

**Analysis and Overview of the
Medicare Shared Savings Program for
Accountable Care Organizations**

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Analysis and Overview of the Medicare Shared Savings Program for Accountable Care Organizations

Forward

The Medicare Shared Savings Program (“MSSP” or “Shared Savings Program”) offers potential opportunities as well as risks to health care providers and suppliers. The immediate challenge for most health care providers and suppliers is to fully understand the final rule governing participation in the program in order to uncover those opportunities, and to minimize and protect against risks as the Shared Savings Program and similar payment models continue to develop. The core principle of the Medicare Shared Savings Program is simple: reward specific improvements in quality and cost containment through a share of the estimated savings that result from these efforts. Although the principle behind the Shared Savings Program may be straightforward, the regulatory requirements for participating in the program and being eligible for the financial rewards are much more complex, to say nothing of the administrative complexities of actually implementing procedures required to achieve “accountable care.”

The rule proposing the establishment of the Medicare Shared Savings Program was met with skepticism and a significant amount of criticism from stakeholders. Many health care providers and suppliers were surprised by the rigid and prescriptive nature of the proposed rule and the unlikely odds in achieving any financial return on an investment in the program. In the preamble to the final rule establishing the Medicare Shared Savings Program, the Centers for Medicare & Medicaid Services (“CMS”) uses the term “prescriptive” 13 times in describing the programmatic requirements. In some of these instances, CMS defends itself against assertions that the rule is overly prescriptive and in other instances CMS acknowledges that some stakeholders requested a more prescriptive approach to specific aspects of the program. Whether CMS has struck a balance between these competing interests—flexibility and prescriptive direction—in the final rule is yet to be seen, but it is clear that the final rule offers many significant improvements over the proposed rule. Notably, the final rule relaxes numerous policy and operational requirements suggested in the proposed rule, including, among other things: (1) removing downside risk from one track during the initial agreement period; (2) modifying how beneficiaries are assigned to an accountable care organization (“ACO”); (3) limiting the establishment and measurement of quality standards; and (4) revising the calculation of incentive payments.

For a reader whose time is limited, this *Client Alert* first provides a short executive summary and analysis of those provisions of the final rule and the companion guidance that we believe are of greatest interest to health care providers and medical device and pharmaceutical manufacturers. For those readers with more time or with an interest in particular aspects of the Medicare Shared Savings Program, we also provide a full summary of the MSSP final rule, detailing changes from the MSSP proposed rule, discussing CMS’s response to the public’s comments, identifying the practical impact of the final rule, and flagging questions and concerns regarding the final rule.

For readers with specific concerns related to compliance matters, this *Client Alert* summarizes the jointly issued CMS and OIG rulemaking waiving the Stark physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law under specified circumstances. Then, this *Client Alert* examines the jointly issued FTC/DOJ final Antitrust Policy Statement. Finally, this *Client Alert* provides a brief overview of the IRS's fact sheet "Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care."

We would be pleased to provide further analyses for individuals or organizations considering participation in the Medicare Shared Savings Program, or to provide guidance to potential ACOs as they apply to, implement, or participate in the Medicare Shared Savings Program.

Introduction and Executive Summary of Changes in the Final Rule

The Patient Protection and Affordable Care Act ("PPACA"), enacted in March 2010, requires that the Secretary ("Secretary") of the Department of Health & Human Services ("HHS") establish a Medicare "Shared Savings Program" by January 1, 2012.¹ The Medicare Shared Savings Program is intended to encourage physicians, hospitals, and certain other types of providers and suppliers to form accountable care organizations ("ACOs") to provide cost-effective, coordinated care to Medicare beneficiaries. At a basic level, an ACO is a network of physicians, hospitals, and other health providers that work together to improve the quality of health care services and reduce costs. The PPACA set forth the foundation of the ACO program under Medicare, but Congress, instead of establishing the details of the program in the statute, authorized the Secretary to determine the parameters of the Shared Savings Program through rulemaking. Physicians, hospitals, physician groups, other providers, policymakers, and many other stakeholders in the health care industry eagerly anticipated the issuance of the ACO final rule. On October 20, 2011, under the authority of the Secretary, the CMS issued the final rule.

The MSSP final rule responds to comments and concerns raised by the public in response to the April 7, 2011 proposed rule on this subject.² CMS received approximately 1,320 comments in response to the MSSP proposed rule. The final rule made a number of notable changes to the proposed rule, including the following:

- CMS had initially proposed two program "tracks" for calculating savings. In Track 1, an ACO would share in only the savings for the first two years, and would be required to

¹ See 42 U.S.C. § 1395jjj.

² See our previous Client Alert, Summary and Analysis of Medicare's Shared Savings Program for Accountable Care Organizations, available at <http://www.healthindustrywashingtonwatch.com/2011/04/articles/regulatory-developments/summary-and-analysis-of-medicare-shared-savings-program-for-accountable-care-organizations/>.

- assume the risk for shared losses in the third year. In Track 2, an ACO would share in savings and risk liability for losses beginning in its first performance year, in return for a higher share of the savings it generates. Under the final rule, participating ACOs still will have the choice of two “tracks” with regard to savings, but Track 1 will not have downside risk; that is, Track 1 participants will only share savings, not losses. The final rule stipulates that after the initial agreement period, if an ACO voluntarily continues to participate in the Medicare Shared Saving Program, it must participate in Track 2, which has a higher sharing rate but also has downside risk.
- CMS is also modifying the method of assigning beneficiaries to the ACO for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable and for determining whether an ACO has achieved savings. CMS had proposed retrospective assignment based on utilization of primary care services with prospective identification of a benchmark population. Under the final rule, CMS will conduct a preliminary prospective assignment of beneficiaries to an ACO. CMS will quarterly provide ACOs with aggregate reports on preliminary prospective assignment, which will include the names, dates of birth, sex, and health insurance claim numbers of beneficiaries that, based on historical data, would be assigned to the ACO. CMS will conduct a final reconciliation of assigned beneficiaries after each performance year based on actual patient utilization.
 - Instead of 65 measures to assess ACO quality in five “domains,” the final rule adopts 33 measures in four domains. In addition, pay for quality performance will be phased in gradually over the ACO’s first agreement period.
 - Under both Track 1 and Track 2, if an ACO meets certain quality standards and otherwise maintains eligibility to participate in the Shared Savings Program, it will share savings with Medicare from the first dollar saved as long as the minimum savings rate has been reached.
 - CMS expanded the entities eligible to form and participate in an ACO to include Federally Qualified Health Centers and Rural Health Clinics.
 - The first ACO agreements will have start dates of either April 1, 2012 or July 1, 2012, and the first performance “year” will be 18 or 21 months. The final rule does not specify application deadlines; instead, CMS has already released sub-regulatory guidance laying out the applicable deadlines.
 - CMS has released information regarding the application process for the Shared Savings Program for the April 1, 2012 or July 1, 2012 start dates. Information regarding applications for potential ACOs wishing to participate in the Shared Savings Program is available on CMS’s website at: https://www.cms.gov/sharedsavingsprogram/37_Application.asp#TopOfPage. The following chart documents the important Notice of Intent (“NOI”) and application

dates. However, CMS notes that the dates are subject to change, and encourages potential applicants to check its website frequently for updates.

