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Revisiting the Medicare Shared Savings Program: An Interagency Effort to Promote Accountable Care

On October 20, 2011, the Centers for Medicare & Medicaid Services ("CMS") released its final rule ("Final Rule") implementing the voluntary Medicare Shared Savings Program ("Program")[1] for accountable care organizations ("ACOs"). The Program was established by Section 3022 of the Patient Protection and Affordable Care Act. The Final Rule was released in conjunction with revised antitrust guidance from the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"), as well as with the establishment by CMS and the Department of Health and Human Services' Office of Inspector General ("OIG") of several waivers from various fraud and abuse laws. As part of this interagency effort to facilitate participation in the Program, the Internal Revenue Service ("IRS") also issued a fact sheet regarding nonprofit organizations' participation in ACOs.

For purposes of background, the Program encourages the formation and operation of ACOs by promising to share Medicare's savings from the Program with those ACOs that meet: (1) eligibility requirements, and (2) quality performance and Medicare cost savings targets (as set forth in the Final Rule). As compared to the March 2011 proposed rule (the "Proposed Rule") and other agency statements at the time, the burdens of the Program's requirements have been reduced, the savings incentives appear to be more attractive, and the clearance obstacles appear to be fewer. At the same time, providers still must evaluate the merits of the Program relative to other opportunities for value-based contracting within CMS and the Center for Medicare and Medicaid Innovation ("CMMI"), as well as with commercial payers.

In addition to starting the Program, in the past year, CMS has launched a number of other programs and initiatives experimenting with new value-based payment models that promote accountable care, such as the Bundled Payments for Care Improvement initiative, the Community-Based Care Transitions Program, and the Pioneer ACO Model. While all these initiatives are voluntary, they involve different degrees of commitment from providers in terms of capital, resources, adjustments in care management capabilities, and risk. Set forth below is a table showing some of the programs and initiatives that have been launched in the past year that providers may want to consider participating in, either alongside the Program or as an alternative to the Program. Notably, although providers can participate in both the Program and the Bundled Payments for Care Improvement initiative,

Notwithstanding the fact that the Accountable Care Act establishes a permanent program rather than a pilot or demonstration, the Program will evolve over time and is only one component of an overall, societal-wide period of testing and experimentation to find pathways for diverse providers to work together and with payers to deliver more accountable care. Because of the Pioneer ACO Model and state and private payer ACO programs, as well as the many other value-based payment initiatives blossoming throughout the U.S., there is a legitimate basis for some optimism that we are making progress in payment and delivery reform, despite the complexity.

Doug Hastings

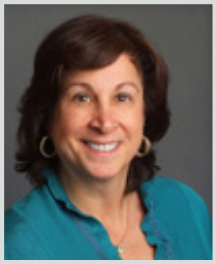
1 Additional information relating to the Final Rule and the Program is available on the CMS website at: https://www.cms.gov/sharedsavingsprogram/. This website provides a link to the advanced copy of the Final Rule, which was released on October 20, 2011. The Final Rule will be published in the *Federal Register* shortly.

in order not to double count savings, Medicare providers and suppliers may not participate in the Program if they are already participating in other Medicare shared savings models, programs, or initiatives. Specifically, the Final Rule indicates that Program participants may not also participate in the following shared savings programs: the Independence at Home Pilot Program, Pioneer ACO Model, Medical Health Care Quality Demonstration, Multi-Payer Advanced Primary Care Practice, Physician Group Practice Transition Demonstration, and Care Management for High-Cost Beneficiaries Demonstrations, among others.

MEDICARE MENU
Voluntary Options

Centers for Medicare & Medicaid Services		Center for Medicare & Medicaid Innovation	
Program	**Date**	**Program**	**Date**
Medicare Shared Savings Program Encourages the formation of accountable care organizations that coordinate care across the care continuum and share in Medicare savings	January 2012	**Hospital Engagement Contractors (Partnership for Patients)** Provides funding for contractors to design programs, conduct training, and provide technical assistance to support hospitals in making care safer and reduce hospital-acquired conditions	October 2011
Community-Based Care Transitions Program (Partnership for Patients) Provides funding to test models for improving care transitions from the inpatient hospital setting to other care settings	Second Quarter 2011	**Innovation Advisors Program** Selects individuals in the health care system (clinicians, health care executives, etc.) to test and refine new models of payment and care delivery focusing on health care finance, population health, systems analysis, and operations research	December 2011
		Pioneer ACO Model Tests alternative payment models that include escalating levels of financial accountability and sharing in Medicare savings — Organizations participating in the Pioneer ACO Model will not be eligible to participate in the Medicare Shared Savings Program	Fourth Quarter 2011
		Advance Payment ACO Model Provides opportunities to participants in the Medicare Shared Savings Program to receive advanced payments to be recouped from shared savings earned	January 2012
		Bundled Payments for Care Improvement Tests models that combine payment for physician, hospital, and other provider services of a predetermined amount during an episode of care	First & Second Quarters 2012 (depending on model)
		Comprehensive Primary Care Initiative Pays primary care providers for improved and comprehensive care management, and provides them with an opportunity to share in savings generated — Multi-payer initiative — Markets participating in a Multi-Payer Advanced Primary Care Practice demonstration are not eligible	Second Quarter 2012

