The Dawning of the Age of Accountable Care? Federal Agencies Reveal Rules for Accountable Care Organizations

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Rushing to avoid being cast as an April Fools' publication, the Centers for Medicare and Medicaid Services (CMS) published its proposed rule implementing the Patient Protection and Affordable Care Act (PPACA)'s Section 3022, the Medicare Shared Savings Program for Accountable Care Organizations (ACOs). The proposed rule is set for publication on April 7, 2011, but an advance copy of 426 pages is available at the Publication Desk of the Federal Register under the CMS section. There is a 60-day public comment period on the proposed rule. In addition to the proposed rule, CMS and the Office of Inspector General (OIG) jointly issued a 27-page notice with comment period for Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center. The Federal Trade Commission (FTC), Antitrust Division of the Department of Justice (DOJ), and the Internal Revenue Service (IRS) also issued press releases and guidance on the impact of participation in the Shared Savings Program on antitrust and taxation considerations. In brief, collectively, these publications address the following topics:

Eligibility and guidance requirements for participation in the shared savings program: The proposed rule defines the scope of individuals/entities who can form ACOs as: (a) ACO professionals in group practice arrangements, (b) networks of individual practices of ACO professionals, (c) partnerships/joint ventures between

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hospitals and ACO professionals, (d) hospitals employing ACO professionals, and (e) certain critical access hospitals (CAHs). CAHs were added by the Secretary, as well as the addition of federally qualified health centers (FQHCs) and rural health clinics (RHCs) as ACO participants in an ACO otherwise formed to meet the requirements. ACOs must have their own taxpayer identification number (TIN), be a legal entity able to conduct business in its state of residence, have a governing body with adequate authority to execute the functions of the ACO, involve community stakeholder organizations and beneficiaries in its governing processes, be clinically integrated and have specific leadership and management structures, among other requirements. Meeting the governance requirements would need to be demonstrated during the application process through supporting documents and materials for each required element. ACO executives must certify that the ACO professionals and participants will be accountable for beneficiaries as part of the application process and execute the required 3-year agreement with CMS (which includes a 60-day advance notice of termination requirement). The ACO must have the ability to receive and distribute savings payments and include a sufficient number of primary care providers and beneficiaries (with a minimum of 5,000 beneficiaries assigned with a process for corrective action if the ACO drops below that number in a given year, followed by termination if assignment is not increased to 5,000 or more the following year).

Establishment of the 3-Year Agreement with CMS: CMS will establish a deadline for ACO applications, CMS will have time to review them, and then, the 3 year term will commence on the following January 1 following approval of the application. This agreement will qualified health centers (FQHCs) and rural health clinics (RHCs) as ACO participants in an ACO otherwise formed to meet the requirements. ACOs must have their own taxpayer identification number (TIN), be a legal entity able to conduct business in its state of residence, have a governing body with adequate authority to execute the

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Assignment of Beneficiaries: A thorny issue for ACOs has been beneficiary assignment because of the direct affect attribution has on savings potential. Beneficiaries will be assigned to ACOs (not “join” the ACO) based on empirical (past) patterns of utilization of primary care services and must be given notice of their provider’s participation in an ACO. The proposed rule mixes a retrospective assignment of beneficiaries for determining eligibility with the provision of aggregate beneficiary level data for the assigned population of Medicare beneficiaries for the benchmark period.

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CMS believes that providing better aggregate data will offset the issues in prior Medicare demonstration projects where only retrospective information was provided. Because of their direct impact on beneficiary assignment, ***primary care practitioners must be exclusive to one ACO***; other ACO participants who do not affect beneficiary assignment (hospitals, specialists, nursing homes, etc.) can participate in multiple ACOs. Primary care physicians are defined as internal medicine, general practice, family practice, and geriatric medicine.

Quality and Other Reporting Requirement: The proposed rule includes 65 measures [based on five "domains" – patient/caregiver experience, care coordination, patient safety, preventive health, and at-risk population/frail elderly health] for use in calculating the ACO Quality Performance Standard. ACOs will receive performance scores on each measure, and a sliding scale of points assessed to ACOs. All of these scores ultimately would be used to calculate the ACO's final sharing rate for shared losses or savings. A focus in the proposed rule is on accurate and full reporting of data, which can be used to effectuate large scale changes to health care delivery and services.

Shared Savings Determination: The formula to determine the achieved shared savings is dependent on quality measures, the type of ACO created, and a number of other factors. An ACO is eligible for shared savings only after obtaining a "minimum savings rate" (MSR) by reducing costs below an expenditure benchmark determined by beneficiary population with adjustments based on demographic factors and/or health status, among other factors. CMS discusses two options for determining the expenditure benchmark and opts for Option 1 which has no risk adjustment and is not adjusted for assigned beneficiaries who die during an assignment year. The likely amount of any Shared Savings to be experienced by an ACO is somewhat vague and unclear in the proposed rule, although the government expects this Program to save over the course of

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a 3 year period, a median of $510 million to a high of $960 million savings, net of any performance payments to others.

