Proskauer

Long Awaited Guidance on Accountable Care Organizations Issued; Many Organizations May Find It Difficult To Participate in 2012

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The concept of an “accountable care organization,” or “ACO,” is not new but was given legal significance by the 2010 health reform legislation (the Act). The Act provides that effective January 1, 2012, Medicare will pay organizations it has qualified as ACOs additional payments for meeting savings and quality targets for care provided to Medicare beneficiaries through the ACO. The Act outlines the essential elements of an ACO – such as an ability to receive and distribute payments – but leaves their definition and qualification to the Department of Health and Human Services (“HHS”) and its Centers for Medicare and Medicaid Services (CMS).

On March 31, 2011, HHS, along with the Federal Trade Commission and the Department of Justice (the Antitrust Agencies) and the Internal Revenue Service, released proposed regulations and guidance describing how an ACO can qualify, and how the agencies will approach the legal issues within their respective jurisdictions raised by ACOs. The coordinated guidance from multiple agencies is welcome and the proposed guidance provides helpful antitrust bright-lines. However, the extensive and in some cases very specific ACO requirements set forth in the proposed regulations, the tight time frames, and the limited proposed waivers from applicable federal health care laws likely make the ACO alternative undesirable for all but the organizations already most advanced down this path. In this alert, rather than providing a comprehensive summary of the proposals, we highlight some important points that will be central to organizations’ decisions on whether or not to pursue an ACO contract for 2012.

In general, CMS has based many of the ACO regulatory proposals on the two often conflicting principles that, on the one hand, ACO participants must have incentives to manage beneficiaries' care and, on the other hand, beneficiaries must not have their freedom of choice of providers restricted. This dichotomy shows in the draft provisions concerning whether providers can participate exclusively in one ACO. Primary care physicians are restricted to participating in only one ACO because the assignment of beneficiaries to ACOs is based on linkage to a primary care physician. Specialist physicians, hospitals, and other providers and suppliers, on the other hand, are prohibited from agreeing to participate exclusively in one ACO, because to do so might lessen competition and give beneficiaries the impression that their choice of provider is limited. Similarly, ACOs are required to have processes to promote coordination of care but are not permitted to do so in a way that would restrict a beneficiary's freedom to seek care from non-ACO providers.

Organizational Form and Governance

The proposed regulations would impose several specific organizational requirements on ACOs reminiscent of early federally qualified health maintenance organizations and Medicare Advantage plans.

- The ACO must be a separate legal entity with a taxpayer identification number authorized under state law to conduct its business.

- The ACO's governing body must include at least one Medicare beneficiary who is not a provider or otherwise connected with the ACO.

- At least 75 percent of the ACO's governing body positions must be held by ACO participants.

- Each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body and each ACO participant must have appropriate proportionate control over governing body decision making.

- ACO participants must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. This may include a meaningful financial investment in the ACO or a meaningful human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss of

the investment is likely to motivate the participant to make the clinical integration program succeed.

Federal Health Care Law Waivers

CMS and the HHS Office of Inspector General (OIG) also issued proposed guidance on the waiver of certain federal health care laws as they apply to ACOs. The Act permits HHS to waive provisions of the Federal Medicare and Medicaid anti-kickback statute (AKS), the Federal physician self-referral law (Stark), and the Federal law imposing civil monetary penalties on hospital payments to physicians to reduce care (CMP) to the extent deemed necessary to implement ACOs effectively. The proposal also waives the application of AKS and CMP to arrangements necessary for and directly related to participation in the Medicare shared savings program that comply with a Stark exception.

The proposed Stark, AKS, and CMP waivers are for allocation of the shared savings payment only. It does not appear that any protection is given to “pooling” the fee-for-service payments to be made to the various providers and suppliers. The establishment of the ACO (for example, its capitalization) is not subject to any waivers under the proposal unless such transaction falls within a Stark exception. Other operational issues also remain impeded by the narrow waivers. For example, the CMS preamble to the proposed regulations notes that while the ACO must have processes to promote coordination of care, the provision of such coordination mechanisms as telehealth and case coordinators may implicate Stark and AKS; no protection is afforded these transactions under the waiver provisions.

