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The Affordable Care Act and Accountable Care Organizations Final Regulations Released

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By Robert Slavkin, Elizabeth F. Hodge, Stephen G. Prom, and Joseph W. N. Rugg

On October 20, 2011, the Centers for Medicare & Medicaid Services (CMS) announced the Interim Final Regulations regarding the formation of accountable care organizations (ACO). As you may recall, these interim final regulations are the follow-up to the proposed regulations initially published by the government in the spring of this year. The final regulations take into account the over 1300 comments submitted to the Department before its June deadline. There have been several significant changes to various aspects of the ACO requirements. These include changes to the beneficiary assignment process, a reduction in the number of quality measures providers will be required to report, implementation of a rolling admissions process, and changes to the models of ACOs which will be implemented.

We recognize that these final regulations will spur much discussion within your organizations. The Healthcare team at Akerman stands ready to assist you as you navigate this new regulatory sea and perhaps begin the process of creating or joining an ACO. We have summarized these changes below.

Deadlines

For the as many as 6,000 groups that, reportedly, have already notified CMS of their intention to submit an application for approval of some form of ACO or other shared savings program (SSP), it is "off to the races." A quick pace is important because, under the final rule, in order to qualify to enter the April 1 or July 1, 2012 start date, applicants must have developed their programs by January 1, 2012, and qualifying applications will be due soon thereafter. Unless otherwise provided in the participation agreement ("Participation Agreement"), initial performance assessment periods ("years") beginning April or July 2012 will end December 31, 2013, hence the initial period of 18 or 21 months. The term of those Participation Agreements will end December 31, 2015. An ACO with a start date of April or July 2012 may request in its application to opt for an interim payment, based on its financial performance for the first 12 months of program participation and quality performance for its first performance year, if it timely reports its first performance year quality measures. Interim payments are conditional and subject to partial repayment if the subsequent reconciliation determines an overpayment. Participants are required to demonstrate an ability to repay if that is the case. For 2013 and all subsequent years, the start date for program participation will be January 1 of that year, a performance year will be the Calendar Year, and the term will be three (3) years.

Those groups that have timely filed notices of intent and have diligently maintained a good pace at monitoring and participating in the rulemaking process, and have developed a matrix of program mechanics, structure and quality assessment measurement tools, are ahead of the game. Those entities that have held off moving forward pending clarification of the rules and deadlines are at a disadvantage to participate prior to 2013, due to the deadlines. In any event, providers that are not involved in a successful SSP at the end of the first several three year programs should be carefully assessing and planning for the eventuality that Medicare patients may not play as important of a role in their patient mix because Medicare fee-for-service patients may be assigned to existing ACOs in the future, creating a de facto barrier to entry, or Medicare reimbursement rates may be severely reduced due to the "success" of the SSP's data. For that reason, providers not presently slated to participate in the race should consider making arrangements to join a SSP during an interim "leg."

Assignment of Beneficiaries

In response to submitted comments, CMS changed the retrospective assignment policy it proposed last spring and adopted a preliminary prospective methodology with final retrospective reconciliation to assigning beneficiaries to ACOs. Commenters were overwhelmingly in favor of prospective assignment of beneficiaries, stating among other things, that prospective assignment is necessary to allow ACOs to plan care appropriately for the patients assigned to them. CMS proposes to create a list of beneficiaries likely to receive care from an ACO based on primary care utilization during the most recent periods for which there is adequate data, and provide a copy of this list to the ACO. Beneficiaries will first be assigned to ACOs based on the utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO based on primary care services provided by other physicians. CMS slightly modified the definition of "primary care services" to include the Welcome to Medicare visit (HCPCS code G0402) and the annual wellness visits (HCPCS G0438 and G0439), in addition to these HCPCS codes included in the Proposed Rule: 99201 through 99215, 99304 through 99340, and 99341 through 99350.

During the performance year, CMS will update the list quarterly based on the most recent 12 months of data to allow the ACO to adjust to likely changes in its assigned population. At the end of each performance year, CMS will reconcile the list to reflect beneficiaries who actually meet the criteria for assignment to the ACO during the performance year. CMS will base determinations of shared savings or losses for the ACO on the final reconciled population. CMS made clear that beneficiary assignment to an ACO is for determination of the population of Medicare Fee-for-Service (FFS) beneficiaries for whose care the ACO is accountable, and for determining whether an ACO has achieved savings. The assignment in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

Lastly, the final rule states that only individuals enrolled in the original Medicare fee-for-service program under Parts A and B may be assigned to an ACO. Beneficiaries enrolled in a Medicare Advantage plan under Part C, an eligible organization under section 1876 of the Act, or a PACE program under section 1894 of the Act, cannot be assigned to an ACO.

Revised Shared Savings Models

The final rule adopts the two shared savings models as set forth in the proposed rule, but with some significant changes. First, there is the "one-sided model" which provides for shared savings among the participants during entire initial agreement period with no sharing of losses in the third year (the first "year" of the initial agreement for ACOs starting in 2012 will be 18 or 21 months). The proposed rule had required that after the first two years, an ACO choosing the one-sided model would transition into the "two-sided model," and its participants would share savings and losses during the third year. Second, there is the "two-sided model" where participants share savings and losses for the entire first agreement period.

