Compliance Advisory:

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ACO Proposed Rule Released

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Potentially Reshapes Health Care Delivery to Medicare Beneficiaries

The Accountable Care Organization proposed rule (Proposed Rule) was finally released by the Centers for Medicare & Medicaid Services (CMS) on March 31, 2011. The Proposed Rule was published in the Federal Register on April 7, 2011 and sets the stage for a possible remake of the health care delivery system for Medicare beneficiaries – at least for those organizations willing and able to throw their hat into the ACO ring.

The Proposed Rule is open for public comment until June 6, 2011. Final regulations are expected later this year.

There are many issues implicated by the Proposed Rule. This Client Alert highlights some of those issues.

Overview

Under Section 3022 of the Patient Protection & Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the PPACA), CMS is required to establish by January 1, 2012 a Medicare Shared Savings Program through accountable care organizations (ACOs). The PPACA and the Proposed Rule conceive of an ACO as a formal legal entity that integrates certain clinical and administrative features of the provider participants in order to improve quality outcomes and achieve savings for the Medicare program. Under the new program, if the ACO participants collectively meet specified quality measures and achieve at least a 2% savings in Medicare expenditures on an annual basis, then the ACO receives 65% of the "savings" as an extra payment. However, there is a flip-side risk to the ACO; if the ACO participants' collective Medicare receipts are 2% or more above the ACO's benchmark, then the ACO must pay back the Medicare program a portion of the difference. CMS refers to this as a "2-sided risk model."

The ACO program is voluntary and Medicare-enrolled providers are not required to join one. Given the requirements, obligations and risks, it is likely that only large networks of physicians and hospitals will be able to form ACOs. There will be considerable cost to establishing an ACO and the 2-sided risk model makes the structure far from ideal for many providers, particularly small health care organizations. There are also a host of legal obstacles which must be scaled to organize and devise the ACO.

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The Goals of an ACO

The Proposed Rule proposes a new vehicle (ACOs) as a mechanism to incentivize health care organizations to rein in Medicare expenditures. CMS sets out a "3-part aim" for ACOs, which underscores its Proposed Rule and beats in the background of all the parts of the proposed program. The criteria for an ACO to be accepted into the program is not so much a collection of hard-and-fast rules, as it is a facts and circumstances test of whether CMS considers the structure of the ACO to meet the 3-part aim. CMS recognizes the structures will need to be creative to meet the goals of the Shared Savings Program and will also need to fit within rules administered by the other enforcement agencies. The 3-part aim is composed of the following goals:

1. "Better care for individuals" – principally through encouraging quality performance outcomes;

2. "Better health for populations" – principally by encouraging preventive care, wellness information, and utilizing an integrated clinical care infrastructure; and

3. "Lower growth in expenditures" – principally through the ACO participants' commitment to lowering Medicare expenditures by decreasing overutiliziation, implementing evidence-based practice guidelines, and other measures.

The 3-part aim is very loose in its construction and represents policy goals of the Medicare Shared Savings Program. CMS provides additional criteria by which it will judge the structure of an ACO in order to accept or reject an ACO application. While many of the criteria CMS discusses in the Proposed Rule are not absolute criteria for acceptance of an ACO application, as a practical matter they set a basic threshold which we expect CMS will look to in the application review and approval processes. The preamble of the Proposed Rule oscillates between encouraging innovative design of the ACO and setting a heavy hand on expecting to see certain criteria met in the application process.

The criteria which CMS sets out as evidence of meeting the 3-part aim include how the ACO is legally structured, a shared governance structure, quality management programs, patient outreach and education programs, detailed plans for using any extra savings payments, and investment in clinical infrastructure.

Who may participate in an ACO?

A health care provider or supplier that is a member of an ACO is referred to as an "ACO participant" under the Proposed Rule. Practitioners who are members of an ACO are referred to as an "ACO professional."

In its proposed form, ACOs are principally designed for hospitals and physicians (including a practice group's ancillary personnel, such as physician assistants and nurse practitioners). The hospital must participate in the Medicare prospective payment system (PPS) or be a critical access hospital which is reimbursed under Method II. Most PPS-exempt hospitals will not be able to participate in an ACO. It is possible for a physician practice to establish an ACO on its own, but the start-up costs are considerable and a physician-only ACO would likely need several hundred physicians in order to spread the risk, raise the start-up capital and be able to treat the minimum number of Medicare beneficiaries (5,000) required to be an ACO.

