Accountable Care NEWS

THE ACO MEDICARE SHARED SAVINGS PROGRAM FINAL RULE

Analysis of Key Changes from the Proposed Rule

By Epstein Becker & Green, PC

1. Context

On October 20, 2011, the Centers for Medicare & Medicaid Services ("CMS") released its Final Rule implementing the voluntary Medicare Shared Savings Program ("Program") for accountable care organizations ("ACOs"), pursuant to Section 3022 of the Patient Protection and Affordable Care Act ("ACA"). The Final Rule was released in conjunction with revised guidance from the antitrust enforcement agencies, the Department of Health and Human Services' Office of Inspector General ("OIG"), and the Internal Revenue Service (collectively the "Agencies"), as part of an inter-agency effort to facilitate participation in the Program.

The Program encourages the formation and operation of ACOs by promising to share Medicare's savings from the program with those ACOs that: (1) meet eligibility requirements; and (2) meet the quality performance and Medicare cost savings targets described in the Final Rule.

continued on page 2

In This Issue

Commentary from National Thought Leaders on the Final ACO Shared Savings Rule

Wes Champion, Senior Vice President
Premier Performance Partners
Premier Healthcare Alliance, Charlotte, NC

"The Premier healthcare alliance supports CMS in its efforts to develop people-centered, sensible regulations for ACOs. Based on our experience in accountable care, we are extremely pleased with many of the provisions such as a no-risk option, first dollar savings, waiving the EHR requirements for participation and a phase-in approach for quality measures. We commend CMS for relaxing many of the excessively prescriptive requirements for management and governance, but look forward to working with them to resolve some of the outstanding issues. CMS' decision to limit its savings split with providers, though, could be seen as a barrier to participation by some, as shared savings payments are critical to transform care delivery. We're also glad beneficiaries are required to be made aware of their ACO participation but are troubled that the agency chose to allow them to opt-out of sharing the data.

Ultimately, this new model of care delivery represents one of our best hopes for overcoming fragmentation. We believe that forming ACOs will achieve greater clinical integration and collaboration among doctors, hospitals and other care providers, as well as foster alignment of accountable care principles across public and private payors. The result will be better, safer and more convenient care delivered at a lower cost for the benefit of America."

continued on page 3

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Editor's Corner

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We owe a special vote of thanks to Doug Hastings, Mark Lutes and the following members of the team at Epstein Becker & Green, PC who produced this excellent analysis of the ACO rule for *Accountable Care News* on short notice:

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Analysis of the ACO Rule *continued from page 1*

As compared to the March 11 original proposal (the "Proposed Rule") and other agency statements at the time, the burden of the Program's requirements has been reduced, the savings incentives appear to be more attractive, and the clearance obstacles are fewer. Of course, providers will still need to evaluate the merits of the Program relative to other opportunities for value-based contracting with the CMS Innovation Center ("CMMI") and commercial payers.

2. Eligibility to Form an ACO

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. ACO professionals are physicians, nurse practitioners, physician assistants, and clinical nurse specialists.

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. Under the Final Rule any Medicare enrolled entities that are not specified as being eligible for the Program can participate through an ACO formed by those described above. The Final Rule also provides 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.

3. Governance

The proposed rule required the ACO to be a legal entity capable of receiving and distributing shared savings, repaying shared losses, and reporting quality performance data. The governing body was required to be composed of ACO provider/supplier participants ("ACO Participants") or their designees who would have at least a 75-percent control of the governing body. The governing body of the ACO was required to include Medicare beneficiary representation. If the ACO is composed 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 provides an exception to the requirements that ACO Participants have at least 75% control of the ACO's governing body and beneficiary representation on the governing body. To qualify for this exception, the ACO must explain why it is not meeting the 75% 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 in the Final Rule.

continued on page 6

Commentary from National Thought Leaders (continued)

"AMCs Welcome, Challenged By New ACO Regulations.

The new CMS regulations for ACOs change the game in many ways, and significantly raise the stakes for Academic Medical Centers (AMCs). Many AMCs do not have large Primary Care Provider (PCP) networks. Most AMCs do not have experience managing population risk, whether professional or global capitation.