Each health care delivery system has its own unique starting point towards accountable care. Now with CMS's publication of the final ACO regulations, along with about a half dozen other voluntary options available from CMS for improving care to Medicare beneficiaries and modifying payment methods, it becomes even more compelling for the senior leadership of health systems to seriously examine whether any of these options would be appropriate for their systems. This should be an imperative, particularly in light of the mandatory Medicare provider payment cuts that are just around the corner.



Lynn Shapiro Snyder

Application Timeline & Agreement Term

For providers considering participation in the Program, the Final Rule establishes a more detailed timeline than the Proposed Rule for applying to the Program. Applications will be accepted beginning in January 2012, with April 1, 2012, and July 1, 2012, being the available start dates for participation in the first performance year. For 2013 and subsequent years, the start date will be January 1.

As originally included in the Proposed Rule, Program agreements will have a minimum term of three years. However, for ACO participants starting on April 1, 2012, the term of the agreement will be three years and nine months. For ACO participants starting July 1, 2012, the term of the agreement will be three years and six months. These ACOs may opt for an interim payment calculation to determine shared savings and losses at the end of their first 12 months of participation. For ACO participants starting in subsequent years, the "performance year" (for purposes of calculating shared savings and scoring quality performance) will be 12 months, from January 1 to December 31.

CMS clearly sought ways in which the agency could reduce administrative burdens, while still encouraging strong beneficiary understanding and engagement in the process. For example, allowing ACO participants to certify that marketing materials adhere to CMS marketing guidelines rather than requiring prior CMS approval achieves a balance that will hopefully allow for more successful communication with beneficiaries.

Lesley Yeung

The Program application requirements remain largely consistent with those set forth in the Proposed Rule. Entities that wish to become an ACO are required to submit an application to CMS along with a number of certifications and supporting documentation. In addition, the ACO must agree that CMS can share a copy of its application with the FTC and DOJ.

As part of the application, an ACO executive who has the authority to legally bind the ACO must certify that the information included in the application is accurate, complete, and truthful. Additional required certifications include:

- That the ACO's providers and suppliers have agreed to be held accountable for the quality, cost, and overall care of the beneficiaries assigned to the ACO;
- That the ACO is recognized as a legal entity authorized to conduct business in each area in which it operates;
- Whether the ACO (or any providers and suppliers that are part of the ACO) has participated in the Program under the same or a different name; and
- Whether the ACO is related to, or has an affiliation with, another ACO participating in the Program, and, if such an affiliation exists, whether the related ACO agreement is currently active or has been terminated.

In addition, supporting information that must be submitted to CMS with an ACO application includes documents that:

- Explain the ACO participants' rights and obligations in the ACO, including how shared savings will encourage quality assurance and program improvement (such as participation agreements and operating policies);
- Describe how the ACO will implement the processes and patient-centeredness criteria, including penalties and remedial measures that will apply if an ACO participant, provider, or supplier does not implement the processes;
- Outline the ACO's organization and management structure;
- Provide evidence to show that the ACO's governing body is an identifiable body that adheres to the control requirements described above;
- Explain the ACO's compliance plan; and
- Provide evidence to demonstrate that the ACO is capable of repaying losses or other monies determined to be owed to CMS, such as evidence that the ACO has acquired reinsurance, placed funds in escrow, obtained surety bonds, established a line of credit, or secured another appropriate repayment mechanism.

Upon request, an ACO must submit documents to CMS that demonstrate the ACO's formation and operations. Such documents may include:

- Charters;
- By-laws;
- Articles of incorporation;
- A partnership agreement or joint venture agreement;
- Management or asset purchase agreements;
- Financial statements and records; and
- Résumés and other documentation regarding the leaders of the ACO.

Finally, an ACO must also provide information regarding the individual participants, providers, and suppliers in the ACO, as well as a description of how it plans to use shared savings payments to achieve specific Program goals and to achieve the "Triple Aim" of better care for individuals, better health for populations, and lower growth in expenditures.