NOIs accepted	Nov 1, 2011 - Jan 6, 2012	Nov 1, 2011 - Feb 17, 2012
CMS User ID forms accepted	Nov 9, 2011 - Jan 12, 2012	Nov 9, 2011 - Feb 23, 2012
2012 applications accepted	Dec 1, 2011 - Jan 20, 2012	Mar 1 - 30, 2012
2012 application approval or denial decision	March 16, 2012	May 31, 2012
Reconsideration review deadline*	March 23, 2012	June 15, 2012
*Date an organization must receive a favorable reconsideration review determination in order to qualify for the start date indicated on the application.		

- ACOs starting either April 1, 2012 or July 1, 2012 will have the option to receive an interim payment if they report CY 2012 quality measures. All ACOs participating in the Medicare Shared Savings Program with April 1, 2012 or July 1, 2012 start dates must report quality measures for CY 2013 to qualify for shared savings in the first performance “year.”
- The proposed rule would have required that 50 percent of primary care physicians be defined as meaningful electronic health record users by the start of the second performance year, but the final rule removed this requirement.
- The final rule modifies the process of assigning beneficiaries to a two-step process. If a beneficiary has received primary care services from a primary care physician, ACO assignment is made based on which primary care physician accounts for the plurality of a beneficiary’s “allowed charges” for primary care services. If a beneficiary has not received any primary care services from a primary care physician, assignment is based on which ACO professional (such as a specialist) accounts for the plurality of a beneficiary’s “allowed charges” for primary care services.

In addition to the MSSP final rule released by CMS, the federal government released several other documents related to ACOs on October 20, 2011, including:

- CMS and the Office of Inspector General (“OIG”) jointly issued an interim final rule with comment period titled “Final Waivers in Connection With the Shared Savings Program” (www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27460.pdf). The document establishes the conditions for waivers of certain provisions of the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law in connection with specific arrangements developed pursuant to the MSSP. The interim final rule sets forth five waivers addressing: (1) start-up arrangements; (2) ACO-related arrangements during the term of the ACO’s participation agreement; (3) distribution of

- the shared savings; (4) compliance with exceptions under the physician self-referral law; and (5) the civil monetary penalty law's prohibition on beneficiary inducement.³
- CMS also released a notice announcing an Advance Payment Model (the "Model") within the Shared Savings Program framework (www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27458.pdf). Only certain ACOs participating in the Medicare Shared Savings Program (namely, physician-owned organizations, critical access hospitals, and rural providers participating in the MSSP) can participate in this Model. The Model is designed to test whether pre-payment could improve the coordination of care and generate Medicare savings more quickly and to a greater extent. Further, the Model is structured to test whether and how pre-payment of future shared savings could bolster physician-owned and rural provider participation in the Medicare Shared Savings Plan. Selected ACOs will receive three types of payments: (1) an upfront, fixed payment; (2) an upfront, variable payment; and (3) a monthly payment of varying amount depending on of the number of Medicare beneficiaries historically attributed to the ACO.
 - The Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") jointly issued a final Antitrust Policy Statement titled, "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (<http://www.federalregister.gov/articles/2011/10/28/2011-27944/statement-of-antitrust-enforcement-policy-regarding-accountable-care-organizations-participating-in>). In the final Policy Statement, the agencies clarify that the policy applies to all provider collaborations that are eligible and intend, or have been approved, to participate in the MSSP, not only collaborations formed after March 23, 2010. In addition, the final Policy Statement no longer contains provisions relating to a mandatory antitrust review. Corresponding to the aforementioned change, the MSSP final rule no longer requires a mandatory antitrust review for certain collaborations as a condition of entry into the MSSP.⁴
 - The Internal Revenue Service ("IRS") issued a fact sheet titled "Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care" (FS-2001-11) (<http://www.irs.gov/newsroom/article/0,,id=248490,00.html>) providing guidance on ACO participation by tax-exempt organizations. In the fact sheet, the IRS confirms that

³ The jointly issued CMS/OIG interim final rule with comment period establishing the conditions for waivers of certain provisions of the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law in connection with specific arrangements developed pursuant to the MSSP, was also published in the November 2, 2011 issue of the *Federal Register*. 76 Fed. Reg. 68012 (Apr. 7, 2011).

⁴ The jointly issued FTC/DOJ final Antitrust Policy Statement was published in the October 28, 2011 issue of the *Federal Register*. 76 Fed. Reg. 67026 (Oct. 28, 2011).

the guidance provided in its Notice 2011-20 issued April 18, 2011 continues to reflect the agency's expectations for participation in the MSSP. The fact sheet also responds to a number of frequently asked questions.

While the PPACA mandates that CMS "establish" the Shared Savings Program no later than January 1, 2012, CMS has indicated that it will begin accepting applications for the Shared Savings Program January 1, 2012, but the scheduled start dates will be April 1, 2012 and July 1, 2012. Applications for participation in the Shared Savings Program are available at http://www.CMS.gov/sharedsavingsprogram/37_Application.asp.

Concerns with the Shared Savings Program

If the Shared Savings Program under Medicare is successful, it is likely that the ACO model, or a similar model that results in more effective payment and service delivery, will spread to other institutions that pay for health care and the patients those institutions cover. In fact, a number of states and private insurers already have adopted or are considering ACO programs.⁵ In a February 3 letter to governors, the Secretary of HHS, Kathleen Sebelius, urged states to use the ACO model in their Medicaid programs.⁶ Further, the PPACA established a pediatric ACO demonstration project and authorized the Center for Medicare and Medicare Innovation ("CMMI" or "Innovation Center") to test other payment and service delivery models.⁷ Under the Innovation Center's authorization to test other payment and service delivery models, the Innovation Center has developed the Pioneer ACO Model and the Bundled Payments for Care Improvement Initiative, among other initiatives. The introduction of a constellation of value-based payment initiatives, such as the MSSP, by both federal and state governments and private payers, suggests, at the very least, the government's and the market's desire to explore different payment models.

There are a number of potential concerns to consider when reviewing the final rule. First, one premise of the ACO model is that physicians and other providers will work together to reduce unnecessary services. However, any shared savings achieved by an ACO might not offset revenue lost from the reduced patient utilization of services. In addition, to establish a

⁵ See, e.g., Cigna, CIGNA's Collaborative Accountable Care Programs Improving Quality and Reducing Costs, http://newsroom.cigna.com/NewsReleases/CIGNA-s-Collaborative-Accountable-Care-Programs-Improving-Quality-and-Reducing-Costs.htm?view_id=3897; S. Bill 807, 88th Leg., Reg. Sess. (Ark. 2011).