For AMCs and for community hospital systems, the original regulations posed too high a hurdle. As relatively few community systems stepped forward, AMCs could duck the question: should AMCs form full ACOs on their own, taking risk for primary care through tertiary and quaternary, or merely serve as a partner to other ACOs? In response to the new regulations, we can expect more community hospital systems to form ACOs – and that AMCs will quickly have to decide on their future role.

We believe that serving as the name brand "advanced specialty care" provider for multiple ACOs will not be enough to sustain AMCs in the long term. Our experience in Southern California suggests that mature provider-based risk-bearing organizations – such as Kaiser Permanente and Healthcare Partners– shift their referral patterns in search of value. That means either purchasing advanced specialty care as a commodity (from whichever system can offer the best quality at an acceptable price), or bringing many tertiary care procedures in-house.

Instead, we believe that our best course, and perhaps that for some other AMCs, will be to embrace the ACO strategy for ourselves and develop long-term partnerships with other ACOs in which we must offer radically improved quality, service for patients and referring systems, and cost… Not an easy task, but the only way forward."

Molly Joel Coye, MD, MPH
Chief Innovation Officer, UCLA Health System
University of California, Los Angeles
Los Angeles, CA

"The Medicare Shared Savings Program (MSSP) ACO regulations restore ones faith in responsive government and democracy. Let's face it, the proposed regulations were tone deaf to the health care community's aspirations for a transformation roadmap that was feasible and viable from a hardnosed business perspective. With the release of the MSSP ACO regulations, the leadership of CMS (and HHS and the White House) demonstrated that they heard the ACO community's many substantial concerns -- and the Administration addressed virtually every criticism with a thoughtful and constructive response.

Now comes the hard part. Having been given a policy blue print that delivers incentives for the construction of collaborative, accountable, and efficient ACOs, will providers step up? Can they deliver the goods? Can they prove the ACO business care? Will CMS revert to its role as regulator, or will it stretch to be a partner in transition, particularly in those parts of the country where coordination, accountability and efficiency are seemingly new ideas?

I'm an inveterate optimist. I think ACOs will coalesce, will drive systemic behavioral change, and will deliver better care to patients and support those who need support. As has been seen time and again, for providers who were trained in, practiced in, and only knew uncoordinated care, moving into a truly coordinated, accountable and supported care delivery system is a revelation."

While successful ACOs may present a new market competitor to some health plans, others will be new market partners. Health plans will build successful relationships with ACOs, offering back-office and management services and even engaging ACOs as part of the plan's network for commercial and Medicare Advantage enrollees.

We're at the beginning of the beginning. Now lets prove that the journey is worth it."

Bruce Merlin Fried, Esq.
Partner, Health Care and Public Law & Policy Strategies
Sonnenschien Nath & Rosenthal LLP
Washington, DC

continued on page 4

Commentary from National Thought Leaders (continued)

"Although not legally a demonstration, the ACO shared savings program plays that role substantively -- trying out a mechanism to pay providers that departs from fee for service but is well short of capitation. So getting the right level of provider participation is essential -- too few providers and little will be learned, while too many providers suggests that the model is not demanding enough of substantive change. CMS has to balance getting the right level of provider participation with maintaining consumer protections and protecting taxpayers.

Clearly, April's proposed rule misfired because providers were repelled by it. CMS appears to have listened carefully and pulled back many of the provisions that bothered providers the most. The key changes are reduction in the number of quality measures, sharing more of the savings with providers, offering a true one-sided model and providing more timely data to providers on which beneficiaries are likely to be attributed to the ACO. The strong provider reaction to the proposed rule was probably helpful to CMS in getting a more balanced model out of the political environment that it must operate in. But whether CMS has truly succeeded in rescuing the centerpiece of the Administration's cost containment will depend on whether it gets the desired number of participating organizations."

