Drinker Biddle

Client Alert
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HHS Issues Proposed ACO Regulations

On March 31, 2011, the Department of Health and Human Services (HHS) issued long-awaited proposed regulations on Accountable Care Organizations (ACO) -- a new delivery and payment model aimed at improving the health of Medicare beneficiaries while reducing the rate of growth in health care spending. ACOs were authorized under the Patient Protection and Affordable Care Act (PPACA). The regulations are subject to a public comment period and possible modifications by HHS based on those comments before they become final. The public comment period expires 60 days from the scheduled April 7, 2011, date of publication.

The regulations provide much needed guidance on key structural and operational issues confronting ACOs, tax and antitrust concerns, as well as waiver design considerations related to the Center for Medicare and Medicaid Innovation (CMMI).

In the coming days and weeks, Drinker Biddle & Reath's Health Care Reform Team will be providing our clients with in-depth analysis and practical business advice on key aspects of the regulations, so please be on the alert for updates regarding targeted webinars and client alerts.

Structure and Operation of ACOs

The Proposed Rule provides information related to the formation, governance, monitoring and termination of ACOs. Of greatest concern to providers and beneficiaries, the Proposed Rule also clarifies issues relating to:

- Medicare beneficiary rights under ACOs;
- Assignment of Medicare beneficiaries to an ACO;
- ACO risk-sharing arrangements; and
- Quality and other reporting requirements.

Medicare Beneficiary Rights Under ACOs

Under the proposed rules, ACOs would be required to notify a Medicare beneficiary that he/she is participating in an ACO. ACO providers would also need to disclose to beneficiaries the financial incentives available to them by participating in the ACO, and

make information about the ACO available to Medicare beneficiaries. ACOs will not affect beneficiary choice, and beneficiaries have the right to see any provider at any time. Beneficiaries may also choose to opt out of participation in an ACO at any time. Medicare beneficiaries choosing to participate in an ACO would have to consent to the disclosure of their health information by Medicare to other ACO providers.

Assignment of Medicare Beneficiaries to an ACO

Beneficiaries would not be required to enroll in a specific ACO; rather, Medicare would retroactively assign beneficiaries to an ACO based on the providers with whom the beneficiary interacted most frequently during the preceding year.

ACO Risk-Sharing Arrangements

The Proposed Rule contemplates both shared savings (upside risk-sharing) and shared losses (downside risk-sharing). This two-sided risk corridor is a departure from PPACA, which authorized only shared savings between ACO providers and Medicare (*i.e.*, no downside risk to ACO providers). However, the model is consistent with MedPAC's recommendations to CMS in November 2010. The shared savings (bonus only) model had been widely criticized for not offering enough financial incentive to providers to encourage greater cost savings through ACOs.

Under the two-sided risk model, ACOs would have a choice to assume downside risk from day one, or elect to defer taking on downside risk until year three. As an incentive to encourage ACOs to assume immediate downside risk, Medicare would share 60 percent of any savings with the ACO, whereas ACOs electing to defer risk assumption until year three would be entitled to only 50 percent of any savings. CMS assumes that this model will encourage sophisticated delivery systems already prepared to assume financial risk to immediately begin assuming risk.

The ACO risk-sharing model contemplates thresholds both for shared savings and shared losses. This mirrors the methodology CMS is using in the Physician Group Practice demonstration. For ACOs opting to assume risk on day one, the ACO would have to achieve a savings of 2 percent above the threshold before the ACO could participate in the savings. Likewise, ACOs would not begin to assume liability for losses until total costs exceed 2 percent of the threshold. Additionally, CMS is proposing a tiered cap on shared losses of 5 percent, 7.5 percent and 10 percent of the benchmark in years one through three, respectively. The ACO's share of both savings and losses would be based in part on the ACO's quality scores.

Quality and Other Reporting Requirements

The proposed rule establishes quality performance measures and a methodology for linking quality and financial performance. An ACO that meets the quality performance standards will be eligible to receive a share of the savings it generates below certain benchmarks. Should an ACO not meet the quality performance standards it may not be eligible for shared savings or may be terminated from the Shared Savings Program.