Eligibility to Form an ACO

Consistent with the Proposed Rule, the Final Rule provides that ACOs can be formed by joint ventures between hospitals and ACO professionals, group practices, hospitals employing ACO professionals, certain Critical Access Hospitals, and networks of ACO professionals (which include physicians, nurse practitioners, physician assistants, and clinical nurse specialists). In addition, the Final Rule added Federally Qualified Health Centers ("FQHCs") and Rural Health Clinics ("RHCs") to the above list of providers and suppliers eligible to form an ACO. Also in a change from the Proposed Rule, the Final Rule permits any Medicare-enrolled providers and suppliers that are not specified as being eligible for the Program to participate by joining an ACO formed by at least one eligible participant. The Final Rule also gives ACOs more flexibility in planning and the ability to address care management challenges that emerge during a performance year by allowing the ACO to add to, or subtract from, its list of participants.

Governance

CMS has adopted most of the governance requirements set forth in the Proposed Rule. Specifically, the ACO must be a legal entity capable of receiving and distributing shared savings, repaying shared losses, and reporting quality performance data. The governing body is required to be comprised of ACO provider/supplier participants ("ACO Participants") or their designees who would have at least a 75-percent control of the governing body. Generally, the governing body of the ACO must include Medicare beneficiary representation. If the ACO is comprised of multiple independent entities, the governing board must be separate and unique to the ACO. For example, an ACO consisting of a hospital and a large independent primary care group practice could not have the same governing body as either the hospital or the primary care group practice.

The Final Rule, however, provides certain exceptions to these requirements to allow for greater flexibility in the manner in which ACOs are governed. Most significantly, the Final Rule provides an exception to the requirements that ACO Participants have at least a 75-percent control of the ACO's governing body and beneficiary representation on the ACO's governing body. To qualify for this exception, the ACO must explain why it is not meeting the 75-percent control and/or beneficiary representation requirement, and how it will otherwise meaningfully involve ACO Participants and/or beneficiaries in the ACO's governance. Additionally, the requirement of "proportionate control" by each ACO participant is eliminated by the Final Rule.

Assignment & Qualification Criteria

CMS retains in the Final Rule the requirement that an ACO must have a strong primary care base and that a minimum of 5,000 beneficiaries must receive a plurality of their primary care from the ACO. In other words, to be "assigned" to an ACO, a beneficiary must receive more of his or her primary care from the ACO than from any other entity outside the ACO. Medicare beneficiaries are "assigned" to an ACO at the end of the reporting year (*i.e.*, retrospectively.)

In response to significant concerns that retrospective assignment would discourage provider participation in the Program and impede efforts by providers to effectively target and focus the care management efforts of the ACO on the assigned beneficiaries, CMS has adopted a preliminary form of prospective assignment in the Final Rule as a supplement to retrospective assignment. While the actual assignment of beneficiaries under the Final Rule will remain retrospective for purposes of calculating the savings, CMS will now provide the ACO with quarterly reports based on the most recent data available, beginning with a report at the start of a performance year, listing the names, dates of birth, sex, and Medicare identifier of beneficiaries who are on track to be assigned to the ACO.

The Final Rule also addresses concerns that limiting assignments to beneficiaries treated by primary care physicians will make it difficult for many provider groups to reach the 5,000-beneficiary threshold necessary to qualify as an ACO under the Program. Whereas the Proposed Rule recognized primary care services provided by only primary care physicians, the Final Rule recognizes primary care services provided by specialists, physician assistants, and nurse practitioners after first identifying those beneficiaries treated by primary care physicians. This change might make it possible for many more provider groups to participate in the Program, such as multispecialty group practices that rely on specialists to provide some primary care services to Medicare beneficiaries.

In response to public comment, another issue addressed in the Final Rule is whether primary care providers must be exclusive to one ACO. CMS clarifies in the Final Rule that this exclusivity restriction applies at the level of the ACO Participant (*i.e.*, the entity with a Medicare-enrolled tax identification number ("TIN")), thus allowing individuals to perform primary care services in other ACOs operating under different TINs.

Shared Savings & Shared Losses

Some providers viewed CMS's requirement in the Proposed Rule that ACOs bear risk under both the Track 1 and Track 2 models as a significant barrier to Program participation. Although under the Proposed Rule, Track 1 ACOs would have been responsible for shared losses beginning in year three of the agreement term, CMS responded in the Final Rule by eliminating shared-loss risk from the Track 1 model.