At this time, HHS has limited who may be ACO participants, but the PPACA allows the Secretary of HHS to add ACO participants as she deems fit in the future. Although ACO participants are limited, ownership of the ACO legal entity is not limited to ACO participants as long as the ACO participants collectively have at least 75% control of the legal entity. The Proposed Rule contemplates that some ACOs may need to seek start-up capital from outside the pool of ACO participants and consequently accommodates non-participants as partners in the ACO enterprise. Although the ACO participants must be enrolled in the Medicare program, the ACO itself does not need to be a participating provider or supplier.

How is the ACO structured?

The Proposed Rule sets out stringent criteria for certain aspects of the ACO. While CMS is not requiring an ACO to be a newly formed legal entity, very few existing legal entities will have an existing management and governance structure which allows for an ACO, absent significant governance changes.

The structure of an ACO must have the following features:

- A formal legal entity recognized by State law in the State(s) in which the ACO functions;
- A common governing body (e.g., Board of Directors) must be established which has control over certain clinical and administrative functions of the ACO participants;
- The ACO participants must have at least 75% control of the governing body;
- "Must demonstrate a mechanism of governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process";
- The governing body must include a Medicare beneficiary representative;
- The ACO will need its own administrative structure and financing arrangements for start-up expenses, how the ACO will handle any payments it receives from Medicare, and any paybacks to Medicare;
- An executive officer must be appointed to manage the day to day functions of the ACO;
- A compliance program for the ACO activities must be established;
- A quality assurance committee must be established for the ACO which has jurisdiction over all ACO participants; and
- The ACO must hire a medical officer who is licensed in the State(s) in which the ACO operates and the medical officer must be physically present in the State(s).

The Proposed Rule is not requiring that the ACO be a not-for-profit entity, but the preamble for the Proposed Rule notes several times that CMS wants ACOs to be designed to encourage participation by not-for-profit organizations. Since the ACO application approval process is discretionary, it seems reasonable to read between the lines that CMS will give preferences to not-for-profit ACO entities.

As noted above, the Proposed Rule contains a controversial provision which requires the ACO to have board representation from the pool of Medicare beneficiaries who are assigned to the ACO. The patient representative must be a full voting member and there must be at least one such representative. The Proposed Rule does not dictate a specific way in which the ACO selects the Medicare beneficiary member for the board, but the election or selection process must be fully developed prior to submitting the ACO application to CMS. The beneficiary representative is part of the "patient-centeredness" commitment which the ACO must demonstrate.

Control Over Clinical and Administrative Matters

When an ACO participant becomes a member of the ACO, there is a certain amount of control over their clinical and administrative operations which they must give over to the ACO. The ACO does not need to be a formal merger of the various ACO participants, but the ACO must have the authority to coordinate clinical care among the ACO participants and manage the implementation of evidence-based medicine guidelines, as well as conduct reviews and audits of the ACO participants' activities.

The 2-sided Risk Model & Savings/Loss Payments

At the heart of the ACO are incentive payments to save Medicare expenditures for the beneficiaries receiving services from the ACO participants. While the Shared Saving Program is cast in terms of "savings" as a way to control costs, it is important recognize what CMS means by "savings." The concept of savings in this program is achieved when ACO participants receive less money from Medicare in a year when the receipts are measured against a benchmark. In the 2-sided risk model, the ACO is also at risk of owing money back to CMS if the ACO participants receive more money from Medicare in a year than their established benchmark.

The way CMS proposes to assess whether the ACO participants have accomplished savings or have caused "loss" to Medicare is to set an "expenditure benchmark" based on the average per capita Medicare payments for an assigned group of Medicare beneficiaries. The expenditure benchmark is then compared against the ACO participants' Medicare receipts for a contract period of three years. The "shared savings/loss" determinations are made annually.

Establishing the ACO's expenditure benchmark is a critical step in the process. The benchmark is based on at least 5000 "assigned beneficiaries." While the assigned beneficiaries are able to receive services from any Medicare-enrolled provider or supplier, these individuals are assigned to an ACO at the discretion of CMS in order to calculate the ACO's benchmark. The proposed approach for assigning a patient to an ACO is for CMS to examine the volume of evaluation and management (E&M) codes billed for a patient by all physicians who have provided care to the patient. The payments for the E&M services are aggregated and whichever physician has a plurality of E&M charges for the patient will be considered the patient's "primary care practitioner." If that physician is an ACO professional, then the Medicare beneficiary is assigned to the ACO. The individuals are informed that they

have been assigned to an ACO. Presumably if a Medicare plurality physician is not participating in an ACO, then the beneficiary would not be assigned to an ACO.

