement or the date that the ACO

voluntarily terminates the participation agreement. If CMS terminates the ACO's participation, then the waiver period ends on the date of the termination notice.

There are five requirements for the ACO participation waiver. Many are similar to those in the ACO pre-participation waiver:

- The ACO has entered into a participation agreement under the Shared Savings Program and is in good standing.
- The ACO meets the governance, leadership and management requirements of the Shared Savings Program.
- The ACO's governing body must make a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.
- There is documentation of the arrangement and the authorization by the governing body. Each must be contemporaneous and the documentation must be maintained for at least 10 years. The documentation requirements are the same as those for the ACO pre-participation waiver.
- The description of the arrangement must be publicly disclosed as required by the Secretary (to be determined in future guidance), except that the financial terms need not be disclosed.

Shared Savings Distribution Waiver

CMS and OIG have maintained the proposed waiver for the distribution of shared savings under the Shared Savings Program with minor modifications. Similar to the waivers described above, the shared savings distribution waiver applies to the Stark self-referral law, the anti-kickback statute and the Gainsharing CMP. The waiver requires meeting the following five criteria:

- The ACO must have an agreement with CMS to participate in the Shared Savings Program and be in good standing.
- The shared savings are earned by the ACO pursuant to the Shared Savings Program.
- The shared savings are earned during the term of the ACO's participation agreement, but the distribution may be after the expiration of the agreement.
- Distributions must be shared (i) among the ACO participants or ACO providers/suppliers that participated in the ACO during the year they were earned; or (ii) used for activities that are reasonably related to the purposes of the Shared Savings Program.
- With respect to the Gainsharing CMP, the shared savings distribution cannot be related knowingly by a hospital to induce a physician to reduce or limit medically necessary services under the direct care of the physician.

CMS and the OIG acknowledge that it is possible that shared savings distributions may also fall within the ACO participation waiver.

Compliance with the Physician Self-Referral Law Waiver

The rule retains the proposed waiver from the anti-kickback statute and Gainsharing CMP for those arrangements that implicate the Stark self-referral law and comply with a Stark exception. The waiver under the rule is broader than under the proposal, as it applies to any arrangement, not just those dealing with the distributions of shared savings. The waiver begins at the start of the participation agreement and ends the earlier of the expiration or termination of the agreement. The three criteria under this waiver are:

- The ACO has a participation agreement with CMS under the Shared Savings Program and is in good standing.
- The financial relationship is reasonably related to the purposes of the Shared Savings Program.
- The financial relationship fully complies with a Stark exception.

Like the proposed waiver, the waiver in the rule creates consistency between the Stark self-referral law and the anti-kickback law in a way that had to date not been permitted with respect to other arrangements. In previous anti-kickback safe harbor preambles, the OIG has been very clear on its position that the Stark self-referral law and the anti-kickback statute are two different laws and that simply because a financial arrangement meets a Stark exception does not preclude the arrangement from violating the anti-kickback statute. In the case of the Shared Savings Program, however, the agencies have determined that the safeguards incorporated into the Shared Savings Program, and a desire not to impede the development of ACOs, warrant a deviation from the general rule.

Waiver for Patient Incentives

The rule creates a new waiver from the beneficiary inducement CMP and the anti-kickback statute with respect to certain items and services that are provided by an ACO, ACO participants or ACO providers/suppliers to beneficiaries for free or at below fair market value. The waiver applies to all beneficiaries, not just those assigned to the ACO. Four requirements must be met:

- The ACO has a participation agreement with CMS under the Shared Savings Program and is in good standing.
- There is a reasonable connection between the items or services and the medical care provided to the beneficiary. For example, CMS and OIG state that a blood pressure cuff for a patient with hypertension

would be permissible, but theater tickets or beauty products would not be. However, certain incentives may still fall under the separate preventive care exception to the beneficiary inducement CMP.