CMS believes that accountability for losses is an important motivator for providers to change their behavior and, to reduce their unnecessary expenditures, the final rule adopts the requirement that all ACOs after their initial agreement period must be in the two-sided model. However, CMS also recognizes that many providers may not be ready to share risk, and the one-sided model is available for them. An ACO in the one-sided model which experiences a loss during the initial agreement period will be allowed to apply to remain an ACO in the two-sided model for a subsequent agreement period.

The final rule adopts the proposed rule's requirement of a minimum savings rate of 2% before there is any shared savings. ACOs in the one-sided model with a smaller population would have a larger minimum savings rate, and ACOs with a larger population would have a smaller rate. The maximum amount to be shared, subject to meeting reporting and quality requirements, is 50% for the one-sided model, and 60% for the two-sided model. Another very important change in the final rule is the elimination of the proposed 25% withhold on all shared savings; now ACOs will share in all savings after meeting the requirements.

Quality Reporting

In the proposed rule, CMS outlined a series of 65 quality measures in five (5) categories: the patient/caregiver experience; care coordination; patient safety; preventative health; and at-risk population/frail elderly health. The proposed plan required providers to report on the 65 measures listed in order for CMS to assess the quality of the care furnished by ACOs. CMS stated in the commentary to the Interim Final Rule that while a few commenters supported all 65 measures, the majority of submissions supported utilizing fewer quality measures that followed the three-part aim currently in use to encourage

participation, reduce reporting burdens and achieve more focused and meaningful improvements to the Medicare program.

Therefore, the number of quality measures was reduced from 65 in five (5) categories to 33 in four (4) categories. The four categories are: patient/caregiver experience; care coordination/patient safety; preventive health and at-risk population. Under at-risk population, there are subcategories of reporting requirements pertaining to four disease states: diabetes, hypertension; ischemic vascular disease and coronary artery disease. CMS does not intend to develop new clinical guidelines for these requirements. Rather, it is CMS' plan to utilize present guidelines for these specifications. We note that while an ACO's first 'year' of operation within this program will actually be eighteen (18) to twenty-one (21) months, per 42 CFR §425.20, quality data for the first year will be based on information reported during calendar year January 1 through December 31, 2012.

OIG Waiver

The CMS and the HHS Office of Inspector General (OIG) jointly issued an Interim Final Rule With Comment Period (IFC) addressing Final Waivers in connection with the Shared Savings Program. This Interim Final Rule establishes waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties (CMP) law provisions to specified arrangements involving ACOs, including ACOs participating in the Advance Payment Initiative. By jointly establishing waivers, CMS and OIG will provide stakeholders with a coordinated approach to the waivers of fraud and abuse laws in connection with the Shared Savings Program. The intent of the waivers is to establish pathways to protect bona fide ACO investment, start-up, operating, and other arrangements that carry out the Shared Savings Program, subject to certain safeguards.

There are five (5) waivers addressing different circumstances:

1. An "ACO pre-participation" waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program, subject to certain limitations, including limits on the duration of the waiver and the types of parties covered;

2. An "ACO participation" waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies broadly to the ACO-related arrangements during the term of the ACO's participation agreement under the Shared Savings Program and for a specified time thereafter;

3. A "shared savings distributions" waiver of the Physician Self-Referral Law, Federal anti-kickback statute and the Gainsharing CMP that applies to distributions and uses of shared savings payments

earned under the Shared Savings Program;

4. A "compliance with the Physician Self-Referral Law" waiver of the Gainsharing CMP and the Federal anti-kickback statute for ACO arrangements that implicate the Physician Self-Referral Law and meet an existing exception; and

5. A "patient incentive" waiver of the Beneficiary Inducements CMP and the Federal anti-kickback statute for medically related incentives offered by ACOs under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimens.

The shared savings distributions waiver and the compliance with the Physician Self-Referral waiver were included in the earlier Waiver Designs Notice while the other three waivers were developed in response to public comments. The waivers apply uniformly to each ACO, ACO participant and ACO provider/supplier participating in the Shared Savings Program. Apart from meeting the applicable waiver conditions, parties do not need to take any additional action to be covered by a waiver, i.e., parties do not need to submit a separate application for a waiver.

An arrangement need only fit in one waiver to be protected. In some cases, an arrangement may meet the criteria of more than one waiver. CMS and OIG say that it is not feasible at this time to enumerate specific protected arrangements given the anticipated wide variation in ACO composition, size, resources and readiness, as well as the goal of fostering innovation, adaptability, and variation in furtherance of quality, efficiency and economy. Failure to fit in waiver is not necessarily a violation of the laws. Existing exceptions and safe harbors might apply to ACO arrangements, depending on the circumstances.

The agencies are seeking comments about the waivers set forth in the IFC. Comments are due sixty days after the IFC is published in the Federal Register.

Other Agencies' Input

Additionally, along with the CMS release:

The Federal Trade Commission and Department of Justice issued a joint Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program regarding the application and enforcement of antitrust laws for ACOs. The final statement applies to all collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Medicare shared savings program (the proposed statement only applied to collaborations formed after March 23, 2010). Also, CMS has withdrawn its proposed requirement that certain ACO applicants be reviewed for antitrust compliance as a

condition of entry into the Shared Savings Program.

Internal Revenue Service issued Fact Sheet FS-2011-11 confirming that its Notice 2011-20 continues to reflect IRS expectations regarding the Medicare Shared Savings Program and ACOs and providing additional information for charitable organizations that may wish to participate in the program.