Paul B. Ginsburg, PhD
President
Center for Studying Health System Change
Washington, DC

"Most of the major provider groups that make up the health-care economy reacted with enthusiasm to the revised regulations that will guide implementation of the Obama administration's initiative to improve care coordination in the Medicare program through newly created accountable care organizations (ACOs). But when the Centers for Medicare and Medicaid Services estimated that only 50 to 270 organizations are expected to apply for ACO status over the next three years with estimated savings of $940 million, I had to wonder whether the pace of progress would be rapid enough to satisfy political pressures to significantly slow the growth of that popular program.

ACOs are one of the few provisions in the Accountable Care Act (ACA) that are supported by both political parties, but they could well part company on this new delivery model once Republicans begin to examine the 696-page regulation and its many dictates to providers. Lastly, the capacity of CMS to administer not only the ACO initiative but countless other provisions of the ACA is certainly a question mark. The agency has increased its contracts with outside organizations to bolster its administrative capacity, but even that may not give it enough management prowess. One of the major outside groups is RTI, a consulting firm based in the Research Triangle of North Carolina, which has been handed major responsibility to assist the Medicare agency."

John Iglehart
Founding Editor, *Health Affairs*
National Correspondent, *New England Journal of Medicine*
Washington, DC

"CMS's Final Rule recognizes many of the attributes of new care delivery models that will help to address the cost, quality and access challenges within our nation's health care system. A majority of those attributes -- including those related to care coordination, patient engagement, access to information by all members of the care team, including the patient, and measurement and accountability -- will require smart investment in a robust health information technology (IT) infrastructure to be successful.

Leveraging provider investments in electronic health records and 'meaningful use' will assist in bringing patient information and evidence-based medicine to the point of care and assuring the electronic capture of much of the information necessary to improve quality and reduce costs. New models of care will also require a data-rich environment enabled by access to and analysis of information -- while effectively managing privacy and security -- from across a range of settings, including hospitals, physician offices, pharmacies, laboratories, health plans and patients. New payment models, such as those outlined in the Rule, combined with policies that build trust in the use of electronic health information, will drive both innovation and much-needed progress in mobilizing information to support significant improvements in the quality, safety and cost-effectiveness of care.

Janet M. Marchibroda
Chair, Health Information Technology Initiative, Bipartisan Policy Center
Executive Director, Doctors Helping Doctors Transform Health Care
Washington, DC

continued on page 5

Commentary from National Thought Leaders (continued)

"Our firm submitted comments on three topics in response to the Accountable Care Organization (ACO) Proposed Draft Regulations. In our initial but not complete review of the newly released regulations, CMS has addressed each topic and modified their position in many ways to improve the program. These three topics are:

(1) The need to include more opportunities for more physicians to participate in an ACO. This is improved in many ways in the final regulations. One example is that the beneficiary assignment to an ACO now includes the services of specialists acting as primary care physicians for patients who do not currently see a primary care physician.

(2) In the proposed regulations, we compared CMS's estimate of $1.7 Million start up costs for an ACO with 5,000 Medicare patients to local part A and B rates, which represent approximately 3% of claim costs. We provided evidence that a more likely start up and annual administrative cost would be 8% for the first 5,000 beneficiaries, and the 7.5% maximum shared savings would never be adequate. In the new rules, CMS has increased the maximum shared savings with the ACO to a more acceptable 10% for the one sided risk model, and 15% for the two sided risk.

(3) Our third comment was about the scope of quality measures and whether an ACO's quality was also measured for care provided to their beneficiaries by non ACO providers. The number of measures has been reduced to a more manageable set. However, CMS confirmed on page 262 that 'ACOs will be accountable for all care received by their beneficiary population, quality measures will reflect the care assigned beneficiaries receive from ACO providers and non ACO providers.'

Our conclusion is that CMS did listen to the issues raised and has come up with revised rules that will encourage a significant portion of physicians and other providers to seek opportunities to participate in Accountable Care. "

Paul Katz
CEO
Intelligent Healthcare
Santa Monica, CA

continued on page 6

Commentary from National Thought Leaders (continued)

"The final Medicare Shared Savings Program Accountable Care Organization (ACO) regulations provide a better opportunity for organizations to succeed and manage their assigned population through the relaxed criteria. There are three significant areas that will positively affect organizations: care coordination, requirements around meaningful use and reliance on electronic health technology.