CMS has proposed a phased-in approach to quality measurement that requires higher standards and new measures over time. For ACOs to meet the quality performance standard, they are required to report quality measures and meet the applicable performance criteria in accordance with certain requirements for each of the three

performance years. For the first year of participation, ACOs would only be required to report quality data to CMS, but would not be required to meet specific quality benchmarks. This, too, is designed to encourage participation in the Shared Savings Program. The agency proposes to score quality in that first year for informational purposes and to help define the benchmarks for the subsequent years. In subsequent program years, quality performance will be based on measure scores.

Specifically, ACOs will be required to meet 65 quality performance measures organized under five domains to be eligible for the Shared Savings Program. The measures for the first year are provided in a detailed table, and include: the domain each of the proposed measures addresses; the measure title; a brief description of the data the measure captures; applicable Physician Quality Reporting System (PQRS) or Electronic Health Record Incentive Programs information; the measure steward or, if applicable, National Quality Forum measure number; the proposed method of data submission for each measure; and the Measure Type. Quality measures for the remaining two years of the three-year agreement will be proposed in future rulemaking. The five key domains within the dimensions of improved care and improved health are:

- Patient/Caregiver Experience;
- Care Coordination;
- Patient Safety;
- Preventive Health; and
- At-Risk Population/Frail Elderly Health.

HHS identifies measures to improve health such as colorectal screening, cholesterol management, tobacco-use assessment, depression screening, hypertension control and osteoporosis management. Measures to improve care such as medication reconciliation, patient registry use, and the percentage of primary care physicians meeting HITECH Act meaningful use requirements are also included. CMS will designate quality performance standards for each measure, including a performance benchmark. A performance score will then be calculated using the quality standards. The quality measure benchmarks are then defined based on Medicare fee-for-service, Medicare Advantage, or ACO performance data. Certain eligible ACO participants may also earn PQRS incentives as a group practice under the Shared Savings Program by meeting its quality reporting standards.

Tax and Antitrust and Other Regulatory Guidance

Simultaneously with the release of the proposed regulations, the HHS Office of Inspector General (OIG), the Federal Trade Commission (FTC), the Anti-Trust of the Department of Justice (DOJ) and the Internal Revenue Service (IRS) issued policy guidance addressing several regulatory issues confronting ACOs and ACO formation:

- A joint CMS and OIG Notice and Solicitation of Public Comments on Waivers in Connection with PPACA;
- IRS Notice 2011-20 seeking comments regarding the need for guidance on participation by tax-exempt entities in the Medicare Shared Savings Program through ACOs; and

- A joint FTC and DOJ Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Anti-Trust Policy Statement).

An overview of the regulatory guidance is provided below.

Tax-Exempt Organizations

In Notice 2011-20, the IRS directly addressed the two primary tax law concerns regarding participation by tax-exempt hospitals and other organizations in ACOs: (1) whether participating in the Shared Savings Program will result in impermissible private benefit and inurement; and (2) whether participation will result in unrelated business taxable income.

First, the IRS set forth a series of conditions under which it "expects" to conclude that an exempt organization's participation in an ACO will not result in impermissible private benefit or inurement. Conditions include use of a written agreement negotiated at arm's length, as well as CMS acceptance of the ACO into the Shared Savings Program. Additional conditions draw largely upon standards previously articulated by the IRS in the context of joint ventures (*e.g.*, Revenue Rulings 98-15 and 2004-51). However, the later conditions' application in the ACO context is unclear given the various entity structures that may be used for ACOs. In addition, the IRS seemingly has *not* included in the ACO guidance the "control test" from its joint venture analysis, presumably given the Shared Savings Program parameters and CMS' ongoing oversight of ACOs.