- The items or services are in-kind. The waiver does not include waivers of co-payments or deductibles.
- The items or services are one of the following:
    - Preventive care items or services or
    - Advance one or more of the following clinical goals
        - Adherence to a treatment regime
        - Adherence to a drug regime
        - Adherence to a follow-up care plan
        - Management of a chronic disease or condition.

The waiver begins when the participation agreement starts and ends when the participation agreement expires or is terminated. Beneficiaries may keep items received prior to the end of the waiver and receive the remainder of any service initiated prior to the end of the waiver. Notably, the waiver for beneficiary inducements does not extend to items or services provided to beneficiaries to encourage them to seek care from ACO participants or ACO providers/suppliers. In fact, the Shared Savings Program regulations explicitly prohibit such actions.

Conclusion

Under the fraud and abuse waivers, CMS and OIG state their intent to protect financial arrangements intended to foster ACOs. Their stated goal was to issue waivers that showed flexibility, adaptability and innovation where the arrangements are consistent with the goals of the Shared Savings Program. The result is broad waivers.

The government, however, will be closely monitoring these arrangements and will endeavor to narrow the waivers where it appears that they are causing negative effects towards Medicare patients or program funds. In addition, ACO applicants will be screened prior to CMS entering into an Shared Savings Program agreement with the ACO. ACO applicants with a history of program integrity issues may be denied entry into the Shared Savings Program. Compliance plans with training for all ACO participants and ACO providers/suppliers are mandatory. The Shared Savings Program rules prohibit an ACO from conditioning participation in the ACO on referrals of non-ACO business. The Shared Savings Program rules also prohibit ACO participants from limiting or restricting referrals to ACO participants and ACO providers/suppliers. While CMS and OIG were willing to provide broad waivers, it is likely due in great part to the comfort they took from the program integrity provisions found in the Shared Savings Program itself.

Antitrust

Most groups applying to participate as ACOs in the Shared Savings Program will applaud the Federal Trade Commission and Department of Justice revisions to their proposed *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program*. The agencies issued their proposed *Statement* on March 31, 2010, requesting public comments. They received 127 comments and, after considering these and after both intra and interagency debates, issued the final *Statement* on October 20. Much stays the same, but the agencies made some substantial and important revisions.

Without question, the most significant change is the jettisoning of the mandatory antitrust agency review-letter requirement. Recall that the proposed *Statement* established a "below 30 percent," "between 30 percent and 50 percent," and "above 50 percent" framework for analysis. In general, ACOs with no participating provider primary service area (PSA) common-service market share above 30 percent enjoyed an antitrust safety zone, and those with shares between 30 percent and 50 percent enjoyed no safety zone but were invited to submit requests to the agencies for an antitrust review letter in which the agency would state whether it likely would challenge the ACO on antitrust grounds. But the proposed *Statement required* any ACO with any common-service PSA market share above 50 percent to obtain a positive antitrust review letter, on an expedited basis (i.e., an answer within 90 days) from the FTC or Antitrust Division, stating that the agency had no intention of challenging the ACO. Absent any letter, or if the applicant obtained a review letter stating that the agency would recommend challenging the ACO on antitrust grounds, CMS regulations prohibited the ACOs from participating in the Shared Savings Program. Indeed, any ACO applicant requesting an antitrust review letter stating an intent to challenge, including those with one or more market shares above 30 percent but not above 50 percent that voluntarily requested a review letter, was barred from the Shared Saving Program by CMS.

The mandatory antitrust review requirement was probably the most criticized aspect of the proposed *Statement*. Critics argued that it turned the agencies into regulatory agencies rather than law-enforcement agencies; that it seemed to establish a rebuttable presumption that any ACO with any common-service market share above 50 percent could exercise market power; that by conditioning Shared Savings Program participation on a positive agency letter, CMS unlawfully subdelegated its authority under the ACA to determine participants to the antitrust agencies; that almost every group applying to participate in the Shared Savings Program would have at least one share above 50 percent and thus face the requirement to obtain a review letter; and that there was simply no justification for the extra hassle the requirement would cause applicants.