The Final Rule gives each ACO the option to choose whether it will be subject to shared-loss risk during its initial performance year. ACOs that do not want to initially assume shared-loss risk have the option of choosing Track 1. ACOs that would like an opportunity to receive a greater amount of shared savings than the maximum amount available under Track 1 and are willing to share losses, if any are incurred, can choose Track 2.

The elimination of "downside risk" for Track 1 ACOs during the initial agreement term will likely permit ACO Participants to gradually ramp up their care management infrastructure over time. Although ACOs participating in Track 1 will not bear shared-loss risk during the initial agreement term, CMS states in the preamble to the Final Rule that all ACOs must participate in the Track 2 model in subsequent agreement periods.

The Final Rule defines "savings" as the difference between (1) actual Parts A and B spending during the relevant time period, and (2) CMS's predetermined spending "benchmark" for the particular ACO that exceeds the minimum

savings rate threshold. The benchmark is risk adjusted, based on historical expenditures attributable to the ACO's assigned beneficiaries. Notably, whereas the Proposed Rule based the risk-adjusted benchmark on historical expenditure data for assigned beneficiaries, under the Final Rule, CMS will restate the risk-adjusted benchmark for each performance year, based on risk-adjusted severity and case-mix scores for assigned beneficiaries. This is extremely significant insofar as it permits ACOs to receive appropriate benchmark consideration of the complexity of their patients even when that complexity has not previously been captured in the risk calculations.

By removing the requirement that all ACOs be exposed to "shared losses," CMS has increased the attractiveness of the Program to potential ACOs that are less experienced in non-FFS payment methodologies. Of course, providers will still need to evaluate the costs associated with participating in the Program, including the opportunity cost of precluding participation in other CMS/CMMI proposals by virtue of joining the Program.

Shawn Gilman

Generally, the Final Rule tracks the Proposed Rule's methodology for calculating shared savings. However, certain variables have been adjusted, such as the shared savings cap, the shared losses cap under Track 2, and the maximum percentage of shared savings. In many cases, these changes may enable ACO Participants to receive a greater share of savings under both Track 1 and Track 2.

Track 1

According to the Final Rule, a Track 1 ACO, depending on its quality scores discussed below, is eligible to share up to 50 percent of the savings it achieves. However, the total amount that a Track 1 ACO will receive under the formula is limited to 10 percent of the ACO's benchmark. The required minimum savings rate for a Track 1 ACO varies between 2 percent and 3.9 percent, depending on the number of Medicare beneficiaries assigned to the ACO, with a lower level of Medicare beneficiaries correlating with a higher minimum savings rate (*e.g.*, an ACO with 5,000 Medicare beneficiaries will have a minimum savings rate of 3.9 percent, and an ACO with 60,000+ Medicare beneficiaries will have a minimum savings rate of 2 percent).

Similar to the methodology used for calculating shared savings for Track 2 ACOs under the Proposed Rule, for Track 1 ACOs, the Final Rule converts the minimum savings rate from a deductible to a "basket" that, once filled, permits first-dollar savings to be subject to the shared savings formula.

Track 2

According to the Final Rule, the required minimum savings rate for all Track 2 ACOs is 2 percent. Assuming that this basket/prerequisite has been satisfied, Track 2 ACOs can share, on a first-dollar basis, up to 60 percent of the savings they achieve, although the payment earned can be reduced under the quality metrics discussed below and it cannot exceed 15 percent of the benchmark. Track 2 ACOs do bear downside risk – carrying exposure of up to 60 percent of the losses, provided that the share does not exceed 5 percent of the benchmark in year one, 7.5 percent in year two, and 10 percent in year three. Consequently, Track 2 ACOs must demonstrate their ability to share in losses by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, or establishing a line of credit as evidenced by a letter of credit that CMS can draw upon.

Under the Final Rule, CMS will not withhold 25 percent of shared savings payments in order to help ensure repayment of future losses. However, the Final Rule requires Track 2 ACOs to fully repay any shared losses to CMS within 90 days of being notified.

Comparison of Shared Savings Methodology in Proposed and Final Rules

Variable	Risk Model	Proposed	Final
Maximum Percentage of Shared Savings	Track 1	52.5%*	50%
	Track 2	65%*	60%
Minimum Savings Rate	Track 1	2.0-3.9%	2.0-3.9%
	Track 2	2%	2%
Shared Savings Cap (payment limit)	Track 1	7.5%	10%
	Track 2	10%	15%
Shared Losses Cap (loss limit)	Track 1	5% (year 3)	N/A
	Track 2	5% in year 1 7.5% in year 2 10% in year 3	5% in year 1 7.5% in year 2 10% in year 3

*The maximum percentage would be 50% and 60%, excluding incentives for FQHC/RHC participation.

