To Participate or Not to Participate: Federal Agencies Issue Proposed Guidance on Accountable Care Organizations

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Introduction. On March 31, 2011, the U.S. Department of Health and Human Services ("HHS") issued over 400 pages of proposed regulations on the structure and operation of Accountable Care Organizations ("ACOs") under The Patient Protection and Affordable Care Act ("PPACA").[i] The proposed regulations are intended to implement Section 3022 of PPACA, which creates a Medicare shared savings program ("Shared Savings Program" or "Program") no later than January 1, 2012. Under the Program, savings from budgeted costs of health care services incurred by Part A and Part B beneficiaries assigned to an ACO will be shared by the providers who participate in the ACO and coordinate that care. As one of the tools under PPACA designed to eliminate the fragmentation that exists in our health care system, ACOs will coordinate treatment of patients across the continuum of care settings, including physician practices, hospitals, skilled nursing facilities, long term care hospitals, and other providers and suppliers of Medicare-covered services.

While the economic advantages to a provider of establishing or participating in an ACO for Medicare beneficiaries may be limited due to, among other things, Medicare funding limitations and an inability to achieve quality and savings benchmarks, it is expected that providers will seek to extend the concept to commercial carriers and self-insured plans, where the economic incentives may prove more substantial. In addition, even if PPACA is ultimately found to be unconstitutional in whole or in part, it is likely that the private sector will continue to explore this integrated ACO model. Further, the ACO and its shared payment concept are not among the provisions of the PPACA that are distasteful to most of its detractors, so similar federal legislation (without the individual mandate) could well follow. The proposed regulations will be published in the April 7, 2011 *Federal Register*, and comments are due by June 6, 2011.[ii]

Basic Requirements. To qualify as an ACO under Medicare, providers must form or join an ACO and file an application with the Centers for Medicare and Medicaid Services ("CMS").[iii] The ACO must have a legal status that will permit the shared savings to be paid to the participating providers and requires a shared governance structure among the participants. If the application is approved, the ACO must sign an agreement with CMS to participate in the Shared Savings Program for three years and accept responsibility for at least 5,000 Medicare beneficiaries.

Participation in the Program is voluntary for both providers and beneficiaries. CMS proposes that Medicare beneficiaries

will be assigned to the ACO in which his or her primary care physician participates during each performance (calendar) year. A primary care physician is defined as one having a primary specialty designation of internal medicine, general practice, family practice or geriatric medicine. Primary care physician services are defined as HCPCS codes 99201-99215, 99304-99340, 99341-99350 and the codes for Welcome to Medicare and annual wellness visits (codes G0402, G0438 and G0439). If a patient has seen more than one primary care physician during a performance year, assignment will be made to the primary care physician with whom the patient has incurred the most charges for primary care services. A primary care physician as defined can participate in only one ACO, whereas other providers are able to participate in multiple ACOs. Although patient assignment is made retroactively based on a patient's actual charges incurred for primary care visits during a performance year, providers will obviously assess their initial ACO participation based on historical Medicare data.

When a beneficiary seeks services, the provider will be required to inform the beneficiary that the provider participates in an ACO. The ACO must implement a system to measure and report on various quality and cost criteria and implement a process of evidence-based medicine that is designed to accomplish cost savings and enhanced quality. Regulators estimate that the Shared Savings Program could save Medicare between $170 million and $960 million over three years.

Shared Savings. Providers in an ACO will continue to receive fee-for-service payments under Parts A and B, and will be eligible to receive additional payments if the ACO meets certain quality and savings benchmarks. Conversely, if those benchmarks are not met, the ACO could be liable for the losses. CMS will establish a benchmark of expenditures for each ACO based on the most recently available three year period, and will also establish a targeted percentage below this benchmark. In order to receive a shared savings payment, the ACO must limit its per capita expenditures to a level that is below this target percentage, **and** meet certain quality and performance standards. There are 65 quality measures that CMS proposes to use, and they encompass the following five categories: (i) patient/caregiver experience of care; (ii) care coordination; (iii) patient safety; (iv) preventive health; and (v) at-risk population/frail elderly health. An ACO that qualifies to share in savings will do so based upon a percentage of the difference between the estimated average per capita expenditure and the target expenditure.

The proposed regulations would also hold ACOs accountable to the downside by requiring repayment for a portion of its losses, *i.e.*, expenditures that exceed its benchmark. To provide flexibility for ACOs with different levels of experience and appetite for risk, CMS is proposing two different risk models. Under the first track, an ACO could operate on a shared savings basis (upside) only for the first two years and be eligible for up to 50% of savings, but would assume risk for any shared losses (downside) in the third year (up to 7.5% of expenditure benchmark). Under the second track, an ACO would share in both savings and losses starting in the first year and at higher rates (maximum of 60% of savings and 10% of expenditure benchmarks).