The IRS also dismissed the unrelated business income issue, reasoning that: (1) the federal government considers the provision of Medicare to be its burden; (2) the Shared Savings Program was established to lessen the government's Medicare burden by promoting quality improvements and cost savings through ACOs; and (3) participation by hospitals and other exempt organizations in ACOs substantially furthers the charitable purpose of lessening the burdens of government. Nevertheless, the IRS stopped far short of concluding that *all* ACO activities would meet this standard. To the contrary, the IRS observed that ACOs might undertake a range of activities (such as shared savings arrangements with payors other than Medicare or Medicaid) that would *not* necessarily further any charitable purpose.

The IRS requested comments on two points: (1) whether additional guidance is needed to facilitate participation by exempt organizations in the Shared Savings Program through ACOs (and, if so, the relevant criteria or requirements needed); and (2) how participation in ACOs engaged in certain non-Shared Savings Plan activities might further exempt purposes.

The IRS remained silent on the question of whether ACOs themselves might qualify for tax-exempt status. The Notice suggests that ACOs participating in the Shared Savings Plan are furthering charitable purposes. However, given that Section 501(c)(3) organizations must satisfy well-established organizational and operational tests for exemption, ACOs may encounter challenges in obtaining recognition as Section 501(c)(3) organizations. In particular, issues may arise if the "owners" of the ACO include physicians and other practitioners, in addition to exempt hospitals or other organizations.

Antitrust Enforcement

The antitrust Policy Statement applies to collaborations (not mergers) among otherwise independent providers and provider groups (ACOs), formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate, in the Shared Savings Program. The proposed antitrust policy statement is open for public comment through May 31, 2011.

The Agencies indicate that they will provide "rule of reason" treatment to ACOs (including ACOs participating in the commercial market) if they meet Medicare requirements for governance, leadership structure, and clinical and administrative processes, but only for the duration of an ACO's participation in the Shared Savings Program. This means that the Agencies will not presumptively treat qualified ACOs as *per se* unlawful price-fixing or market allocation agreements. It also means that ACOs not structured around the Medicare criteria will not be entitled to any favorable presumptions.

The Agencies will apply a "streamlined" analysis based on an ACO's market share in the primary service area of each ACO participating provider. In other words, an ACO's market share will be evaluated by product line (*e.g.*, inpatient services, outpatient services by category, and physicians by specialty). Higher market shares will be associated with greater antitrust risk. The Policy Statement sets out the agencies' methodology for calculating primary service area market shares.

As with other health care enforcement policy statements, the Policy Statement defines a "safety zone" (safe harbor) within which the Agencies will not challenge the formation or operation of an ACO. The criteria are:

- Independent ACO participants that provide the same service (a common service) must have a combined share of 30 percent or less of each common service in each participant's primary service area.
- Hospitals and ambulatory surgery centers must have a non-exclusive relationship to the ACO regardless of their primary service area market shares. Physicians and other providers may have either an exclusive or non-exclusive relationship with the ACO. Exclusivity is evaluated both in terms of the legal relationship between the provider and the ACO and in terms of how the ACO operates in practice.
- Under a "rural exception," an ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis and qualify for the safety zone, even if the inclusion of those physicians causes the ACO's primary service area market share of any common service to exceed 30 percent. Also, an ACO may include rural hospitals on a non-exclusive basis and qualify for the safety zone, even if the inclusion of a rural hospital causes the ACO's share of any common service to exceed 30 percent in any participant's primary service area for that service.
- Any ACO participant with a greater than 50 percent share in its primary service area of any service that no other ACO participant provides in that primary service area must have a non-exclusive relationship to the ACO. Additionally, an ACO that includes a dominant provider may not require a commercial payor to contract exclusively with the ACO or otherwise restrict the payor's ability to contract or deal with other ACOs or provider networks.

Agency review is mandatory for certain ACOs. An ACO, except one that qualifies for the rural exception, cannot participate in the Shared Savings Program if its primary service area share exceeds 50 percent for any common service unless, as part of the CMS application process, the ACO provides CMS with a letter from one of the federal agencies stating that the reviewing agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws. The proposed Policy Statement outlines the review process.