⁶ See Letter from Kathleen Sebelius, Secretary, Department of Health & Human Services, to Governors, available at <http://www.hhs.gov/news/press/2011pres/01/20110203c.html>. Note that § 2706 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, authorizes a pediatric accountable care organization demonstration project.

⁷ 42 U.S.C. § 1396a note.

successful ACO under the MSSP's parameters will likely require a significant investment of time, effort and money. In fact, in the final rule, CMS estimates that an average ACO participating in the Shared Savings Program will spend \$580,000 in start-up investment costs and \$1.27 million in ongoing annual operating costs.⁸ Even after spending the expected start-up investment costs and ongoing operating costs, there is no guarantee that an ACO will achieve savings. An additional issue related to the formation of an ACO is that the reporting requirements under the statute essentially mandate data systems and an organizational structure that small providers might not have the resources to create.

An ACO's quality performance score will have a significant impact on whether it qualifies for a shared savings payment and the amount of the shared savings it receives. Accordingly, providers and suppliers considering participation in an ACO should carefully consider whether the proposed ACO can report and exceed the minimum threshold of performance in the quality measures. CMS finalized 33 required quality measures for year one, with the potential for new measures to be identified in future rulemaking. Because the quality measures identified by CMS determine, in part, potential savings achieved by an ACO, providers and suppliers that choose to form an ACO are likely to devote significant resources to achieving the specific benchmarks identified by CMS and adapting to new benchmarks as CMS changes the quality measures over time.

In the final rule, CMS estimates that between 50 and 270 ACOs will participate in the Shared Savings Program.⁹ Because it seems evident that the Shared Savings Program will evolve over time, the experiences of the first ACOs participating in the program will shape the future of the program. Therefore, while it would be beneficial to have robust participation in the Shared Savings Program to best inform future changes to the program, some potential ACOs might be reluctant to participate in the first round of the MSSP, knowing that the program will evolve over time.

The final rule lacks specific references to certain types of providers, such as post-acute care providers. This lack of references may be attributed to the CMS's stated desire to "to allow for greater flexibility regarding the specific structure and requirements of an ACO." Nevertheless, the lack of specific guidance for certain types of providers may complicate the development and implementation of a meaningful role for certain types of providers in the Shared Savings Program. However, it is notable that the final rule requires an ACO to submit to CMS a description of how the ACO will implement certain "patient-centeredness criteria" required to participate in the MSSP. The final rule describes the criteria an ACO must meet in order to be considered "patient-centered" under the MSSP. According to the final rule, the ACO must

⁸ 76 Fed. Reg. 67802, 67969 (Nov. 2, 2011).

⁹ 76 Fed. Reg. 67802, 67962 (Nov. 2, 2011).

“define, establish, implement, evaluate, and periodically update processes to... [c]oordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers.”¹⁰ The above quoted provision contains the strongest language regarding an ACO’s potential inclusion of various provider types.

Despite concerns regarding participation in the Medicare Shared Savings Program, there are other considerations in deciding whether to create or participate in an ACO. Physicians may have an incentive to join an ACO because “savings” achieved by an ACO will be created by decreased hospital utilization and costs (i.e., decreased Medicare Part A expenditures)—but physicians are unlikely to see decreased utilization of their services (i.e., Medicare Part B expenditures and reimbursement will stay the same) and will receive share in the savings achieved by an ACO through any decreased hospital utilization. Hospitals may have an incentive to join ACOs because they wish to reduce hospital readmissions or improve other quality measures that may become increasingly important to their reimbursement. In the alternative, a hospital facing decreased utilization by Medicare patients as a result of successful participation in an ACO may be able to open beds to non-Medicare patients—this could also provide an incentive to join an ACO.

It is likely that some, if not most, of the ACOs applying to participate in the Shared Savings Program will already have the structure and infrastructure necessary for successful, profitable participation in the Shared Savings Program. For other providers and suppliers considering joining an ACO or forming an ACO, the significant start-up costs and ongoing expenses, paired with questionable financial rewards, may make the Shared Savings Program less attractive than other, innovative payments models such as the Bundled Payments for Care Improvement Initiative. Therefore, providers and suppliers considering participation in or the formation of an ACO may wish to further explore and weigh the costs and benefits of other Medicare payment models currently being implemented by CMS.

The Medicare Shared Savings Final Rule - Detailed Review and Analysis

Introduction and Important Definitions

Introduction

In the preamble to the final rule, CMS briefly describes the three-part aim of the MSSP and refers readers to the proposed MSSP rule for a full discussion of the goals of value-based purchasing. The Shared Savings Program has a three-part aim that consists of the following:

- Better care for individuals
- Better health for populations
- Lower growth in Medicare Part A and B expenditures

¹⁰ 42 C.F.R. § 425.112 (2011).

In introducing the final rule, CMS remarked that it received approximately 1,320 public comments in response to the proposed MSSP rule. CMS explained that, in general, negative comments focused on the overly prescriptive and burdensome nature of the proposed rule. In response to these concerns, the final rule’s preamble states, “Where possible we have tried to reduce or eliminate prescriptive or burdensome requirements that could discourage participation in the Shared Savings Program.”¹¹ Although the final rule provides significantly more flexibility, the Medicare Shared Savings Program is a rules-based government program with highly specific parameters. Participants that fail to meet these parameters may be terminated from the program or be required to adopt corrective actions.

Important Definitions

CMS uses the following defined terms that are particularly important to understanding the Shared Savings Program:

- **Accountable care organization (ACO):** a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a Taxpayer Identification Number (“TIN”), and is formed by one or more eligible ACO participants.¹²
- **ACO participant:** an individual or group of ACO provider(s)/supplier(s), that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants that is provided to CMS in the ACO’s application.¹³
- **ACO provider/supplier:** an individual or entity that—(1) is a provider or a supplier; (2) is enrolled in Medicare; (3) bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) is included on the list of ACO providers/suppliers that is provided to CMS in the ACO’s application.¹⁴
- **ACO professional:** an ACO provider/supplier who is either of the following: (1) A physician legally authorized to practice medicine and surgery by the state in which he performs such function or action.; (2) A practitioner who is one of the following: (i) A physician assistant; (ii) A nurse practitioner; (iii) A clinical nurse specialist.

¹¹ 76 Fed. Reg. 67802, 67804 (Nov. 2, 2011).

¹² 42 C.F.R. § 425.20 (2011).

¹³ *Id.*

¹⁴ *Id.*

Establishing an Agreement with the Secretary

Start Date Options

Responding to concerns about the feasibility of a January 1, 2012 start date, CMS will accept applications for two potential start dates in 2012: April 1, 2012 and July 1, 2012. The agreement period for ACOs with either of the 2012 start dates will end December 31, 2015. CMS indicated that it would provide additional, subregulatory guidance regarding the application process and deadlines for the 2012 start dates. CMS has published this application information at: https://www.cms.gov/sharedsavingsprogram/37_Application.asp#TopOfPage. For ACOs that have an April 1, 2012 start date, the first “performance year” will be 21 months, ending December 31, 2013. For ACOs that have a July 1, 2012 start date, the first “performance year” will be 18 months, ending December 31, 2013. The subsequent performance years will be 12 months in duration.