Perhaps as a result, the agencies deleted in the final *Statement* any requirement that any ACO applicant obtain an antitrust review letter from either antitrust enforcement agency—a major change in policy at both

CMS and at the agencies. The *Statement* does invite "newly formed ACOs" (i.e., "ACOs that, as of March 23, 2010 . . . had not yet signed any contracts with private payers [or] participated in the Shared Savings Program") that wish "further antitrust guidance" to request an antitrust review letter; non-"newly formed ACOs" cannot obtain review letters. Under the final *Statement,* however, participation in the Shared Savings Program is not conditioned on a positive letter as it was under the proposed *Statement*. The information the applicant must submit to the agencies to obtain a review letter has been modified from that required under the proposed *Statement*, and the final *Statement* invites ACO applicants requesting a review letter to submit other information that might be helpful in assessing the ACO's likely effect on competition. The agencies have also clarified that although the reviewing agency may ask for additional information, its doing so does not extend the 90-day period in which the agency will respond to the request—although the party requesting a letter may voluntarily give the agency more time.

In conjunction with the now-voluntary review-letter process, the agencies issued a list of "Frequently Asked Questions about Voluntary Expedited Review" and a "cover sheet" that newly formed ACOs must submit to the agencies, along with a request letter, to start the review-letter process.

Another significant change is the scope of the *Statement's* coverage. The proposed *Statement* did not apply to networks applying to participate in the Shared Savings Program that formed prior to March 23, 2010, or to applicants that constitute single entities rather than "collaborations" of otherwise independent providers. Several commentators criticized both of these "exemptions" from the *Statement's* coverage, believing networks formed prior to March 23, 2010 or through mergers raise the same anticompetitive potential as those formed after that date or those comprised of a single entity.

The final *Statement* applies to all collaborative ACO applicants regardless of when formed, but it "does not apply to single, fully integrated entities." As the *Statement* indicates, however, provider mergers resulting in single entities are subject to Section 7 of the Clayton Act, which prohibits mergers likely to substantially lessen competition. Moreover, the agreements resulting in the formation of the single ACO entity ACO are subject to Section 1 of the Sherman Act, which prohibits agreements that unreasonably restrain competition.

The final *Statement* also clarifies the types of providers that constitute ACO "participants" and are thereby covered by the *Statement*. The proposed *Statement* was somewhat unclear in this respect. It clearly applied to physicians, hospitals, and ambulatory surgery centers; the question was whether it also applied to other types of providers that might provide services through the ACO, such as nursing homes, DME companies, hospices, and the like. If so, for purposes of determining antitrust safety-zone protection and estimating market power, it might have been necessary to calculate PSA market share for them. The *Statement* clarifies this by noting that

"[a]n ACO participant can be an independent physician solo practice, a fully integrated physician group practice, an inpatient facility, or an outpatient facility." The *Statement* provides explicitly that it "does not apply to other types of providers (e.g., clinical laboratories or nursing homes)," but only to "physician specialties," "inpatient facilities, and outpatient categories."

As in the proposed *Statement*, the final *Statement* includes what, in effect, is a conclusive presumption that the ACO is sufficiently integrated so that its joint negotiations with payers are ancillary restraints and accorded rule-of-reason analysis if the ACO meets the Shared Savings Program eligibility requirements. The agencies note, however, that CMS's monitoring of the ACO's cost, utilization, and quality information "will help [them] determine whether the CMS eligibility criteria have required a sufficient level of clinical integration to produce cost savings and quality improvements, and may help inform the Agencies' future analysis of ACOs and other provider organizations." This suggests that the agencies, down the road, may re-evaluate whether compliance with the ACO eligibility requirements justifies the more lenient rule-of-reason analysis. Or perhaps the agencies are suggesting that the results of the Shared Savings Program may determine whether networks not participating in the Shared Savings Program, but contracting only with commercial insurers, are sufficiently clinically integrated if their clinical integration program includes the characteristics embodied in the CMS eligibility requirements.

