OBER | KALER
Attorneys at Law

HEALTH CARE LEGISLATION UPDATE - ISSUE 4

May 10, 2010

By: Christi J. Braun and Alan J. Arville

Accountable Care Organizations to Focus on Quality and Cost Savings

By Christi Braun

Following the recent trend of paying health care providers for the quality, rather than the quantity, of their services, Congress included in PPACA a special payment program under Medicare for delivery of care through accountable care organizations (ACOs) (sections 3022 and 10307), and a pediatric ACO demonstration project under Medicaid (section 2706). In general, the following organizations of providers, which possess a mechanism for shared governance and a legal structure that allows for receipt and distribution of incentive payments, are eligible to participate in the program as ACOs:

- A group practice of physicians, physician assistants, nurse practitioners, or clinical nurse specialists
- Networks of group practices, such as independent practice associations (IPAs) or other provider-controlled organizations
- Physician-hospital organizations (PHOs) or other joint ventures or partnerships of hospitals and independent providers
- Integrated delivery systems or other fully-integrated organizations of hospitals and their employed physicians and ancillary providers

To be recognized as an ACO, a provider organization must:

- Sign a participation agreement for a minimum term of three years (with the Secretary of the Department of Health and Human Services (HHS) for the Medicare program and the state for the Medicaid/CHIP demonstration)
- Have processes in place to promote evidence-based medicine and report on quality and cost measures
- Engage patients in their care
- Coordinate care among ACO providers
- Meet patient-centeredness criteria still to be established by HHS

For the Medicare program, the organization must also have a sufficient number of primary care providers—physicians and extenders—to service the Medicare fee-for-service beneficiaries assigned by HHS, which will number at least 5,000.

PPACA adds a new section 1899 to Title XVIII of the Social Security Act and requires by January 1, 2012 that HHS establish a program to incentivize providers participating in an ACO to deliver efficient, high-quality items and services under Medicare Parts A and B. HHS is to establish process, outcome, patient satisfaction, and utilization measures to assess the care ACOs provide, as well as performance standards. Based on an ACO's historic beneficiary expenditures for Parts A and B, HHS also is to establish a risk-adjusted cost benchmark and a percentage below the benchmark that the ACO must meet. ACOs that submit the measures data—in the form and manner specified by HHS—and achieve the performance standards will be eligible to receive a share of any savings that is at least the established percentage below the benchmark. Regardless of the outcome, ACO providers will continue to be paid on a fee-for-service basis as they would under parts A and B. HHS may, however, use incentive payment models other than the shared savings model, including a partial capitation model for ACOs that are "highly integrated" and capable of bearing financial risk.

The Medicaid and CHIP pediatric ACO program is a four-year demonstration project, which will start January 1, 2012. States may apply to HHS to participate in the demonstration project. PPACA authorizes participating states to allow pediatric providers that meet the above ACO requirements—and those HHS later establishes—to be recognized as a pediatric ACO. Like the Medicare program, the Medicaid/CHIP demonstration project requires participants to meet

quality guidelines before each pediatric ACO may earn incentive payments. After consulting participating states and pediatric providers, HHS will establish quality guidelines to ensure Medicaid and CHIP patients treated by pediatric ACOs do not receive lower quality care as a result of the cost incentives. Each participating state, in consultation with HHS, will set annual minimum savings levels its pediatric ACOs must achieve for the Medicaid and CHIP services they provide. To receive incentive payments, a pediatric ACO must meet HHS's quality guidelines and achieve savings greater than its state's minimum level. The actual incentive payments, which HHS may cap, will be equal to a portion of the excess savings the pediatric ACO achieves.

Ober|Kaler's Comments: Nowhere in the two PPACA sections on ACOs did Congress address the potential antitrust risk providers may face in developing an ACO. Yet, only an integrated physician group practice or a hospital system and its employed physicians meets the statutory ACO definition and does not face a risk of violating Section 1 of the Sherman Act, which prohibits agreements that restrain competition among competitors. And, in working to obtain a sufficient base of primary care providers through the merging of practices or employment of previously competing physicians, a physician group practice or hospital system may risk violating Section 2 of the Sherman Act, which proscribes monopolization, or Section 7 of the Clayton Act, which disallows acquisitions or mergers that may substantially lessen competition. Thus, prudent providers should assess their antitrust risks before developing an ACO.