Quality Measures

Quality-measure reporting and performance attainment are important components of CMS's oversight of ACO Participants. To share in any savings generated through the Program, an ACO must satisfy certain quality performance standards.

In response to concerns that the Proposed Rule imposed on providers an unmanageable number of quality measures for evaluating performance and calculating shared savings, CMS reduced the number of measures from 65 to 33 and the number of quality domains from five to four in the Final Rule. The four quality domains include patient/caregiver experience care, coordination/patient safety, preventive health, and at-risk population.

In the Proposed Rule, CMS suggested moving ACO Participants from "pay for reporting" in the first performance year to "pay for performance" in subsequent years. While the Final Rule maintains this same structure, payment based on achieving minimum attainment levels will be phased in during the second and third performance years. Eligibility for shared savings in year two will depend on achieving minimum attainment levels for 25 measures and the reporting of the additional measures. By year three, eligibility will be based on achieving minimum attainment levels for 32 measures and the reporting of one additional measure.

To assist in the reporting of quality data to CMS and to spur the adoption of electronic health records ("EHRs"), CMS had proposed a requirement that at least 50 percent of an ACO's primary care physicians be "meaningful users" of EHRs by the start of the second performance year of the three-year agreement. However, CMS acknowledges in the Final Rule that the 50-percent meaningful use requirement may be a roadblock to participation and eliminated this requirement. Nonetheless, to emphasize the importance of EHR adoption, CMS has adopted one structural measure related to EHR incentive program participation and is requiring that this measure be double weighted for purposes of scoring and determining an ACO's performance.

To strike a balance between maintaining high performance standards and setting feasible attainment goals, CMS has also modified the Program so that ACOs only need to achieve the minimum attainment level on 70 percent of the measures in each domain. This brings another level of comfort to providers that are worried that savings earned

could be compromised by the arbitrary application of these metrics. However, to illustrate the importance of the double weight applied to the EHR measure, if an ACO fails to completely and accurately report the EHR measure, the ACO would miss the 70-percent cutoff for the care coordination domain and, thus, would not be eligible to share in savings.

Data Sharing

In the Final Rule, CMS stated that it will share Medicare beneficiary claims data with an ACO upon request to assist the ACO with managing population health, coordinating care, and improving the quality and efficiency of care. It was proposed that the ACO would not receive the data in patient identifiable form until the beneficiary had been seen by a primary care ACO Participant during the performance year, was informed about how the ACO intended to utilize the data, and had an opportunity to opt out of such use.

Successful population health management depends on early identification of "frequent flyers," the inappropriate use of ERs, and avoidable inpatient stays. The Proposed Rule erred on the side of maximum advanced notice to beneficiaries, threatening to derail these important initiatives. Although "details will follow," this change goes in the right direction.

Mark Lutes

Given the centrality of advance data analysis and care management to address the utilization of data relating to complex patients and patients suffering from chronic conditions, many thought that this methodology posed a serious barrier to the timely application of lower-cost care paths for these beneficiaries. In the Final Rule, CMS has modified the data-sharing proposal to allow the ACO to contact beneficiaries before they are seen by an ACO Participant during the performance year, using the quarterly list of beneficiaries likely to be assigned to the ACO provided by CMS. However, CMS preserves the beneficiaries' ability to opt out of data sharing. Beneficiaries have 30 days to decline data sharing and must be given the opportunity again during the next face-to-face encounter to decline to have their claims data shared with the ACO.

Antitrust

On October 20, 2011, the FTC and DOJ jointly released a final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program ("Final Statement"). Consistent with the proposed statement issued in April 2011 by the FTC and DOJ ("Proposed Statement"), the Final Statement accords a presumptive "rule of reason" treatment to the concerted action of provider groups that are "eligible and intend or have been approved to participate" in the Program.[2]

Notably, in a significant departure from the Proposed Statement, the FTC and DOJ are no longer requiring ACOs in which two or more independent participants have a collective market of greater than 50 percent for shared services to request an antitrust review. The FTC and DOJ will, of course, monitor the competitive effects of ACOs using aggregate claims data provided by CMS, but they will not introduce a "clearance" requirement into the ACO application process. The decision to remove the clearance requirement eliminates a significant administrative burden that many believed would discourage participation in the Program.

Patricia Wagner

Organizations operating an accountable care venture outside the context of the Program will want to be aware of the conduct that antitrust enforcement agencies note could raise competitive concerns, particularly if the venture has a significant market share.