Timing and Process for Evaluating Shared Savings

When participating in the Shared Savings Program, an ACO will be eligible to receive shared savings for each year of the agreement period if it meets the quality measure and savings requirements. In the preamble to the proposed rule, CMS debated utilizing a three-month or a six-month run-out period¹⁵ to evaluate shared savings. There is an inherent delay between the time when a service or supply is furnished to a Medicare beneficiary and when the claim for that service or supply is submitted to CMS. A longer run-out period allows for more complete and accurate utilization and expenditure data, but would also delay the evaluation of shared savings.

The final rule determines that a three-month run-out period will be utilized to calculate the benchmark and per capita expenditures for a performance year, with the application of an appropriate “completion percentage.”¹⁶ The completion percentage is designed to account for claims that are not yet complete after the three-month lag.

Which New Program Standards ACOs are Expected to Adopt During Their Participation in the Shared Savings Program

In the proposed rule, CMS argued the merits of requiring an ACO to comply with regulatory changes made to the Shared Savings Program during an ACO’s agreement period. Under the final rule, ACOs will be responsible for complying with all regulatory changes, such as changes to the quality measures, with the exception of: eligibility requirements concerning the structure

¹⁵ The claims run-out period is the time between when a Medicare-covered service has been furnished to a beneficiary and when the final payment is actually issued for the respective service.

¹⁶ 76 Fed. Reg. 67802, 67838 (Nov. 2, 2011).

and governance of ACOs, how sharing rates are calculated, and how beneficiaries are assigned. In order to inject flexibility into the requirement that ACOs comply with modified regulatory standards, the final rule allows an ACO to voluntarily terminate its agreement in instances where regulatory changes are made that the ACO believes will impact of the ability of the ACO to continue to participate in the Shared Savings Program.

What Happens if an ACO Has Significant Changes During Agreement Period

An ACO may experience significant changes to its structure during an agreement period. For example, ACO participants may drop out of the ACO; an ACO's eligibility to participate in the Shared Savings Program may change; and the government or court could order the reorganization of an ACO. In the proposed rule, CMS listed possible actions it may take in response to a "significant change," and suggested that an ACO must notify CMS at least 30 days in advance of a "significant change."

According to the final rule's preamble language, CMS received more comments about the management of significant changes to an ACO during an ACO's agreement period than any other proposal. In response to these comments, the final rule allows ACOs to add or subtract ACO providers/suppliers during the course of an agreement period, but ACOs must notify CMS within 30 days of these changes. In addition, ACOs must notify CMS within 30 days of any "significant change," defined as "an event that occurs resulting in an ACO being unable to meet the eligibility or program requirements of the Shared Savings Program."¹⁷ A significant change could result in, for example, adjustments to an ACO's benchmark or an ACO's termination from the Shared Savings Program.

Analysis and Potential Issues for Applicants

- The final rule requires that ACOs comply with modifications made to the Shared Savings Program's regulatory scheme, with limited exceptions. Thus, during the agreement period, an ACO could face changes in the quality performance standards, mandated processes for quality management and patient engagement, and patient-centeredness requirements. The regulatory changes CMS imposes as the Shared Savings Program progresses could increase the burden of participation in the Shared Savings Program. While an ACO would have the ability to terminate its agreement if any regulatory changes occur that effect the ACO's ability to participate in the Shared Savings Program, an ACO may have already invested significant time, money, and effort into the creation and development of the ACO.

¹⁷ 76 Fed. Reg. 67802, 67839 (Nov. 2, 2011).

- The start dates of April 1, 2011 and July 1, 2011, combined with the quality requirements in the first performance year of an ACO's participation in the Shared Savings Program (that an ACO report all required quality measures completely and accurately), allow an ACO to "ramp up" to the Shared Savings Program's quality measures requirements. However, because an ACO is required to report on all quality measures during its first performance year, an ACO must have the resources to report such quality measures prior to commencement in the Shared Savings Program. As a consequence, an ACO must have the tools necessary for quality reporting and must be prepared to quickly implement a process for quality reporting during the first performance year.
- If an ACO would like to participate in the Shared Savings Program and start participation in 2012, it must submit a Notice of Intent no later than 5 p.m. EST on the dates noted below. The submission of an NOI does not obligate a potential applicant to apply to the Shared Savings Program, but failing to submit an NOI will preclude an ACO from being able to apply to the Shared Savings Program. For a start date of April 1, 2012, CMS must receive an NOI from potential applicants by 5 p.m. January 6, 2012. For a start date of July 1, 2012, CMS must receive an NOI from potential applicants by 5 p.m. February 17, 2012. Note that these dates are subject to change, and that potential applicants should visit CMS's website, at https://www.cms.gov/sharedsavingsprogram/37_Application.asp#TopOfPage, for further information and up-to-date deadlines.

Eligibility to Form ACOs, Legal Structure, Governance, Leadership and Management Structure, and Operations

General Requirements

There are several "general requirements" for ACOs participating in the MSSP. These general requirements include: the ACO must certify its accountability for beneficiaries; an ACO's authorized executive must sign an MSSP participation agreement between CMS and the ACO; an ACO must serve a population of at least 5,000 Medicare beneficiaries during the course of its agreement period; and an ACO must identify the TINs and NPIs of ACO participants on its MSSP application, and provide updates to CMS if the list of ACO participants changes.

There are a few notable aspects to the general requirements for ACO participation in the Shared Savings Program. First, if the number of Medicare beneficiaries assigned to an ACO dips below the 5,000 beneficiary threshold required by statute in any given performance year, CMS will issue a corrective action plan ("CAP") to the ACO. However, if the number of beneficiaries assigned to the ACO remains below 5,000 at the completion of the performance year after CMS issues the corrective action plan, the ACO will be terminated from the Shared Savings Program.

Second, CMS clarified the exclusivity of providers necessary for the assignment process, explaining that ACOs will identify ACO participants through taxpayer identification numbers or TINs, not the National Provider Identifiers (“NPIs”), which allows a physician to participate in more than one ACO. In the proposed rule, CMS stated that an ACO participant on whom beneficiary assignment is based must be exclusive to one ACO. CMS, in the final rule, acknowledged that the program “does not necessarily require exclusivity of each primary care physician (ACO provider/supplier) whose services are the basis for such assignment. For example, exclusivity of an ACO participant leaves individual physicians free to participate in multiple ACOs if they bill under several different TINs. Similarly, an individual physician can move from one ACO to another during the agreement period, provided that he or she has not been billing under an individual TIN.”¹⁸

The final rule’s preamble further explains that solo practitioners on whom ACO assignment will be based cannot participate in more than one ACO unless as a participant in an additional ACO, the solo practitioner will be billing under a different TIN.