Related Legal Issues. Much has been written since the PPACA was enacted about the legal issues facing providers who wish to establish an ACO. Recognizing that ACOs will implicate a variety of federal laws, HHS has coordinated with several federal agencies to release three additional documents simultaneously with the issuance of the proposed regulations.

Fraud & Abuse: CMS and the HHS Office of Inspector General ("OIG") issued a joint notice with comment period detailing proposals for waiving the application of certain prohibited referrals and inducements to ACO providers under the physician self-referral law ("Stark Law"),[iv] the anti-kickback statute ("ATK Statute"),[v] and the civil monetary penalties law ("CMP Law").[vi] These laws limit the ability of providers to pay or be paid for referrals of patients or for reducing the level or quality of care provided. The proposed waivers would apply in the following three circumstances: (i) to the

distribution of shared savings payments by an ACO to its provider participants; (ii) to the distribution of shared savings payments by an ACO to other persons for activities necessary for and directly related to the ACO's participation in the Program; and (iii) for the ATK Statute and the CMP Law only, to certain financial relationships that are necessary for and directly related to the ACO's participation in the Program and that comply with an exception to the Stark Law. The joint notice will be published in the April 7 *Federal Register*, and comments are due by June 6, 2011.[vii]

Antitrust: Concurrently with the introduction of the proposed new regulations, the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") jointly issued a proposed antitrust policy statement addressing the antitrust implications of the Program, entitled "Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (the "Policy Statement").[viii] Because the antitrust laws generally limit the ability of independent providers to negotiate with payors jointly on reimbursement rates for their services, the potential antitrust issues raised by ACOs are quite significant. To address these potential concerns, the Policy Statement is designed to ensure that "providers have the antitrust clarity and guidance needed to form procompetitive ACOs that participate in both the Medicare and commercial markets." The Policy Statement will apply to collaborations (excluding mergers) formed after enactment of PPACA for the purpose of participating in the Program. As explained in the Policy Statement, the FTC and the DOJ intend to apply the "rule of reason" to an ACO's activities in the commercial market if the ACO uses the same governance leadership structure and clinical/administrative processes in that market that it uses in the Medicare market.

The Policy Statement would also establish a "safety zone" for certain ACOs that, absent extraordinary circumstances, will not face antitrust challenge. The safety zone is limited to those non-exclusive ACOs that the FTC/DOJ considers highly unlikely to raise any significant competitive concerns. To qualify for the safety zone, independent ACO participants who provide a common service must have a combined share not in excess of 30% for any common service in each participant's common primary service area ("PSA"). Where the market share is between 30-50%, no safety zone will be applicable, but the Policy Statement makes clear that the ACO is not necessarily unlawful. An ACO in this category may seek express approval of its activities from the FTC or DOJ, if the ACO desires a degree of antitrust certainty, but no such approval is required. Where an ACO applicant has more than 50% market share for any common service that two or more independent ACO participants furnish to patients in the same PSA, however, the ACO applicant must obtain approval from the DOJ or FTC stating that it will not challenge or recommend challenging the ACO. An adverse determination from the DOJ or FTC will bar the applicant from participation in the Program. Comments to the Policy Statement are due by May 31, 2011. It is likely that there will be considerable comment around the definitions of "common service" and "primary service area."

Tax: Anticipating that many tax-exempt organizations will participate in ACOs, the Internal Revenue Service ("IRS") issued Notice 2011-20 requesting comments regarding whether or not existing IRS guidance is sufficient for tax-exempt organizations that intend to apply for the Program.[ix] A primary issue is whether a tax-exempt organization's participation in an ACO will result in prohibited inurement or impermissible private benefit. The IRS does not anticipate that it will, in light of CMS' oversight of the Program. In addition, the IRS indicated shared savings payments from an ACO to a tax-exempt organization generally would not result in unrelated business taxable income, provided Shared Savings Program requirements are met. Comments to the notice are due by May 31, 2011.

Important Considerations. Before embarking on the establishment of or participation in an ACO, a provider should carefully consider a number of factors in addition to the legal issues discussed briefly above. Below are highlights concerning some key factors.