Antitrust Guidelines

Also on March 31, 2011, the Antitrust Agencies issued a Proposed Joint Policy Statement (Policy Statement) to clarify the antitrust analysis of newly formed collaborations among independent providers that seek to become ACOs. The Policy Statement recognized the importance of balancing two competing interests associated with ACOs: (1) the need for flexibility to ensure that ACOs have an opportunity to achieve substantial efficiencies through innovations and clinical integration and (2) the need to ensure that the antitrust analysis of ACO applicants and the enforcement of antitrust regulations remains sufficiently rigorous to protect both Medicare beneficiaries and commercially insured patients from anticompetitive behavior.

The Policy Statement indicates that the Antitrust Agencies will use a streamlined analysis that evaluates the ACO's share of services in each ACO participant's service area with bright-line thresholds. The numerical analysis will be carried out in a prescribed manner and will focus on the percentage of providers of each "service" (e.g., physician specialty) who are ACO participants.

- **Safety Zone**. Absent extraordinary circumstances, the Antitrust Agencies will not challenge ACOs that fall within a thirty percent provider service area safety zone. Falling within the safety zone requires that for any service in which there are two or more providers, the ACO participants make up thirty percent or less of the providers of that service. Hospitals and ambulatory surgery centers must participate in ACOs on a nonexclusive basis regardless of market percentage.

- **Safety Zone in Rural Areas**. In rural areas, the ACO may include one physician per specialty from each county on a nonexclusive basis and qualify for the safety zone even if the thirty percent threshold is exceeded.

- **Mandatory Review**. Proposed ACOs that have more than a fifty percent share of the provider service area for any service (even if it is only one service) must apply for antitrust review. CMS will not approve ACO participation unless this review has been completed and the ACO has received a letter that the relevant Antitrust Agency has no present intention of prosecuting or recommending prosecution.

- **In Between**. Proposed ACOs falling in between the thirty percent and fifty percent thresholds may, but are not required to, seek antitrust review and also can observe some safeguards to help protect against antitrust violations.

CMS's proposed rule and the Antitrust Agencies' Policy Statement provide for an expedited, ninety-day antitrust review and specify the information that must be provided. The CMS proposed rule further specifies that if, after the initial ACO approval, the ACO's providers change so that the fifty percent threshold is exceeded in a specialty, the ACO must seek and obtain a no-prosecution letter from the relevant Antitrust Agency.

Time Lines

ACOs will be asked to enter into three-year agreements to participate in the shared savings program. The participation and measurement cycle will be the calendar year. The preamble to the draft regulations recognizes that some ACO hopefuls may not be ready to get an application in for participation starting January 1, 2012, and indicates that CMS is considering an optional 3-½-year contract period beginning July 1, 2012 (with the first contract period being 18 months instead of one year) to provide some applicants more time to prepare.

Savings will be measured with data cut off at 6 months after the end of the measurement year, at which point most claims for services provided during the year will have been submitted. Thus, ACOs will be more than halfway through the next year of their contract before they know how they did in the preceding year.

The Antitrust Agencies will provide expedited antitrust review for ACOs. However, the time frame may not be realistic for 2012 participation. The Policy Statement indicates that the ACO must provide the application for review to the Antitrust Agency ninety days before CMS's ACO application deadline and, further, that the application to the Antitrust Agency must include the CMS application. For example, if the CMS deadline is November 1, the potential ACO must submit its request for review to the Antitrust Agency, including its completed CMS application, by August 3. This seems unrealistic.

Assignment of Beneficiaries, Shared Savings Payments, and Downside Risk

To measure an ACO's performance, Medicare beneficiaries are assigned to an ACO retroactively for the year based on the identity of the primary care physician who provided the most primary care services to the beneficiary during the year. This may be a majority or a plurality of services and is based on dollar reimbursement (total allowed charges for primary care services by that physician). Thus, the ACO does not know during the year which beneficiaries will be assigned to them. Nor will the ACO know whether an ACO beneficiary has been hospitalized or has used non-ACO services. The expectation here is that all Medicare patients will be treated by the ACO as if they will be assigned to the ACO, whether in the end they are or not.