Distribution of Shared Savings

The final MSSP rule specifies that CMS will distribute any shared savings an ACO achieves directly to the ACO as identified by its TIN. While the final rule does not prescribe how savings must be distributed, it does require that a potential ACO describe in its application how “it plans to use potential shared savings to meet the goals of the program.”¹⁹ Accordingly, ACO participants must negotiate among themselves how to distribute shared savings or use the shared savings to invest in programs and technology to improve the coordination of care.

Legal Structure and Governance

Legal Entity

An ACO must be a legal entity that is recognized and authorized to conduct its business under applicable state law and is capable of: (1) receiving and distributing shared savings; (2) repaying shared losses; (3) establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including quality performance standards; and (4) performing other ACO functions identified in the statute.

The preamble of the final rule stipulates that CMS will not require that existing legal entities appropriately recognized under state law form a new and separate legal entity to participate in the Shared Savings Program. As an example, a hospital employing ACO professionals may be eligible to participate as an ACO in the Shared Savings Program without developing a new

¹⁸ 76 Fed. Reg. 67802, 67810-11 (Nov. 2, 2011).

¹⁹ 76 Fed. Reg. 67802, 67816 (Nov. 2, 2011).

legal entity. However, CMS further states that if an existing entity would like to incorporate providers and suppliers that are not currently part of its existing legal structure, the entity must establish a new legal entity in order to provide all ACO participants with a mechanism for shared governance and decision making.

In its Shared Savings Program application, a proposed ACO would be required to provide evidence that it is recognized as a legal entity in the state in which it was established, and that it is authorized to conduct business in each state in which it operates.

Mechanism for Shared Governance

An ACO is required to establish and maintain a governing body such as a board of directors, board of managers, or any other governing body that provides a mechanism for shared governance and decision making for all ACO participants. An ACO would not need to form a new and separate governing body, as long as its current governing body is able to meet all other criteria required for an ACO governing body. If an entity is not forming a new governing body, it would be required to show, in its application, that it meets all other criteria required for ACO governing bodies.

Despite objections to its proposal, CMS finalized the requirement that an ACO be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries, and specifically that ACO participants must have at least 75 percent control of the ACO's governing body. However, CMS did not finalize its proposal to require an ACO's governing body to have "proportionate control for ACO participants, giving each ACO participant a voice in the ACO's decision making process."²⁰ In the preamble to the final rule, CMS confirms that the rule does not stipulate how the voting control will be apportioned among ACO participants.

At least one Medicare beneficiary served by the ACO who has no conflict of interest (and no family member with a conflict of interest) must serve on the governing body.

The final rule permits an ACO to request an exception to the rule's governing body requirements. To receive an exception, the ACO must describe: (1) why it seeks exemption from these requirements; and (2) how the ACO will involve ACO participants in innovative ways in ACO governance, or provide meaningful representation in ACO governance by Medicare beneficiaries, or both.

Leadership and Management Structure

An ACO must have a leadership and management structure that includes clinical and administrative systems. Thus, an ACO must meet the following criteria: (1) have an executive,

²⁰ 76 Fed. Reg. 19528, 19541 (Apr. 7, 2011).

officer, manager, or general partner who manages operations, whose appointment and removal are under control of the organization's governing body, and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes; (2) have a senior-level medical director who would manage clinical management and oversight; (3) participants must have a meaningful commitment to the ACO's clinical integration, through a meaningful financial investment or a meaningful human investment; (4) have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program; (5) develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of the proposed regulation; and (6) have an infrastructure, such as information technology, that allows the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization.

ACOs with "innovative leadership and management structures" may apply for an alternative leadership and management structure than what is described above, but they must describe in their application how the ACO will perform the leadership and management functions without the specific leadership regime the rule outlines.

Assigning Medicare Beneficiaries to ACOs

Introduction

General Introduction

The statutory language establishing the Shared Savings Program mandates that CMS assign beneficiaries to ACOs "based on their utilization of primary care services" provided by a physician.²¹ However, the statute left CMS with the discretion to determine the specifics of the assignment process, such as what primary care services were, and what level of utilization was required for assignment.

The final rule lays out a two-step process for assignment. As a preliminary step, CMS identifies all beneficiaries who received primary care services, as defined by the final rule, with a physician who is an ACO provider. Then, as a first step, CMS will assign beneficiaries to an ACO based on the utilization of primary care services provided by primary care physicians. Beneficiaries will be assigned to ACOs based on the plurality of a beneficiary's allowed charges for primary care services. Next, as a second step, if a beneficiary has not received any primary care services from a primary care physician, it can be assigned to an ACO based on the primary care services provided by any other type of physician, such as a specialist. However, the second step takes into account the allowed charges for primary care services provided by any ACO professionals, including nurse practitioners and physician assistants. Thus, under the second

²¹ 42 U.S.C. 1395jjj(c) (2011).

step, a beneficiary will be assigned to an ACO if his or her allowed charges for primary care services from any ACO professionals, including physicians, nurse practitioners, and physician assistants, are greater than the allowed charges for any ACO professionals associated with another ACO or not associated with an ACO at all.

Beneficiary Exercise of Free Choice

CMS characterizes beneficiary assignment under the Shared Savings Program as an “alignment,” which emphasizes the exercise of free choice by beneficiaries in determining which providers and suppliers to utilize. In fact, the final rule codifies the idea of a beneficiary’s exercise of free choice with respect to ACOs, stating, in § 425.400(b), “Beneficiary assignment to an ACO . . . 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.”

What Beneficiaries May Be Assigned to ACOs

Only certain Medicare beneficiaries may be assigned to an ACO, namely individuals enrolled in the original fee-for-service program under Medicare Parts A and B. Dual-eligible individuals enrolled in the original Medicare FFS program may also be assigned to ACOs. However, Medicare beneficiaries enrolled in a Medicare Advantage plan under Medicare Part C or a PACE program cannot be assigned to an ACO.