In order to qualify to be an ACO, the ACO participants must collectively have at least 5,000 Medicare beneficiaries who have a primary care practitioner who is participating in the ACO. The ACOs may have more than 5,000 beneficiaries assigned to them and the Proposed Rule discusses thresholds in various formulas which go to as high as 60,000 assigned beneficiaries. Because it will be virtually impossible for a physician to know for certain that he or she qualifies as the patient's primary care practitioner under the Proposed Rule, the ACO must presumably recruit as many physicians as possible in order to qualify. This approach is specifically designed to draw into the ACO specialties which are most likely to have high volumes of E&M services, such as family medicine, geriatrics, and other internal medicine specialties such as cardiology and oncology. Again, the ACO design model is not conducive to smaller physician groups and organizations. As such, the number of ACOs may be limited.

While the assigned beneficiaries may seek services wherever they desire and the ACOs are precluded from discouraging beneficiaries from seeking services elsewhere, it remains to be seen whether and how often beneficiaries will go outside the ACO network to seek services. The beneficiaries will have representation in the ACO governance. The ACO is designed with the intention to provide integrated care, wellness and preventive services. The ACO will be also be required to communicate with the assigned beneficiaries in some manner about the ACO and its services, but the Proposed Rule strictly prohibits the ACO from communicating with the assigned beneficiaries about the ACO unless the communications are pre-approved by CMS.

Once the expenditure benchmark is identified, then each year the Medicare payments to ACO participants are compared to the established benchmark. The expenditure benchmark is adjusted every three years and it also uses an annual escalator. Medicare payments for Part A and Part B covered items and services are paid as normal directly to the ACO participants, but all of the Medicare payments are aggregated for purposes of the annual comparison. The ACO participants rise or fall together.

While there are certain two year transitional provisions that an ACO can choose in order to minimize the initial risks (but these transitional options require a greater savings percentage to qualify for the extra payments), the Shared Savings Program is designed to trigger savings or losses for ACOs at 2% deviations from the established benchmark. The ACO is paid 65% of the "shared savings" after demonstrating it received less than 2% of the expenditure benchmark for its assigned beneficiaries. Meanwhile, the ACO must repay Medicare up to 10% for "shared losses" over the 2% deviation. A shared loss is when Medicare pays the ACO participants more than the expenditure benchmark in a given year.

Managing Shared Savings/Losses

When the ACO receives payments from "shared savings," the money is not paid to the ACO participants but is paid directly to the ACO. Likewise, if the ACO must repay Medicare due to "shared losses," then the ACO must raise cash for the repayment. In order to hedge for years that may require a repayment, CMS will withhold 25% of any annual payments to the ACO so that future repayments for "shared losses" can be offset against the withheld amount. The 25% withholding is paid out to the ACO at the end of each three year cycle. As noted above, the ACO need not (and likely will not) be a Medicare participating provider or supplier, although the ACO participants must be Medicare participating providers/suppliers. The withhold is designed, in part, to address that issue. As Medicare would not be able to recoup overpayments from the ACO by withholding future Medicare payments due and owing the ACO, the withhold attempts to manage that overpayment risk.

Since monies are to be paid to the ACO for the services of the ACO participants and those monies will presumably be distributed by the ACO to the ACO participants over the course of time, the ACO must have a well-developed and finely tuned plan on how to address possible refunds. Will it only distribute a portion of monies to the ACO participants or will it require a type of "call" from the ACO participants to cover "shared loss" payments to CMS?

CMS notes that "the statute does not establish any requirements for the manner in which shared savings payments are distributed." Nevertheless, the Proposed Rule has a very high bar for how ACO participants may receive any distribution from the ACO savings payments. The Proposed Rule is designed to encourage the ACO to re-invest the money into infrastructure and technology which continues to advance the 3-part aim.

Quality Assurance Program

It is insufficient for the ACO to merely achieve "savings" greater than 2%. The Proposed Rule requires the ACO to achieve certain quality performance measures as well. Consequently, in order to be eligible for the extra money under the Shared Savings Program, the ACO must meet quality performance criteria and hit the savings triggers.

There are 65 quality measures set forth in the Proposed Rule. They are organized generally around five "domains": patient/caregiver experience (7 measures); care coordination (16 measures); patient safety (2 measures); preventive health (9 measures); and at-risk population/frail elderly health (31 measures). Many of the at-risk measures are focused on specific disease types, such as diabetes, heart failure, coronary artery disease, hypertension, and chronic obstructive pulmonary disorder.

The ACO must also establish a quality assurance and process improvement committee that "would establish internal performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, and hold ACO providers/suppliers accountable for meeting the performance standards."

Electronic Record and Data Sharing Requirements

To qualify as a group practice in an ACO, physicians must participate in a Physician Quality Reporting System incentive under the Shared Savings Program, and report ACO quality performance measures.