The ACO antitrust safety zone, together with its "rural exception" and "dominant participant limitation," from the Proposed *Statement* remain. The safety zone, as before, applies to any ACO with no PSA common-service market share above 30 percent, as long as any hospital and ambulatory surgery center ACO participants participate in the ACO on a non-exclusive basis—i.e., remain free to participate in other ACOs and to contract with payers through other networks or directly on an individual basis outside of the ACO. The only change appears to be in the definition of a participant's PSA. Both the proposed *Statement* and final *Statement* provide that a participant's PSA includes the zip codes from which the participant draws 75 percent of its patients, but the proposed *Statement* required that those zip codes be contiguous while the final *Statement* does not.

The final *Statement* includes a much stronger warning than the proposed *Statement* against ACO participants, regardless of their market shares or whether the ACO meets the safety-zone requirements, sharing competitively sensitive information, particularly the prices they charge payers when contracting outside of the ACO. As did the proposed *Statement*, the final *Statement* also provides that ACOs with "high PSA shares" "may wish to avoid" certain other forms of exclusionary conduct, such as discouraging payers from steering patients to non-ACO participants, tying the sale of ACO services to payers' not contracting with non-ACO participants for other services, and entering into exclusivity arrangements with ACO participants preventing them from contracting with payers through channels other than the ACO. But the final *Statement* recognizes

explicitly that, depending on the specific facts, exclusivity in the context of networks such as ACOs can be competitively benign or even procompetitive.

The agencies have expanded somewhat the appendix explaining how to calculate ACO PSA common-service market shares. This, however, will remain a burdensome task that many ACO applicants may need to undertake, even absent submitting a request for an antitrust review letter—for example, to determine whether the ACO will enjoy safety-zone protection.

All in all, the final *Statement* is a significant improvement although, most assuredly, many of those submitting comments to the agencies about the proposed *Statement* will believe that it could have been improved to a greater extent than it was.

IRS Provides Additional Guidance to Tax Exempt Participants of ACOs

In Fact Sheet 2011-11 (the Fact Sheet), the IRS confirms that previously released IRS Notice 2011-20 (discussed separately here) continues to reflect IRS expectations as to how existing IRS guidance applies to tax-exempt organizations that participate in the Shared Savings Program through ACOs. Although the Fact Sheet generally reiterates, in question and answer format, the guidance provided in IRS Notice 2011-20, it also offers some noteworthy additional guidance, as discussed below.

Private Inurement and Private Benefit

In IRS Notice 2011-20, the IRS set forth five factors that a tax-exempt participant in an ACO could satisfy to avoid "inurement" or "impermissible private benefit" that could jeopardize its tax-exempt status. The Fact Sheet clarifies, however, that whether inurement and impermissible private benefit results depends on the facts and circumstances and that not all five factors necessarily need to be satisfied.

Control of ACO by Tax-Exempt Entity

The Fact Sheet states that tax-exempt participants do not necessarily need to have control over the ACO to ensure that the ACO's participation in the Shared Savings Program furthers a charitable purpose. The IRS expects that CMS regulation and oversight of the ACO will be sufficient to ensure that participation in the Shared Savings Program furthers the charitable purpose of lessening the burdens of government.

Tax Status of ACO

IRS Notice 2011-20 did not address whether the ACO entity itself could qualify for tax-exempt status. The Fact Sheet, however, recognizes that an ACO engaged exclusively in Shared Savings Program activities can qualify for federal tax-exemption, since the IRS expects Shared Savings Program activities will generally further the charitable purpose of lessening the burdens of government. The Fact Sheet also recognizes that an ACO engaged in both Shared Savings Program and non-Shared Savings Program activities could potentially qualify for tax-exemption under Section 501(c)(3) as along as it engages exclusively in charitable activities and satisfies other general requirements for tax exemption.

Electronic Health Records Technology

The Fact Sheet confirms that the 2007 IRS memorandum relating to electronic health records applies to a charitable organization participating in the Shared Savings Program through an ACO.

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