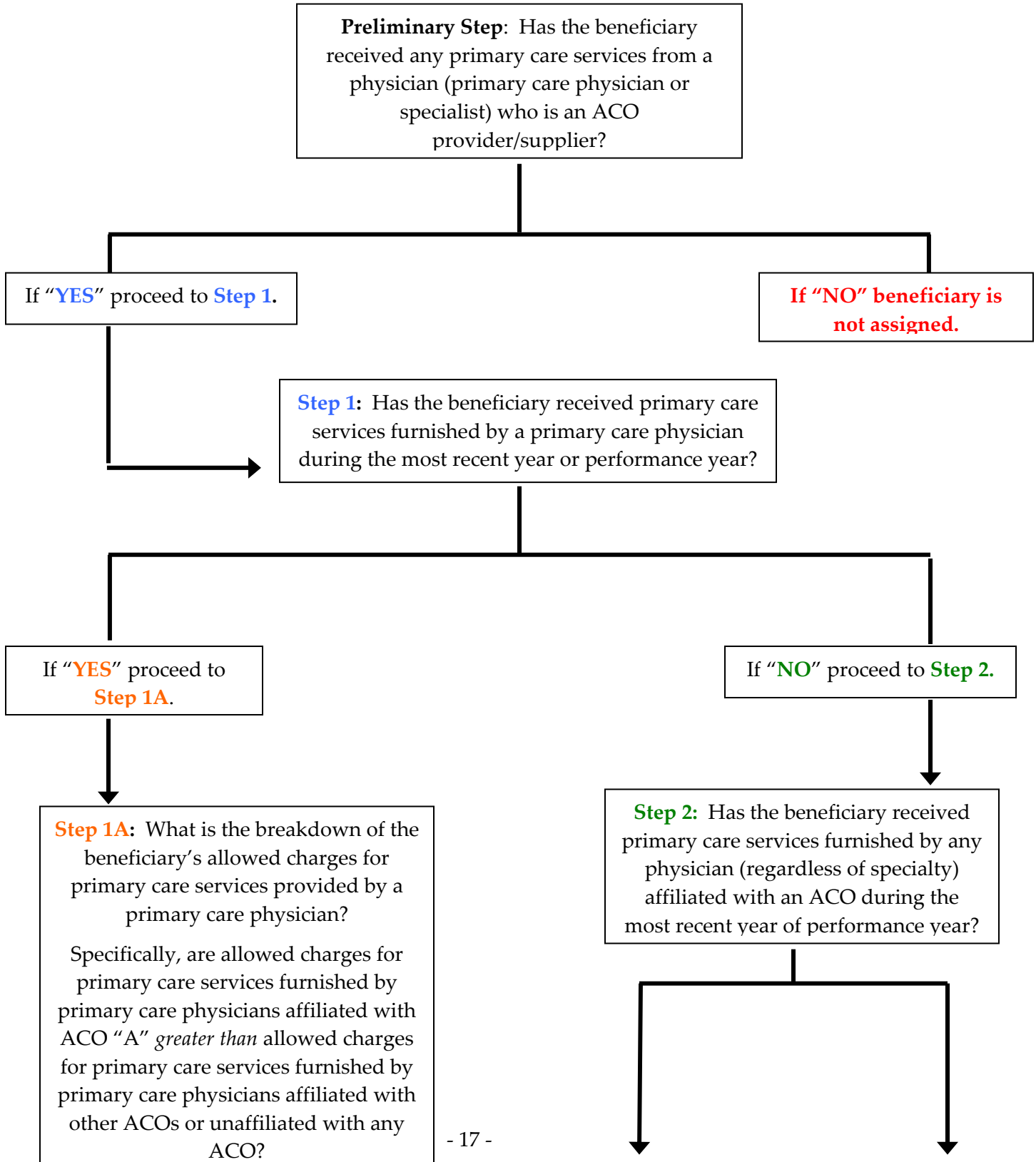
Definition of Primary Care Services

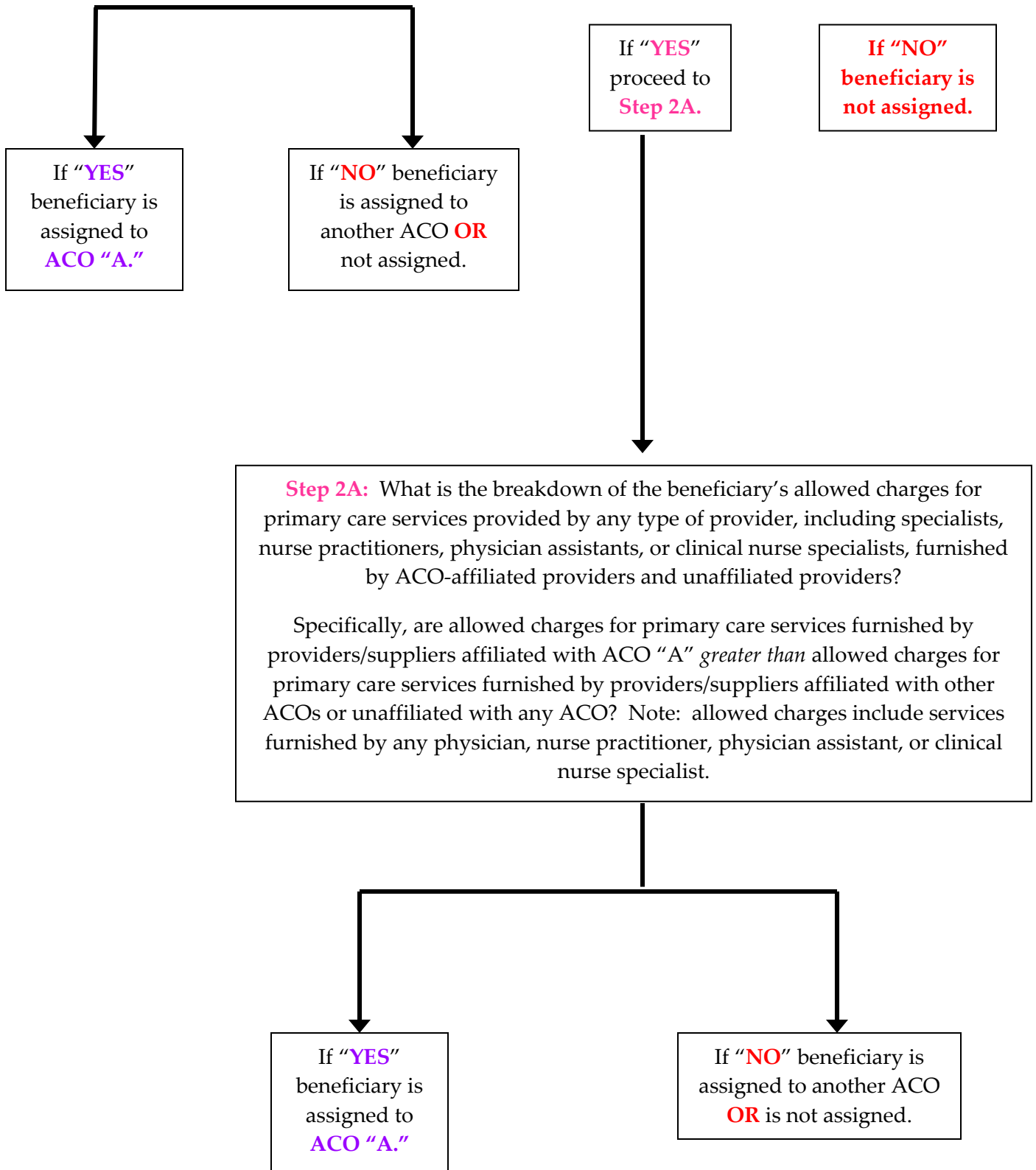
CMS will utilize specific HCPCS codes to define “primary care services.” Specifically, the Shared Savings Program will include the following HCPCS codes as primary care services: 99201 through 99215 (office/outpatient visits); 99304 through 99340 (nursing facility visits/domiciliary home visits); 99341 through 99350; (home visits); Welcome to Medicare visit (G0402); and annual wellness visits (G0438 and G0439). In addition, the final rule establishes a cross-walk for these codes to certain revenue center codes used by Federally Qualified Health Centers (“FQHCs”) and rural health clinics (“RHCs”). In the preamble to the final rule, CMS notes that it believes that the inclusion of codes for SNF visits is appropriate because “these codes represent basic evaluation and management services that would ordinarily be provided in physician offices if the beneficiaries were not residing in nursing homes.”²²

The final rule provides that for assignment purposes, primary care services can be provided by primary care physicians and other types of physicians, such as specialist physicians. Although many comments urged CMS to include other non-physician practitioners such as physician assistants and nurse practitioners, for the purposes of assignment based on the provision of primary care services, it declined to do so, citing statutory constraints.