The most significant changes in the final ACO regulations are around the measures for establishing quality performance scoring. The final regulations move from 65 proposed measures to 33 final measures. They also limit the requirement around advanced care coordination across the patient's care continuum. Initially, this was a major concern of many organizations since creating an advanced integrated technical infrastructure was very expensive, and in some cases cost prohibitive to organizations.

The final regulations appear to create a nice balance between driving care coordination around patient quality outcomes to reduce costs, and not overburdening organizations with significant new infrastructure investments."

Daniel J. Marino
President and CEO
Health Directions
Oakbrook Terrace, IL

"There's no question that the future direction of health care is toward a more integrated, coordinated delivery system that provides the right care in the right setting. Many hospitals and doctors are already partnering with commercial payers to move down that path; CMS has now provided a viable option for moving the Medicare business in that direction as well. The combination of first-dollar shared savings, streamlined quality standards, and an upside-only participation track will likely gain the interest of a significant number of hospitals across the country. Not that becoming an ACO will be easy; to succeed, hospitals will need to create tight physician alignment, invest in powerful analytical tools that allow them to harness the power of clinical IT, and transform the way care is delivered to patients suffering from chronic disease. Those building blocks will be critical to thriving across the coming decade in any scenario; the final ACO rule gives hospitals and doctors a new economic logic to invest in them."

Chas Roades
Chief Research Officer
The Advisory Board Company
Washington, DC

The Final ACO rule—A Major Improvement…

After the proposed rule burst the bubble of enthusiasm for ACO's, the Administration has released a final rule that should reignite some of the earlier enthusiasm. Among the many changes in the 600+ page rule, four that I regard as among the most important are that:

1) ACO's will not be required to take down-side risk in year 3 but those that do will be able to share more of the savings than those that only agree to share savings
2) Beneficiaries won't be assigned retrospectively; instead they will be assigned quarterly with an end of year reconciliation
3) The required quality metrics to be reported are reduced from approx 65 to approx 35, and
4) Savings for those that exceed the threshold will begin with the first dollar of savings

Whether many of the groups that had talked about becoming ACOs will actually apply as a result of the newly released rule and if they do, whether they will end up saving money is another issue, but now there is at least a possibility that ACOs could become a serious component of delivery system reform.

Gail Wilensky, PhD
Senior Fellow
Project Hope
Bethesda, MD

Analysis of the ACO Rule *...continued*

4. Assignment & Qualification Criteria

To qualify as an ACO, the ACO must have a strong primary care base and 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 any other entity outside the ACO. Medicare beneficiaries are "assigned" to an ACO at the end of the reporting year (i.e., retrospectively.)

Although the actual assignment of beneficiaries will be retrospective for purposes of calculating the savings, CMS will now provide the ACO with quarterly reports, beginning with a report at the start of a performance year, listing the names, dates of birth, sex, and Medicare identifier for beneficiaries who are on track to be assigned to the ACO based on the most recent data available. Whereas the Proposed Rule only recognized primary care services provided by 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.

ACO participants that perform primary care services for an ACO and provide the basis for assigning beneficiaries to the ACO cannot perform primary care services as part of any other ACO.

The Final Rule only applies this restriction at the level of the ACO Participant (i.e., the entity with a Medicare enrolled tax identification number ("TIN")) thus allowing individuals to perform services in other ACOs under different TINs.

5. Application Timeline & Agreement Term

Applications will be accepted beginning in January. Program agreements have a minimum term of 3 years. April 1, 2012 (term of the agreement is 3 years and 9 months) and July 1, 2012 (term of the agreement is 3 years and 6 months) are the available start dates for participation in the first performance year.

For agreements beginning on April 1, 2012 and July 1, 2012, the first performance year will be 21 months and 18 months respectively. 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 2013 and subsequent years, the start date will be January 1 and the "performance year," for purposes of calculating shared savings and scoring quality performance, will be 12 months, from January 1 to December 31.

