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The New ACO Regs: They're Here (Well, Sort of …)

Part one in a series of client advisories focusing on the proposed ACO regulations

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The much-anticipated proposed regulations for the Medicare Shared Savings Program and accountable care organizations (ACOs) were released late last week by the Centers for Medicare & Medicaid Services (CMS), just over one year after the passage of the Patient Protection and Affordable Care Act (PPACA). In a welcomed display of federal agency coordination, CMS' proposed rules were coupled with the release of several other affiliated proposals:

- Joint CMS and U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) notice outlining proposals for a waiver of the federal Stark law, the anti-kickback statute, and certain provisions of the civil monetary penalty law in connection with the Shared Savings Program;

- Joint Federal Trade Commission and Department of Justice Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program; and

- Internal Revenue Service notice regarding the need for guidance on participation by tax-exempt organizations in the Shared Savings Program through ACOs.

CMS is requesting comment on these proposed regulations over the next 60-day period, ending on June 6, 2011.

What is perhaps most striking about this release is the extent to which CMS acknowledges the complexity of the Shared Savings Program and the conceptualization of ACOs. Given these factors, the proposed regulations, while providing a large amount of detail, are also very much a "proposal": CMS is requesting comment in connection with almost every concept. It is clear that we should expect the rules governing the formation and operation of ACOs to evolve over time. This is both a blessing and a curse given the complexity of the regulations and the substantial financial and operational investment that will be required to become an ACO.

Further, although CMS has allowed for some flexibility and discretion in the creation and operation of ACOs under the Shared Savings Program, overall, the requirements appear daunting—at least for organizations that are newly forming. Some of the highlights and areas of controversy are:

- **Application and acceptance; governance.** ACOs must complete an application and be accepted into the Program—there is no automatic acceptance, and ACOs may be terminated from the Program with financial penalties if they do not continually meet Shared Savings Program requirements. CMS has provided for a flexible governance structure, however all ACO participants, as well as beneficiaries, will be required to have representation of some sort, and a voice within the governance structure. Additionally, there are limitations on ACO involvement by certain entities, including non-Medicare providers. Such broad-based participation and involvement in governance will no doubt require further clarification in the final rule.

- **Beneficiaries may opt out.** Providers participating in an ACO will need to notify Medicare beneficiaries of their ACO affiliation, the existence of financial incentives to the provider participants, and provide the beneficiaries with the option of using a non-ACO provider. This notice is to be given at the time the beneficiary seeks care from the provider. Beneficiaries may also prohibit the sharing of their personal health data within the ACO. CMS clearly states that beneficiaries may seek care from *any* provider, reaffirming the fact that ACOs cannot be closed networks.

- **Retroactive assignment.** Under the proposed regulations CMS will retroactively assign Medicare beneficiaries to ACOs based on where the beneficiary received the plurality of his/her primary care services during the previous year. CMS believes that this retroactive assignment will encourage ACOs to approach cost savings and quality consistently for all Medicare fee-for-service beneficiaries, not just those upon whom the ACO is being evaluated.

- **Risk-sharing.** Departing in part from PPACA, CMS is introducing mandatory financial risk-sharing by ACOs. ACOs may assume a portion of down-side financial risk associated with their beneficiaries' cost of care

commencing with the ACO's participation in the Shared Savings Program. All other ACOs must assume down-side financial risk for their respective beneficiaries' cost of care in year three. The ACO's share of savings and losses will be tied to the ACO's quality scores, and its ability to take risk at the commencement of its participation in the Program. However, ACOs must achieve a minimum threshold of savings before qualifying for any portion of the shared savings. What will surely remain a burning question in many providers' minds is how to get comfort around financial risk, while simultaneously having no ability to identify with certainty their assigned beneficiaries let alone to limit or control their behavior.

- **Quality reporting and performance.** There are initially five quality domains that form the basis for determining, benchmarking, rewarding, and improving ACO quality performance: (1) patient experience of care; (2) care coordination; (3) patient safety; (4) preventive health; and (5) at-risk population/frail elderly health. Within those five domains, there are 65 quality performance measures identified for the first year of the Shared Savings Program. Additional measures will be identified and proposed, and ACOs will be expected to meet higher standards and new measures over time. ACOs will be required to report on each of the quality metrics during the first year. In years two and three quality performance standards must be met.

- **Health information technology (HIT).** Under the proposed regulations, at least 50 percent of the primary care physicians within the ACO must be "meaningful EHR [electronic health records] users" by the start of the second year in order to continue participation in the Shared Savings Program.

- **Antitrust review.** ACOs will be required to engage in a detailed analysis of their market shares and, if those shares exceed a 50 percent threshold, the ACO will have to obtain approval from the federal antitrust enforcement agencies *before* CMS will qualify them for participation in the Shared Savings Program.

- **Limited Stark, anti-kickback and CMP waivers.** CMS' and the OIG's initial proposal to create a waiver from compliance with the federal Stark law, anti-kickback statute, and the civil monetary penalty (CMP) rule is exceedingly narrow. However, the agencies are asking for additional comment on whether and how to broaden the proposed waiver in order to encourage more Program participation. Therefore, there may be a good chance the waiver will be expanded in future iterations of the rule.

There is some flexibility for providers incorporated under this proposed rule. However, CMS has clearly set the bar very high. If the requirements in the final and future rulemaking are not relaxed, the number of ACOs in the market participating in the Shared Savings Program may be far fewer than anticipated, and at the very least, it will take some time for organizations to reach a point when they can qualify for participation. The existence of these proposed rules will cause many providers to re-examine their calculations for anticipated return on investment. In the alternative, given the potential opportunities under alternative demonstration projects and commercial payor-led initiatives, organizations may decide to shift their focus and strategy.

The new regulations are detailed and complex, and will require much further in-depth analysis.

Over the next few weeks, we will be issuing a number of separate advisories focusing on specific topics raised by the new regulations and the affiliated guidance and requests for comments including:

- Antitrust
- Structure and governance
- Fraud and abuse, and waivers
- Beneficiary attributions and safeguards
- Quality metrics
- Shared savings calculations
- State law restrictions
- When things go wrong or circumstances change

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Stay tuned … and in the meantime, if you have any questions, please contact us.