While the Federal Trade Commission, Department of Justice Antitrust Division, and the states' attorneys general will not investigate or sue an ACO for contracting with a federal health benefit program under PPACA, it is unlikely that an ACO would form solely to take advantage of the Medicare and Medicaid incentive programs. In fact, PPACA states that HHS may give preference to ACOs who are participating in similar arrangements with private payers. As such, PPACA provides an incentive to ACOs to contract with health insurers and other third-party payors. If the ACO is an IPA, PHO, or other provider-controlled organization of independent, competing physician practices, though, joint contracting with payors—even if Medicare recognizes the organization as an ACO—could be a *per se*, or automatic, violation of the Sherman Act unless the ACO's activities result in significant integration of the providers and joint contracting is ancillary, or reasonably necessary, to the achievement of higher quality, lower cost care by the ACO. There is no guidance from federal or state antitrust authorities on formation or operation of ACOs. Because ACO contracting involves the sharing of financial risk (upside for the shared savings model and downside for the capitation model), it is possible that the federal agencies' guidance related to financial risk-sharing joint ventures may apply. Without knowing whether that risk qualifies as substantial, though, it is unclear whether the antitrust enforcers would agree that the risk leads to integration of the providers and the joint price setting by ACO providers is reasonably necessary. The quality and cost goals of an ACO mesh, though, with those of a clinical integration organization. And the FTC has provided some guidance on what an organization needs to look like and do to be clinically integrated. Therefore, IPAs and PHOs seeking to contract as ACOs may first want to implement a clinical integration program.

Gradual Closing of Medicare Part D "Donut Hole" and New Coverage Gap Discount Program

By Alan J. Arville

The most significant change to the Medicare Part D prescription drug benefit imposed by PPACA and the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act) is the gradual phasing down (and eventual phase out) of the coverage gap (also known as the donut hole). The *coverage gap* refers to the lapse in Medicare Part D coverage that occurs once a beneficiary reaches a coverage limit ($2,830 in 2010). Once this coverage limit is met, the beneficiary must pay 100 percent of his or her drug costs until the beneficiary reaches the point when "catastrophic" coverage is triggered ($4,550 in 2010).

Retroactive to January 1, 2010, section 1101 of the Reconciliation Act provides immediate relief to Part D beneficiaries by requiring HHS to provide a $250 rebate to each Part D beneficiary who reaches the donut hole (to be determined on a quarterly basis). Beginning January 1, 2011, PPACA shrinks the donut hole by reducing beneficiary copayments each year, until the donut hole is essentially eliminated by 2020 (i.e., by 2020, the Part D "standard" benefit coinsurance percentage will be reduced to 25 percent, which is the same that applies prior to reaching the

donut hole).

In addition to the gradual phase-out of the donut hole, PPACA establishes the Medicare Coverage Gap Discount Program (Medicare Discount Program). In general, the Medicare Discount Program requires drug manufacturers (as a condition to coverage of the manufacturer's drugs under the Part D program) to provide a discount equal to 50 percent of the negotiated price of *applicable drugs to applicable beneficiaries. Applicable drugs* generally include drugs covered by the beneficiary's plan and approved under "a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act." *Applicable beneficiaries* do not include beneficiaries entitled to low-income subsidies.

On April 30, 2010, CMS issued a guidance document explaining how it intends to implement the Medicare Discount Program, and is accepting comments to the guidance through May 14, 2010.[1] CMS states that it explored the viability of a model (that seemed to be contemplated by PPACA) utilizing third-party administrators to directly adjudicate payments to pharmacies for providing discounts at the point of sale. CMS determined, however, that the HIPAA electronic pharmacy claims billing standard could not support the transfer of necessary information from the Part D sponsor to the third-party administrator to determine whether the claim qualifies for the discount. Therefore, CMS is moving forward with a model, effective January 1, 2011, that requires the Part D sponsor to calculate the discount amount at the time of initial claim adjudication and provide the discount payment to the pharmacy. CMS will utilize a contractor to facilitate the collection of the discount payment *from* manufacturers and payment to Part D sponsors that provide the discount to applicable beneficiaries.

Finally, PPACA also amends the federal antikickback statute by adding a new exception for the discounts provided by drug manufacturers to beneficiaries pursuant to the Medicare Discount Program.

Ober|Kaler's Comments: With the new Medicare Discount Program, PPACA has established a new, complex mechanism that will involve creating and amending various contracts between CMS, drug manufacturers, pharmacies, Part D sponsors, pharmacy benefit managers and third-party contractors to facilitate the adjudication of claims, transfer of information and distribution of funds. In addition to the operational challenges inherent in implementing this new system, a new arena for disputes is likely to emerge.

NOTES

[1]The April 30 CMS guidance that provides detailed information regarding the implementation, transfer of information, and distribution of funds in connection with the Medicare Discount Program is available at http://www.cms.gov/PrescriptionDrugCovContra/01_Overview.asp.