2 Additional information relating to the Antirust Policy Statement is available on the FTC website at: http://www.ftc.gov/opp/aco/.

Providers should note that the analysis for determining whether one is within the safety zone is not a traditional market share analysis or simply an analysis based on the number of providers in the area. Determining whether an ACO falls within the safety zone will require the application of an alternative method for calculating market share that is based on the "Primary Service Area" of each ACO Participant.

Ross Friedberg

Consistent with the Proposed Statement, the Final Statement also provides a safety zone for certain ACOs if they meet the standards required by CMS and their independent participants do not have a collective market share for shared services of greater than 30 percent. The market share determination must be made whenever two or more independent participants have a shared service, and the assessment must take into account the Primary Service Area of each of those participants.

Moreover, the Final Statement provides guidance for those ACOs in which two or more independent participants have a collective market share of greater than 30 percent for shared services. Five types of conduct that "may raise competitive concerns" are identified, including the improper sharing of competitively sensitive information and conduct that does or could "prevent private payers from obtaining lower prices or better quality services for their enrollees," such as the tying of an ACO's services to the private payer's purchase of other services from providers outside the ACO. Finally, for an ACO to be within the safety zone, the Final Statement requires all hospitals and ambulatory surgery centers to be non-exclusive and requires any dominant provider (any provider with a greater than a 50-percent market share in its Primary Service Area) to be non-exclusive.

Fraud and Abuse

It is a huge step that the Department of Health and Human Services has decided that waivers are necessary to carry out the Program. Until now, there was no certainty that the provider community would not have to fend for itself through the quagmire of the fraud and abuse laws in ACO development and operation. Nevertheless, the waivers still require some tweaking if they are going to be useful to those establishing ACOs.

Carrie Valiant

Also on October 20, CMS and OIG issued an Interim Final Rule with comment period that establishes five waivers of application of the Physician Self-Referral Law ("Stark Law"), the federal anti-kickback statute ("Anti-Kickback Statute"), the civil monetary penalty ("CMP") provisions prohibiting hospital payments to physicians to reduce or limit services (the "Gainsharing CMP"), and the CMP law prohibiting inducements to beneficiaries (the "Beneficiary Inducements CMP") involving ACOs under the Program, including ACOs participating in the Advance Payment ACO Model to be administered by CMMI. However, CMS and OIG specifically note that these waivers do not apply to other demonstration programs sponsored by CMMI (*e.g.*, Pioneer ACOs); instead, any waivers required under these programs will be addressed separately. [3]

As previously noted, CMS and OIG are issuing the waivers as an "Interim Final Rule with comment period." The public will have 60 days from the date of publication in the *Federal Register* to submit comments. Although the Social Security Act generally requires that at least 30 days pass before a final rule become effective after the issuance or publication of the rule, the Secretary of the Department of Health and Human Services ("HHS") proposes to waive the 30-day delayed effective date on the grounds that such as delay would be contrary to public interest. In the preamble to the Interim Final Rule with comment period, CMS and OIG reference that, in connection with the Proposed Rule, a number of commenters stated that ACO applicants would "forego applying until final waivers have become effective and sufficient time has elapsed to allow the applicants to use the waivers in a manner that would support their applications and the purposes of the program." In light of those comments, the Secretary of the HHS (through these agencies) stated that "a 30-day delay in the effective date for the final waivers could jeopardize an ACO's ability to submit timely an application for a participation agreement commencing in 2012."

3 Additional information relating to the Interim Final Rule with comment period is available on the OIG website at http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp.

In the Proposed Rule, CMS and OIG proposed *two* specific waivers. In the Interim Final Rule with comment period, these agencies have developed *five* distinct waivers addressing different circumstances:

1. An "ACO pre-participation" waiver of the Stark Law, the Anti-Kickback Statute, and the Gainsharing CMP: applies to ACO-related start-up arrangements in anticipation of participating in the Program, subject to certain limitations, including limits on the duration of the waiver and the types of parties covered;
2. An "ACO participation" waiver of the Stark Law, the Anti-Kickback Statute, and the Gainsharing CMP: applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the Program and for a specified time thereafter;
3. A "shared savings distributions" waiver of the Stark Law, Anti-Kickback Statute, and Gainsharing CMP: applies to distributions and uses of shared savings payments earned under the Program;
4. A "compliance with the Physician Self-Referral Law" waiver of the Gainsharing CMP and the Anti-Kickback Statute: applies to ACO arrangements that implicate the Stark Law and meet an existing exception; and
5. A "patient incentive" waiver of the Beneficiary Inducements CMP and the Anti-Kickback Statute: applies to medically related incentives offered by ACOs under the Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