²² 76 Fed. Reg. 67802, 67853 (Nov. 2, 2011).

Two-Step Assignment Process





Preliminary, Prospective Assignment with Retrospective Reconciliation

CMS will provide ACOs participating in the Shared Savings Program with information related to beneficiaries preliminarily assigned to the ACO. This preliminary, prospective assignment will be based on beneficiaries' primary care utilization during the most recent periods for which adequate data is available, and will be updated quarterly. At the beginning of an ACO's agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS will provide, upon the ACO's request, the following information regarding preliminary prospectively assigned beneficiaries whose data was used to generate the aggregate data reports: (1) beneficiary name; (2) date of birth; (3) health insurance claim number ("HICN"); and (4) sex.

At the end of each performance year, CMS will reconcile the list of preliminary, prospectively assigned beneficiaries with a list of beneficiaries that actually meet the assignment criteria. This retrospective, reconciled list of assigned beneficiaries will form the basis of determinations for shared savings or losses.

Majority Versus Plurality Rule for Beneficiary Assignment

In the final rule, CMS adopts a plurality rule in order to assign beneficiaries to a particular ACO. Under the plurality rule, a beneficiary will be assigned to an ACO if he or she incurred more allowed charges related to primary care services from that ACO than from any other provider. CMS will utilize the total allowed charges related to primary care services, rather than a simple count of the number of primary care services a beneficiary received, in order to determine where a beneficiary received the plurality of his or her primary care services.

Analysis and Potential Issues for Applicants

- According the final rule's preamble, commenters were "overwhelmingly in favor of prospective assignment."²³ Commenters argued that prospective assignment was important to fully engage beneficiaries in the ACO model and necessary for ACOs to appropriately manage and plan for their patient populations. In response to these comments, CMS finalized a hybrid prospective/retrospective assignment approach, prospectively identifying an ACO's preliminary population based on historical utilization data, and then reconciling assignment at the end of an ACO's performance year. According to the final rule's preamble, in adopting this approach, CMS attempted to emphasize the prospective nature of the approach. In addition, CMS notes in the final rule's preamble that the Pioneer ACO Model utilizes a prospective approach to assignment, and that it plans to carefully review the results of prospective assignment under the Pioneer

²³ 76 Fed. Reg. 67802, 67862 (Nov. 2, 2011).

ACO model. CMS also notes that the Pioneer ACO Model's results could inform a change in the assignment approach under the Shared Savings Program.

- The final rule's approach to assignment, while complicated, seems to be as inclusive as possible given the statutory framework. For example, the second step of the assignment process recognizes primary care services provided by specialists, and if at least one primary care service has been provided by a specialist, also recognizes primary care services provided by other practitioners, such as physician assistants, nurse practitioners, and clinical nurse specialists. At the same time, however, the assignment methodology focuses on primary care services provided by primary care physicians by first determining whether a beneficiary has received primary care services from a primary care physician.
- Because beneficiaries are assigned based on a plurality of primary care services, an ACO-assigned beneficiary could still receive much of his or her care outside of an ACO. This could make it difficult for an ACO to manage an assigned beneficiary's care.
- Although under the final rule, an ACO would receive information regarding beneficiaries that would be assigned to it based on historical data, an ACO does not know, with certainty, what beneficiaries will determine its shared savings or shared losses calculations until after the performance year ends. Retrospective assignment, even with preliminary, prospective information regarding beneficiaries that may be assigned to an ACO, could make it challenging for an ACO to effectively coordinate and manage care for ACO-assigned beneficiaries.

Quality and Other Reporting Requirements

Introduction

An ACO's ability to receive shared saving payments, and the amount of any payment, is dependant upon the ACO's performance against a set of quality measures. CMS modified its initial proposal by dramatically reducing the number of quality measures. The final rule removes those measures perceived as redundant, operationally complex, or burdensome, and retains those that CMS perceives as necessary to maintaining a high standard of ACO quality. The quality measures adopted in the final rule are intended to focus on populations, processes, and outcomes, and not high-cost services or utilization. CMS contends that cost and utilization issues will be better addressed through the general incentive to achieve shared savings, rather than specific quality measures.

Quality Measures

For the first year of the Shared Saving Program, CMS has identified 33 quality measures that are organized into four categories referred to as "domains." The domains include:

(1) patient/caregiver experience; (2) care coordination/patient safety; (3) preventative health;

and (4) at-risk population. Of the 33 measures, 12 are within the domain for “at-risk population” and relate to major cost drivers such as diabetes treatment, heart failure, and coronary artery disease. Quality measures for the remaining two years of the three-year agreement will be proposed in future rulemaking. Although CMS anticipates a “relatively static set of quality measures” for the three-year agreement period, ACOs are required to comply with any measures updates made in future rulemaking as clinical guidelines change and the “measure owners” update their measure requirements.

The rule describes the 33 quality measures but does not list the measure specifications. Instead, CMS indicates that the specifications will align with existing measures to the extent possible, such as the existing measures published by the National Quality Forum. In relying heavily on existing quality measures, CMS did not propose measures that are explicitly related to cost savings or resource-use that may be directly tied to the overuse or appropriateness of care. Similarly, the proposed quality measures do not directly address post-acute care beyond measures tied to the general coordination of care and patient safety.

Many providers interested in the Shared Savings Program were concerned that CMS would mandate an unachievable level of use of electronic health records (“EHR”). In the proposed rule, quality measures #19-23 addressed care coordination and the use of information systems, including electronic health records (“EHR”). Of these measures, CMS finalized only #20 “Percent of PCPs Meeting Stage 1 Meaningful Use Requirements” with a significant revision. The final rule does not require that 50 percent of an ACO’s primary care physicians be “meaningful users” of EHR by the start of the second performance year as originally proposed. An ACO will meet measure #20 if its primary care physicians successfully qualify for an EHR Incentive Program incentive. They need not be deemed meaningful users. CMS emphasizes its intent to “refine and expand” the quality measures in future rulemaking, and to expand the reporting mechanisms to include measures that are EHR-based.

Phase-In of Pay for Performance

In year one of the program, ACOs are required to report on *all* performance measures in order to qualify for shared saving payments (referred to as “pay for reporting”). In years two and three, an ACO’s score against the performance measures dictates the amount of shared savings it may recoup (referred to as “pay for performance”).