The federal agencies indicate that ACOs that do not meet the "safety zone" criteria but fall below the mandatory review threshold nonetheless may be pro-competitive, based on a rule of reason analysis. Such ACOs may seek expedited review from the agencies, but such review is not mandatory. The Policy Statement identifies five categories of conduct that the agencies believe would be indicative of competitive concerns:

- Preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers (*e.g.*, "anti-steering" clauses in payor contracts);
- Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO and vice versa. For example, an ACO that includes one hospital from a multi-hospital system may not condition its contract on a payer contracting with all hospitals or ACOs in that system, or offer the payer a better price for contracting with all hospitals or ACOs;
- Contracting with physician specialists, hospitals, ambulatory surgical centers, or other providers (but not primary care physicians) on an exclusive basis;
- Restricting a commercial payer's ability to make provider cost, quality, efficiency, and performance information available to its enrollees; and
- Sharing the ACO's provider participantsm' competitively sensitive pricing or other data that could be used to set prices or other terms for services they provide outside the ACO.

Although this agency Policy Statement is more detailed, it is not markedly different in terms of its limited tolerance for market shares above 30 percent than the agencies' 1996 Policy Statement, concerning provider network arrangements. The current proposed Policy Statement applies only to ACOs in which the providers are not integrated (*e.g.*, financial risk sharing). Presumably, integrated arrangements will continue to be evaluated under the 1996 Policy Statements and traditional antitrust principles for integrated joint ventures.

Fraud and Abuse Law Waivers

In the joint CMS and OIG Notice, the Administration announced its intent to make waivers for ACOs as consistent as possible across existing federal fraud and abuse laws, including the Physician Self-Referal Law (Stark Law), the Anti-Kickback Statute and certain civil monetary penalties (CMP) applicable to hospital payments to physicians to reduce or limit services (Gainsharing CMP Statute). HHS also indicated its intent to apply the waivers uniformly to all qualified ACOs, ACO participants and ACO providers/suppliers.

As a threshold matter, to qualify for any of the proposed waivers, the ACOs would be required to enter into an agreement with CMS to participate in the Shared Savings Plan. ACOs, ACO participants and ACO providers/suppliers would also be required to comply with the CMS agreement, as well as the Shared Savings Plan and its implementing regulations. Thus, the transparency, reporting and monitoring requirements built into the Shared Savings Plan regulations are meant to serve as a deterrent to fraud or abuse.

In the Notice, HHS seeks comment on waiver programs. The first type of waivers are very limited waivers applicable to the distribution of shared savings earned in conjunction with participation in the Shared Savings Plan. Limited waivers are also discussed with regard to remuneration necessary for ACO activities and operations under the Shared Savings Program. HHS also requests comments on what types of additional, and perhaps broader, waivers may be necessary to achieve the shared savings goals of the Shared Savings Plan.

Limited Waivers

Stark Law Waivers

HHS specifically seeks comments on waiver of the Stark Law applicable to (1) the distribution of shared savings received by an ACO to, or among, ACO participants and ACO providers/suppliers or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Plan – including achieving its quality and shared savings goals. As proposed, the waivers would apply to ACO participants and providers/suppliers during the year in which the shared savings were earned by the ACO. All other financial relationships with referring physicians, both within and outside the ACO, would need to meet an existing Stark Law exception.

Anti-Kickback Statute Waivers

HHS also seeks comment on its proposal to waive the Anti-Kickback Statute under the same circumstances detailed above with respect to the Stark Law. In addition, HHS proposes to waive Anti-Kickback Statute applicability to any financial relationship between, or among, an ACO, ACO participants and ACO provider/suppliers necessary for, or directly related to, the ACO's participation in and operations under the Shared Savings Plan that implicates the Stark Law and fully complies with an existing Stark Law exception.

While compliance with the Stark Law ordinarily does not immunize conduct under the Anti-Kickback Statute, and arrangements that comply with Anti-Kickback Statute requirements can still run afoul of the Stark Law, HHS recognizes that, when coupled with the specific safeguards proposed under the SHARED SAVINGS PROGRAM, risk of fraud or abuse under these circumstances is low.