While the pre-participation waiver is seen as an important step toward facilitating ACO development, the agencies will need to expand its scope in order to take into account ACO structures that were created prior to this issuance and may not have been documented "contemporaneously" with the particularity required to qualify for the waiver. In addition, it will be difficult for many to qualify for this waiver because, not only must the parties to the arrangement include the ACO itself, but the ACO's governing body must have already made (and duly authorized) a determination that the arrangement is reasonably related to the purposes of the Program. These organizational requirements ignore the realities that startup ACOs may need time to organize corporately and determine a precise governance

David Matyas

The agencies should be commended for having seriously considered the comments that were provided and for expanding not only the scope of the waivers to include the Beneficiary Inducements CMP but also the parties to which these waivers would apply. Instead of simply addressing the waivers in terms of physicians and hospitals, the agencies recognized that, in order to be successful, ACOs will need to also include (and hence the waivers will need to apply to) a broad array of entities in the health care industry, such as drug and device manufacturers, distributors, durable medical equipment suppliers, home health agencies, etc.

Continuing on the general theme of greater transparency in health care, two of the key waivers (the ACO pre-participation waiver and the ACO participation waiver) include arrangement disclosure requirements. While the government is not requiring the disclosure of the financial or economic terms of the arrangement, these disclosure requirements could have a chilling effect on those considering these waivers, as the information is disclosed not only to the government but also to the public. The government has indicated that guidance on the time, place, and manner of the arrangement disclosure is forthcoming. As such, interested parties should provide comments on these disclosure requirements.

Jason Caron

While the waivers are described as "self-implementing," they are not so easily implemented, in that they require a level of contemporaneous documentation and recordkeeping that was not even hinted at in HHS's waiver proposal. Moreover, they require public disclosure of a description of each arrangement for which waiver protection is sought, as well as a statement to HHS if the ACO is ultimately abandoned, which may prove to be a substantial hurdle to taking advantage of the waivers as potential ACO developers should not be forced to choose between obtaining a necessary waiver and revealing sensitive information that should be irrelevant to qualifying for the waiver. **– Carrie Valiant**

structure while, at the same time, the parties (hospital, physicians, etc.) may be moving forward with such things as infrastructure improvements and care process design that will later be folded into the ACO as in-kind contributions.

These waivers have been developed and promulgated as an Interim Final Rule – not merely as "guidance." As such, it is unclear whether, from an APA perspective, publishing them in the preamble section of the Federal Register *and posting them on the agencies' websites will be sufficient without actually being published in a specific section in the* Code of Federal Regulations. **– David Matyas**

In contrast to the issuance of most final rules (including interim final rules) in which the text of the actual rule is defined as being located in a particular section of the *Code of Federal Regulations*, CMS and OIG stated in the preamble to the Interim Final Rule with comment period that the text of the waivers will simply be included in the *Federal Register* and posted on the agencies' websites, but not actually be codified into the regulations. The agencies requested comments from the public on this approach:

> For ease of reference, the entire set of waivers and applicable requirements is set forth in section IV.B. of this [Interim Final Rule with comment period]. We will also make the waiver text available on both the CMS and OIG Web sites. Because the waivers cover multiple legal authorities and to ensure that the waivers, if modified, remain consistent over time and across relevant laws, we are not codifying the waivers in the *Code of Federal Regulations*. We solicit comments about this approach.

Tax-Exempt Organization Issues

The IRS also released on October 20, 2011, a fact sheet (FS-2011-11) updating and clarifying its initial analysis in Notice 2011-20 regarding the participation by Section 501(c)(3) tax-exempt organizations in the Program through an ACO. The fact sheet provides clarification of some of the guidance in Notice 2011-20, which should give tax-exempt organizations enhanced comfort when participating in ACOs.

Importantly, the fact sheet clarifies that the list of factors from Notice 2011-20 that the IRS provided as demonstrating that a tax-exempt organization's participation in an ACO does not result in private inurement or private benefit is disjunctive, and that "no particular factor must be satisfied in all circumstances to prevent inurement or impermissible private benefit." The IRS reiterated that whether impermissible inurement or private benefit occurred will depend on the entirety of facts and circumstances and that strict or literal compliance with the factors is not always required.

The fact sheet is particularly valuable in that it demonstrates that the IRS will be reasonably flexible in applying tax restrictions to Section 501(c)(3) organizations participating in an ACO. With this greater flexibility, however, comes a degree of uncertainty. Although given the degree of regulatory oversight coming from other agencies and the familiarity most organizations already have with inurement and private benefit issues, the amount of risk and uncertainty created by the fact sheet should not be overstated.