Two Tracks for Participation (Completely At-Risk and At-Risk Year 3 Only): CMS proposes that ACO participants have two models to choose from: (a) Two-Sided Model (fully at risk from day 1), which provides higher shared savings, but requires more integration and sophistication to manage risk adequately, and (b) One-Sided Model (sharing in any achieved savings from year 1, but at risk for shared losses starting in year 3 when model automatically transitions to the Two-Sided Model), which provides lower shared savings, but doesn't require the same level of experience with population management or risk. Note this is somewhat different from prior discussions where the Shared Savings Program was not intended to require a participant to be at risk to share in the savings. With each model or track, there is a maximum sharing cap (7.5% of the ACO's benchmark for the One-Sided Model and 10% for the Two-Sided Model). With the Two-Sided Model, shared losses are also capped to some extent and there is a minimum loss rate of 2% regardless of size.

Monitoring and Termination of ACOs: The proposed rule addresses the possible monitoring methods (site visits, financial and quality data analysis, complaint investigations, audits) and the potential sanctions that CMS may impose (up to and including termination) on an ACO. The proposed rule speaks in terms of "heightened oversight" followed by termination from the program when certain factors are involved, including avoidance of at-risk beneficiaries, quality performance issues, material noncompliance with reporting obligations, inadequate resources, noncompliance with notification requirements, and many others. There is a process for reconsideration.

Coordination with Other Agencies and Other Agency Programs: As illustrated by the flurry of multiple government agencies issuing guidance or documents related to the

Shared Savings Program on the same day, all the documents cross-reference each other and promote the need for coordination among federal agencies. In addition, the proposed rule clarifies that participants must choose between the Shared Savings Program and other savings programs under Medicare Part A and B available (Independence at Home Medical Practice Demonstration program, Medicare Health Care Quality Demonstration programs, Medical home demonstrations with shared savings component (only), Physician Group Practice Transition Demonstration (but PGP sites will be transitioned into the Shared Savings Program).

Waivers from the Stark Physician Self-Referral law, the Anti-Kickback Statute, and the Civil Monetary Penalties (CMPs) law: The subject of a separate notice with comment period, the OIG and CMS propose limited waivers to each of these laws (virtually identical in content). All waivers require official participation in the Shared Savings Program (meaning execution of a 3 year agreement with CMS and compliance with that agreement). One type of waiver would protect distributions to or among ACO participants; another would protect payments or financial relationship or activities "necessary for and directly related to" the ACO's participation in the Shared Savings Program. The proposed waiver of the CMPs' prohibition of payments made to reduce or limit ***any*** items or services to beneficiaries would still prohibit the limitation of "***medically necessary***" items or services. The CMP waiver also permits any distribution to the hospital and physician being ACO participants (as well as a proposed waiver for distributions for activities necessary for and directly related to ACO's participation and operations under the Shared Savings Program). The waivers would last the term of the ACO's agreement with CMS. The government seeks comments about these proposed waivers, as well as other potential areas for waivers:

- Arrangements related to establishing the ACO,

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- Arrangements between or among ACO participants related to ongoing operations of the ACO and achieving ACO goals,
- Arrangements between the ACO and its participants and outside individuals or entities,
- Other financial arrangements for which a waiver would be necessary,
- Distribution of shared savings from private payers,
- Beneficiary inducements, and
- Use of existing exception and safe harbors (particularly as to electronic health records).

Other issues related to waivers include the duration of waivers (longer or shorter than proposed) and the timing of waivers.

Antitrust Rule of Reason and Safety Zones: The FTC and DOJ memorialize their prior position that ACOs would, in general, be subject to analysis under the rule of reason (but not in cases where price fixing or other improper activities exist), while creating a safety zone, which, like Anti-Kickback Statute safe harbors, isn't required for antitrust compliance, but fitting within a safety zone confirms compliance. ACOs not fitting into the safety zone (and having certain market share or other suspect characteristics) must request a 90-day expedited review of the proposed ACO arrangement to determine its propriety. The guidance published by the FTC and DOJ requests public comments and includes additional examples of antitrust analysis, interpretation of clinical integration, and other potential ACO characteristics or arrangements. The FTC and DOJ guidance considers that ACOs may wish to go beyond the Medicare Shared Savings Program and work with commercial payors.

IRS and Nonprofit Taxation: The IRS joins the other federal agencies in issuing guidance and a solicitation for comments as to whether existing IRS guidance sufficiently permits tax-exempt organizations to participate in ACOs under the Medicare Shared Savings Program, as well as in ACOs with commercial payors. Because tax-exempt organizations may participate in ACOs with private parties, there is the possibility that this could result in inurement or impermissible benefit to a private party, risking the tax-exempt organizations' tax status. The IRS guidance also discusses taxation of unrelated business income.

Conclusion: These publications encompass numerous pages of text, but still leave many questions (and flexibility) as to how the Shared Savings Program will operate. Fortunately, the proposed rule and other documents can be refined through future meetings and the opportunity for public comments, which were called for in the publications and their associated press conference. The remarks of Dr. Don Berwick, Administrator of CMS, at the announcement of the proposed rule summarize the government's hope for ACOs: to reform the provision of health care by reducing the adverse consequence caused by the fragmentation of payment. The goal is seamless, patient-centered care, where patients and providers are true partners. Finally, the government perceives ACOs as a win for providers and a win for patients by better aligning their interests and coordinating care. Time will tell whether ACOs will truly represent the dawning of a new age for health care.

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