CMP Statute Waivers

Similar to the waivers discussed above, HHS also proposes to waive application of the CMP Statute with respect to distributions of shared savings received by an ACO under the Shared Savings Program provided that:

- The payments are not knowingly made to induce a physician to reduce or limit medically necessary items or services; and
- The hospital and physicians are ACO participants or ACO providers/suppliers or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.

A CMP waiver would also extend to any financial relationship between, or among, the ACO, its participants and its providers/suppliers necessary for and directly related to participation in and operations under the Shared Savings Program that implicates the Stark Law and complies with an existing Stark Law exception.

Broader Waivers

In addition to the limited waivers proposed by HHS described above, HHS seeks comment regarding waivers for financial arrangements that would be necessary to carry out the provisions of the Shared Savings Program. Such arrangements include: (1) arrangements related to establishing the ACO; (2) arrangements between or among ACO participants and/or provider/suppliers related to the ongoing operations of the ACO and achieving ACO goals; (3) arrangements between the ACO, ACO participants and/or ACO providers/suppliers and outside individuals or entities; (4) distribution of shared savings from private payors; and (5) other financial relationships for which a waiver would be necessary. HHS also requests comment on whether waivers are necessary for ACO arrangements that meet the existing Stark Law exception and corresponding Anti-Kickback Statute safe harbor applicable to electronic health records, but that occur after the 2013 sunset date applicable to that exception/safe harbor. Finally, HHS requests comment on whether it may be necessary to waive the Social Security Act's beneficiary inducement prohibition in connection with the Shared Savings Plan.

HHS has deferred until promulgation of final regulations whether and how it will exempt ACOs from the reach of the fraud and abuse laws. HHS indicated its continued concern that, even with the transparency protections built into the Shared Savings Plan. regulations, the variety of structures and payments that may be utilized to achieve ACO goals may be manipulated to the benefit of physicians and other referral sources.

Center for Medicare and Medicaid Innovation (CMMI) — Continuing to Explore New Models for ACO Development

Established by the Affordable Care Act, the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) is tasked with identifying and testing innovative payment and service delivery models that can: improve health care delivery and quality; address underlying causes of poor health; and reduce health care expenditures through care improvements. In addition to its release of the proposed rule for the implementation of Accountable Care Organizations, CMS and the HHS Office of the Inspector General jointly issued a notice and request for comment on proposals for waiving certain federal laws as they related to the Shared Savings Program. The notice specifically asks for comments by June 6, 2011, on waiver design considerations for the Shared Savings Program, as well as separate waiver authority for the CMMI, given that the Center will be testing and modeling other potential shared savings programs.

CMMI Role and Responsibilities

The ACO and CMMI efforts intersect and overlap as the CMMI will work to test alternate payment models other than those outlined in the ACO proposed rule in order to continue to establish options for implementation. For providers and suppliers, the

agency envisions that the CMMI will serve as a resource as they seek to develop into an ACO. For the agency, the vision is that the CMMI may be helpful in identifying different benchmarking methods as ACO efforts move forward. The agency hopes that as the CMMI gains experience with different ACO payment models it can help in identifying ways to improve the Shared Savings Program in the future.

Restrictions in Relation to ACOs and the CMMI

The Affordable Care Act set limitations to prohibit providers of services and suppliers from participating in multiple shared savings programs. As such, providers and suppliers will not be permitted to participate in both the ACO Shared Savings Program and shared savings models tested by the CMMI. The agency will also be working to ensure that a process is in place to prohibit duplication of payments for beneficiaries involved with providers and suppliers who are in the Shared Savings Program and models tested by the CMMI.

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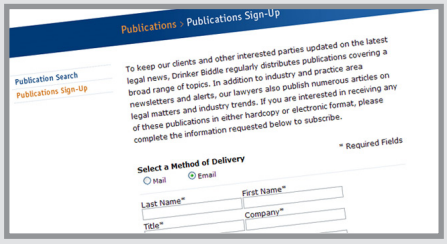

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