The expenditure benchmark for measuring shared savings will be calculated for each ACO based on the past three-year cost experience of a hypothetical assigned Medicare population. This is the population that would have been assigned to the ACO based on primary care usage over those years. Notably, the expenditures measured include Part A and Part B services but do not include Part D (prescription drug) expenditures, so prescribing patterns do not play into the measured cost savings or losses.

In order for ACOs to have some idea of the patients that may be assigned to them, CMS will provide ACOs with the names of the individual beneficiaries who would have been assigned to the ACO based on historical data. CMS will also provide aggregate data on that population's historical utilization of services.

While the Act does not mandate "downside" as well as "upside" sharing (that is, ACO sharing of losses with CMS), under the proposed rules ACOs will be required to share losses as well as gains (savings). ACOs can elect to share only savings (the upside) for the first two years of their first contract or can elect to begin sharing losses and savings immediately. For ACOs that are sharing losses, the proposed rules prescribe a higher maximum shared savings amount of 10 percent but phase in the maximum loss amount (from 5 percent in the first year to 10 percent in the third year). The proposed regulations require ACO applicants to provide assurances that they will be able to cover the payment of losses should they occur. This can be done through a letter of credit, additional CMS withholding of positive savings payments, reinsurance, putting funds in escrow, or several other mechanisms. Because all ACOs will have to participate in sharing losses during the term of their first three-year contracts (whether in the first or the third year of the contract), ACO applicants will be asked to demonstrate at the time of application how losses will be covered even if they are electing the upside-only option for the first two years. The preamble notes that risk sharing may in some cases implicate state regulations concerning risk-bearing entities and asks for comments on this issue. Further, the preamble notes that funding a loss can implicate Stark and AKS issues.

Finally, twenty-five percent of shared savings payments otherwise due to the ACO will be withheld by CMS to be paid at the end of the ACO's three-year contract (unless they are used earlier to offset losses).

Other Significant Operational Restrictions and Requirements

In addition to the organizational requirements described above, the proposed regulations impose a number of operational requirements on ACOs. A few of these are:

- CMS must approve all marketing materials used by the ACO and changes thereto.
- ACO providers must post notices in their places of business that they are participants in an ACO.
- The ACO must have a compliance plan.
- The ACO's clinical management and oversight must be managed by a full-time senior-level board-certified medical director.
- Before CMS can provide beneficiaries' personal health information to the ACO, beneficiaries must be asked in person if they want to opt out of permitting Medicare to share this information.
- At least 50 percent of an ACO's primary care physicians must be meaningful EHR users, using certified EHR technology, by the start of the second year of the contract.
- Sixty-five quality measures in five domains must be met by the ACO for any shared savings to be paid, regardless of the amount of savings. For the first year, the quality measures will be satisfied if there is complete reporting, regardless of the quality reported; for subsequent years, standards must be met. For one domain, namely, patient experience of care, a specific survey must be used.
- The ACO must make information about its participants, its board, its committees, and its shared savings or loss performance available to the public.

IRS Notice on Tax Exemption

On March 31, 2011, the IRS also issued Notice 2011-20 (the Notice) asking for comments on the guidance, if any, needed concerning the effect of ACO participation on tax-exempt organizations such as hospitals. The Notice does not address, or ask for comments on, whether an ACO can itself be tax-exempt. Rather, the Notice is focused only on whether an exempt organization's participation in an ACO could endanger the organization's tax exemption or created unrelated business taxable income.

Based on existing authorities, the Notice indicates that a tax-exempt hospital's participation in an ACO would not endanger its tax-exempt status so long as the ACO was created and operated on a fair market value basis as between its participants, and the ACO had a Medicare contract. Further, the Notice points out that receipt of Medicare shared savings payments by an exempt organization would not be treated as income from an unrelated trade or business because the ACO's activities may lessen the burdens of government. The Notice suggests that shared savings payments received from private payors might not similarly lessen the burdens of government. The Notice does not conclude that such payments would be treated as income from an unrelated trade or business but asks for comments. The Notice does not discuss or ask for comments on how a hospital's receipt of shared savings payments is different from the receipt of payments for delivery of health care which, of course, would be related to exempt purposes.

Comments are being accepted on all the ACO draft guidance.