In one sense, the IRS should be applauded for the restraint it shows. By allowing the existing principles and rules to dictate the analysis, the IRS is allowing for creativity and avoiding the creation of an intricate web of regulatory requirements. On the other hand, the lack of clear guidance creates some risk that organizations may not feel comfortable accepting.

Dale Van Demark

One of the critical issues raised by Notice 2011-20 is whether tax-exempt organizations participating in an ACO through a joint venture would risk their exempt status or expose themselves to potential liability for unrelated business income tax. In fact, the IRS requested comments on whether additional guidance should be provided as to whether non-Program activities of a joint venture ACO would jeopardize a tax-exempt organization's exempt mission or result in unrelated

business income tax. While the fact sheet does not propose a definitive answer, it provides what could be critical guidance.

Health care providers forming ACOs should take some comfort in this additional guidance, as it demonstrates that the IRS is open to recognizing the many ways an ACO may further a tax-exempt purpose. **– Dale Van Demark**

As a general rule, Section 501(c)(3) organizations may incur unrelated business income tax and potentially jeopardize their tax-exempt status by engaging in activities that are not considered "related" to their tax-exempt charitable mission. In Notice 2011-20, the IRS indicated that joint venture ACO participation in Medicaid shared savings programs could be seen as furthering the charitable purpose of relieving the poor and distressed or the underprivileged, thus not jeopardizing the exemption of a tax-exempt participant or creating the risk of unrelated business taxable income. The example provided – Medicaid Shared Savings Program participation – is quite narrow.

In the fact sheet, the IRS expands this example, noting that "an ACO's activities related to serving Medicaid or indigent populations might further the charitable purpose of relieving the poor and distressed or the underprivileged." This expansion of what the IRS could consider as activity furthering an exempt purpose should provide comfort to tax-exempt organizations. Although existing rules and principles regarding joint venture participation still apply, the IRS's recognition that a broader array of activities could be considered to further the exempt purposes of a tax-exempt participant demonstrates that the IRS will not impose an overly narrow interpretive context for ACO participation.

Advance Payment ACO Model

With the Final Rule, CMMI announced the testing of an "Advance Payment ACO Model," an initiative to provide selected participants in the Program with advance payments to invest in the infrastructure necessary for ACO operations.

This model is available to two types of organizations: (1) ACOs that do not include any inpatient facilities and have less than $50 million in total annual revenue, and (2) ACOs in which the only inpatient facilities are Critical Access Hospitals and/or Medicare low-volume rural hospitals and have less than $80 million in total annual revenue. ACOs that are co-owned with a health plan are ineligible for participation in the model.

Participants in the model will receive three types of payment: (1) an up-front, fixed payment; (2) an up-front, variable payment based on the number of historically assigned beneficiaries; and (3) a monthly payment based on the number of historically assigned beneficiaries. CMS will recoup the advance payments from the shared savings earned by the ACO. Applications to participate in the model will be made available shortly and are due with the Program application.

This model begins to address the barriers to participation by providers, many of whom face difficult choices in their allocation of capital.

Conclusion

Compared to the Proposed Rule, the Final Rule provides more flexibility and fewer obstacles for organizations interested in exploring shared savings. For interested organizations, this may be a good opportunity to look at redesigning care delivery systems and forming partnerships with other providers in order to share in savings achieved from these care coordination efforts. However, participation in the Program should be evaluated alongside the other accountable care opportunities currently available through CMMI. While some providers may already have the care management capabilities to succeed under the Program in 2012, others may want to consider taking a stepwise approach by first participating in accountable care initiatives through CMMI or with commercial payers that will not require as significant an up-front investment of time, resources, and capital, but will allow for the transition to a more value-based provider model.

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Join Epstein Becker Green, KPMG, and JHD Group on Nov. 9 for a joint webinar:

Healthcare Transformation Accelerates: What Could the MSSP and Other Value-Based Purchasing Initiatives Mean for Your Organization?

Epstein Becker Green, KPMG Healthcare, and the JHD Group invite you to join the fourth webcast in a series that will explore the new regulations and the broader implications of moving toward payment systems that reward enhancements to quality, cost, and access.

The 120-minute session, which will dedicate 30 minutes to Q&A, will focus on how organizations can begin to connect the dots from the final MSSP rule to accountable care organizations, the increasing movement across the industry to new quality and cost-based payment models, and the regulations' strategic and operational implications for care delivery systems.

Wednesday, November 9, 2011
1:00 pm - 3:00 pm EDT

*For those interested, please click **here** to register.*

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