At least 50 percent of an ACO's primary care physicians must be meaningful EHR users, using certified EHR technology as defined in the HITECH Act and subsequent Medicare regulations.

CMS may terminate an ACO agreement if fewer than 50 percent of an ACO's primary care physicians are not meaningfully EHR users, using certified EHR technology.

CMS recognizes that ACOs may require beneficiary data in order to best structure its programs and achieve its intended results. To facilitate the exchange of that data, ACOs must have a data-use agreement with CMS. CMS also anticipates that ACOs may desire beneficiary specific data. CMS believes that it has legal authority to disclose such data to ACOs, but CMS proposes to allow Medicare beneficiaries assigned to ACOs to opt-out of such beneficiary-specific data sharing. The ACO must supply beneficiaries with a form that allows them to opt-out.

CMS will share aggregate data regarding the ACO's population several times per year. Data from CMS will include financial performance; quality performance scores; aggregate metrics on the assigned beneficiary population; utilization data at the start of the agreement period based on historical beneficiaries; and identification of historically assigned beneficiaries used to calculate the benchmark.

Compliance Program

In an important policy move by CMS, the Proposed Rule would require that all ACOs adopt a compliance program in order to be accepted into the Shared Savings Program.

The Proposed Rule does not require that the compliance programs have all seven of the traditional elements of an effective compliance program. Rather, the ACO must have at least the following five elements:

1. A designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body;

2. Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;

3. A method for employees or contractors of the ACO or ACO providers/suppliers to report suspected problems related to the compliance official;

4. Compliance training of the ACO's employees and contractors; and

5. A requirement to report suspected violations of law to an appropriate law enforcement agency.

The preamble to the Proposed Rule suggests, "[t]o achieve an effective compliance program, an ACO may also want to consider coordinating its compliance efforts with existing compliance efforts of its ACO provider/suppliers." While the ACO may utilize the compliance initiatives of the ACO participants, there nevertheless needs to be an overarching compliance program. The ACO participants will need to agree upfront on how this will work and understand the jurisdiction of the compliance programs for their organizations.

No Appeal Rights

Another controversial dimension to the Shared Savings Program is that ACOs will have no ability to appeal decisions by CMS. The only exceptions to this are denials of the ACO's initial application, and termination of the ACO from the program as the result of an allegation that the ACO is steering away high-risk beneficiaries who could cause the ACO participants' Medicare expenditures to increase.

The PPACA specifically prohibits anyone from seeking "administrative and judicial review" of CMS's decisions in managing the Shared Savings Program. CMS has interpreted this to mean that ACOs will not be able to appeal CMS's determinations as to whether the ACO has met the quality and savings triggers, nor will the ACO be able to appeal a CMS demand for repayment if CMS determines the ACO triggers the "shared loss" rules.

Coordination with Other Agencies

The proposed design and structure of the Shared Savings Program and ACOs raises a number of legal issues and concerns outside the purview of CMS. As such, CMS was not alone in releasing ACO material on March 31. Other agencies which issued documents include the HHS-Office of Inspector General (OIG), the Federal Trade Commission (FTC) and the Department of Justice (DOJ), as well as the Internal Revenue Service (IRS).

The OIG and CMS issued a joint notice entitled, "Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center." (The Innovation Center is the area within CMS which will manage the Shared Savings Program.) The document requests comments on waiving the physician self-referral law, anti-kickback statute and civil monetary penalties law for ACO arrangements. The PPACA specifically granted HHS the ability to waive these laws to enable the development of ACOs.

The FTC and DOJ also issued a joint policy statement with comment period regarding the potential antitrust and price fixing implications of an ACO when competitors join in the ACO. The antitrust document sets out "safety zone" guidance on how the ACO can be structured to provide assurance that there would be no antitrust prosecutions or challenges from FTC or DOJ. The document also sets out different levels of scrutiny the ACO must undergo depending upon the level of market share for the ACO. The public comment period for this document will be open until May 31, 2011.

The IRS also solicited comments as to whether existing guidance relating to the Code provisions governing tax-exempt organizations was sufficient for those tax-exempt organizations planning to participate in the Shared Savings Program through an ACO and, if not, what additional guidance was needed.

Final Observations

The organization, design and operation of ACOs under the Proposed Rule (and the other agency documents) are complex. It remains to be seen how many providers and suppliers will be willing and able to participate and, if so, whether their participation will be sustainable. There will likely be significant and critical public comments to the Proposed Rule, which may lead to further modifications. Nonetheless, if you are interested in participating or organizing an ACO, you need to begin considering your design, management and operation plans and attendant legal issues today.

If you have any questions about ACOs, please contact:

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