6. Shared Savings & Shared Losses

Each ACO has 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 Final Rule has eliminated shared-loss risk from Track 1, whereas, under the Proposed Rule, Track 1 ACOs would have been responsible for shared losses beginning in year three of the agreement term.

The Final Rule defines "savings" as the difference between (1) actual Parts A and B spending during the relevant time period, and (2) the CMS 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.

The Proposed Rule based the risk adjusted benchmark on historical expenditure data for assigned beneficiaries. Under the Final Rule, CMS will re-state the risk adjustment benchmark for each performance year based on risk-adjustment 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 been previously captured in the risk calculations.

Track 1

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 2.0 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 2.0 percent).

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 share formula.

continued on page 7

Analysis of the ACO Rule *…continued*

Track 2

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% of the benchmark. Track 2 ACOs do bear "downside risk" – carrying exposure to up to 60 percent of the losses provided that that share does not exceed 5 percent of the benchmark in year 1, 7.5 percent in year 2, and 10 percent in year 3. 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.

Table 1: 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

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

7. Quality Measures

Quality measure reporting and performance attainment is an important component of CMS' oversight of ACO Participants. To share in any savings generated through the program, an ACO must satisfy certain quality performance standards.

The Final Rule reduces the number of measures from 65 to 33 and the number of quality domains from five to four. The four quality domains include: patient/caregiver experience; care coordination/patient safety; preventive health; and at-risk population.

CMS proposed to move 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 reporting of the additional measures, and by year three, eligibility will be based on achieving minimum attainment levels for 32 measures and 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.

CMS recognized in the Final Rule that the 50 percent meaningful use requirement may be a roadblock to participation and eliminated this requirement. However, 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 also has 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 worried that savings earned could be compromised by arbitrary application of these metrics. On the other hand, 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 cut-off for the care coordination domain and thus not eligible to share in savings.

continued on page 8

Analysis of the ACO Rule *…continued*

8. Data Sharing

Upon request, CMS will share Medicare beneficiary claims data 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 how the ACO intended to utilize the data, and had an opportunity to opt-out of such use.

Given the centrality of advance data analysis and care management to address the utilization of chronic and complex patients, 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. 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.

9. Overlap with Other Shared Savings Programs

So as 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 (e.g., the Independence at Home Pilot Program, Pioneer ACO Model, Medical Health Care Quality Demonstration, Multipayer Advanced Primary Care Practice, Physician Group Practice Transition Demonstration, and Care Management for High-Cost Beneficiaries Demonstrations).

Notably, providers could participate in the Bundled Payments for Care Improvement initiative coincident with the Program.

10. 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; or (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 the Model.

Participants in the Model will receive three types of payment: (1) an upfront, fixed payment; (2) an upfront, 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.

11. Antitrust

The Department of Justice and Federal Trade Commission jointly released a final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Programs ("Final Statement"). The Final Statement accords 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…"

The Final Statement also provides a safety zone to 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. Notably, the market share determination must be done whenever two or more independent participants have a shared service, and the assessment must take into account each of those participant's Primary Service Area.

Moreover, the Final Statement provides guidance to those ACOs where two or more independent participants have a collective market share of greater then 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 of 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 50-percent market share in its Primary Service Area) to be non-exclusive.

continued on page 9

Analysis of the ACO Rule *…continued*

Most significantly, the antitrust agencies 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 agencies will of course monitor the competitive effects of ACOs using aggregate claims data provided by CMS but will not introduce a "clearance" requirement into the ACO application process.

12. Fraud and abuse

CMS and OIG issued an Interim Final Rule with comment period creating five waivers related to the Physician Self-Referral Law, the Federal anti-kickback statute, and certain Civil Monetary Penalties. These include:

- An "ACO pre-participation" waiver that applies to ACO-related start-up arrangements;
- An "ACO participation" waiver that applies during the term and for a specified time thereafter;
- A "patient incentive" waiver for medically-related incentives offered by ACOs to beneficiaries to encourage preventive care and compliance with treatment regimes;
- A "shared savings distribution" waiver; and
- A "compliance with Stark Law" waiver.

The waivers are contingent on documentation and governing body approvals as well as possible "public disclosure" requirements.

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