First, the scope of the ACO should be considered. Because it is currently limited to Medicare fee-for-service business (Medicare Advantage patients are excluded), the economic benefits of participation may initially be minimal. However, the government predicts that ACOs could earn up to $800 million (median estimate) in bonus payments over three years. In addition, the experience that a provider gains early on in managing risks attendant to an ACO could pay off in the future if ACOs and similar integrated care models proliferate in other government programs and in the commercial markets. Section 2706 of the PPACA already provides for a pediatric ACO demonstration project that would allow providers to share in savings achieved under federal/state Medicaid and CHIP programs. The demonstration project is expected to begin on January 1, 2012.

Second, before incurring significant expense in establishing an ACO, it would be appropriate to reflect on the failed history of similar efforts to establish integrated health systems since the early 1980s. A failure in the Program will be costly. The government estimates that start-up investment and first year operating costs for all ACOs in the Program could total between $132 million and $263 million. These projections are based upon the assumption by CMS that the Program will have between 75 and 150 ACOs.

Third, the nature of the reimbursement needs to be carefully analyzed. A Medicare ACO will continue to pay providers on a fee-for-service basis for their services, and the shared savings payments (if any) will be in addition to the normal fee for service arrangement. Alternative arrangements such as capitation, bundled reimbursement, pay for performance, episode-based case rates and similar innovative reimbursement models could also be implemented, particularly with respect to ACOs contracting with commercial carriers or self-insured plans. How will the savings be measured? Which providers will be called on to provide the most savings?

Fourth, a provider should evaluate carefully the data driven measurement and monitoring capabilities of the ACO. To be successful, economic credentialing, electronic health records, demographic and clinical status measurement and monitoring of utilization patterns all need to be carefully thought through and implemented. It is also critical to understand which providers will control the data that will be used to monitor and measure any performance based reimbursement, as control of that data may implicate overall organizational control.

Fifth, it is important to understand how the incentive compensation will be received and shared among participating providers by the ACO. Obviously, if the rewards are paid disproportionately to those who are not in a position to control cost, or who fail to control cost, the direction and success of the ACO may be affected. The same holds true for distribution of downside risk among providers in an ACO if it incurs losses. Regulators estimate that ACOs could be responsible for repayment of up to $40 million for services that do not meet benchmark/quality standards.

Finally, it is critically important that providers conduct thorough due diligence to determine their ACO status (primary care physician or not; if so, with how many and what profile of assigned patients) and their market share. These are threshold determinations that drive each provider's ACO feasibility analysis. Due diligence in selecting other providers to partner with in forming an ACO is also important. A provider's success will be a function of the collective performance of the other participants in its ACO. Because beneficiaries are free to use providers outside of their assigned ACO, this incentivizes participants to furnish quality care so that its beneficiaries will want to continue to use the providers within its ACO. If beneficiaries become dissatisfied with their ACO providers, they could switch to primary care physicians in

another ACO. This could jeopardize the original ACO's ability to maintain its minimum threshold of 5,000 beneficiaries, resulting in possible termination from the Program.

Conclusion. Given the far-reaching impacts that ACOs will have on the success of health care reform, this Alert is intended as an introductory publication addressing the high points of this new model for patient care. As the ACO regulations are commented upon, finalized and implemented in the coming months, we anticipate publishing additional Alerts that will focus on selected legal issues surrounding ACOs, and from the perspective of the various types of providers who will be affected. While it may be unclear how the proposed guidance will change prior to final publication, at least one thing is for certain, and that is ACOs present an exciting and challenging opportunity and risk for providers.

Should you have any questions, please communicate with Pat Devine (757-629-0614;), Dan Santos (757-282-5020;),or another member of the Williams Mullen Health Care Team.

[i] Pub. L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152.

[ii] The proposed regulations may be viewed at the following link: http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf.

[iii] Under PPACA, the following four types of groups may independently form an ACO: (a) ACO professionals in group practice arrangements; (b) networks of individual practices of ACO professionals; (c) partnerships or joint venture arrangements between hospitals and ACO professionals; (d) and hospitals employing ACO professionals. Pursuant to discretion afforded by PPACA, HHS has also stated in the proposed regulations that critical access hospitals are eligible to independently form ACOs. Under the proposed regulations, other providers who are enrolled in Medicare may participate in ACOs but cannot form them independently, including skilled nursing facilities, long term care hospitals, federally qualified health centers and rural health centers.

[iv] Section 1877(a) of the Social Security Act ("Act").

[v] Section 1128B(b) of the Act.

[vi] Section 1128A(b)(1) and (2) of the Act.

[vii] The CMS/OIG joint notice may be viewed at the following link: http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7884.pdf.

[viii] The Policy Statement may be viewed at the following link: http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf.

[ix] The IRS notice may be viewed at the following link: http://www.irs.gov/pub/irs-drop/n-11-20.pdf

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