	Year 1	Year 2	Year 3
Pay for Performance	0	25	32
Pay for Reporting	33	8	1
Total	33	33	33

The first performance year of the ACO agreement period will begin April 1, 2012 or July 1, 2012 and end December 31, 2013. However, the quality performance for the first performance year will be based on complete and accurate reporting of measures January 1, 2013 through December 31, 2013. The pay for performance phase-in of measures will begin at the start of the second performance year on January 1, 2014.

Quality Performance Score

ACOs must meet a minimum threshold of performance in the quality measures (e.g., 30th percentile of performance) and achieve scores for higher performance in order to realize the financial gain. An ACO's failure to meet the minimum threshold performance for any of the 33 quality measures would result in a warning and may lead to termination from the program in a subsequent year if performance is not improved. In addition, ACO performance on each quality measure is scored with the score for each quality measure determined by either the absolute or relative benchmark, depending on the standard. For performance between the minimum threshold and the benchmark, the ACO would score points on a sliding scale based on a 2 point maximum for each of the 33 measures, as described in the following table:

ACO Performance Level	Quality Points (all measures except EHR)	EHR Measure Quality Points
90+ percentile FFS/MA Rate or 90+ percent	2 points	4 points
80+ percentile FFS/MA Rate or 80+ percent	1.85 points	3.7 points
70+ percentile FFS/MA Rate or 70+ percent	1.7 points	3.4 points
60+ percentile FFS/MA Rate or 60+ percent	1.55 points	3.1 points
50+ percentile FFS/MA Rate or 50+ percent	1.4 points	2.8 points
40+ percentile FFS/MA Rate or 40+ percent	1.25 points	2.5 points
30+ percentile FFS/MA Rate or 30+ percent	1.10 point	2.2 points
<30 percentile FFS/MA Rate or <30 percent	No points	No points

The scores for each quality measures are then added together within each of the four domains and divided by the maximum possible domain score to determine the relative performance in each domain. The domains are weighted equally in determining the ACO's total performance score. The performance score is then multiplied against the 50 percent shared savings pool for one-sided ACOs or 60 percent shared savings pool for two-sided ACOs.

Incorporating Other Reporting Requirements Related to the Physician Quality Reporting System

CMS incorporates into the Shared Savings Program existing reporting requirements and payments related to the Physician Quality Reporting System. In particular, the Shared Savings Program incorporates the Physician Quality Reporting System group practice reporting option (“GPRO”) and allows ACO participant providers and suppliers to constitute a group practice for purposes of qualifying for a Physician Quality Reporting System incentive payment. Such eligible professionals would be required to submit data through the ACO on the quality measures using the GPRO tool. Of the 33 measures CMS adopted for performance year one, seven are collected via patient survey, three are calculated via claims, one is calculated from EHR Incentive Program data, and 22 are collected via the GPRO web interface.

In order to facilitate the collection of the seven measures collected through survey, the administration of an annual patient experience of care survey will be paid for by CMS in 2012 and 2013. Starting in 2014, ACOs participating in the Shared Savings Program must select a survey vendor (from a list of CMS-certified vendors) and will pay that vendor to administer the survey and report results using standardized procedures developed by CMS.

Professionals participating in the EHR Incentive Program or the Electronic Prescribing Incentive Program must separately qualify and pursue those incentive payments outside of the ACO program. In subsequent years, CMS proposes to further align the Shared Savings Program and the EHR Incentive Program through future rulemaking.

Analysis and Potential Issues for Applicants

- The reduction in the number of quality measures from the proposed rule is welcome news. However, any expansion of the quality measures in future rulemaking adds to the risk and uncertainty associated with participating in the Shared Savings Program. In particular, CMS may adopt new measures associated with the use of EHR that will require ACO participants to dramatically expand the scope of their EHR capability.
- For health systems and long-term care providers it is unclear what measures, if any, related to hospital-based care and post-acute care may be adopted in the future. CMS declined to adopt measures it viewed as hospital-centric believing that it would be difficult to require this measure for an ACO composed of primary care physicians that does not have a hospital participant.
- The phase-in of the pay for performance will allow participants a relatively short amount of time to gain experience with collecting and reporting the quality measures. Beginning in the second performance year, quality performance scoring will reduce the total amount of shared savings payments from an ACO’s cost reduction. Because an ACO is unlikely to achieve a perfect score in every

quality measure, the quality performance scoring will reduce the payment made to the ACO in performance years 2013 and 2014.

- Organizations contemplating participation in the Share Savings Program should consider the likelihood of achieving a high performance level in each of the measures, and the cost of implementing procedures and adopting technology needed to achieve those levels.

Payments to ACOs—How Savings and Losses Are Shared

Introduction

ACO participants would continue to receive payment under the original Medicare fee-for-service (“FFS”) program under Parts A and B in the same manner as the FFS payments would otherwise be made. In addition, ACOs will receive payment for shared Medicare savings, *if* the ACO both: (1) meets the quality performance standard; and (2) demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures.

CMS revised the proposed rule to make the Shared Savings Program “more financially rewarding to ACOs.”²⁴ Under the final rule, ACOs participating in the Shared Savings Program have the option of two potential tracks. In Track 1, ACOs would not be responsible for any shared losses at any point during the initial, three-year agreement period. This option would be a shared-savings only model. However, if the ACO voluntarily decides to continue participation in the Shared Savings Program after the first agreement period, the ACO would be required to enter Track 2, a shared-savings and shared-loss model, for subsequent agreement periods. ACOs participating in Track 1 would be eligible for a smaller percentage of shared savings, with a maximum sharing rate of 50 percent. The final rule refers to Track 1 as the “one-sided” payment model. In Track 2, ACOs would be required to share any losses in all three years of its agreement period, but would also be eligible for a higher percentage of shared savings, with a maximum sharing rate of 60 percent. The final rule refers to this as the “two-sided” payment model.

The final rule also permits ACOs that experience a net loss during the first agreement period to continue participation in the Shared Savings Program for a second agreement period. However, ACOs that experience a net loss in their initial agreement period must identify, in their application for the second agreement period, the reasons for the net loss and how they will prevent losses and potentially achieve savings in the future. CMS also notes in the preamble that it plans to design and test several alternative payment models through the Innovation Center, which it may adopt as part of the Shared Savings Program in the future. However, the

²⁴ 76 Fed. Reg. 67802, 67912 (Nov. 2, 2011).

final rule contains little specific information regarding the alternative payment models being developed and tested by the Innovation Center.

Benchmarks

Establishing a Benchmark

CMS will establish the expenditure benchmark for an ACO by computing per capita expenditures for beneficiaries who would have been assigned to the ACO in each of the prior three most recent years in which data is available, using a three-month claims run-out with a completion factor. The benchmark acts as surrogate measure of what Medicare Parts A and B expenditures would have been in the absence of an ACO. In setting the benchmark, CMS will take into account Medicare Parts A and B payments made on behalf of Medicare beneficiaries that would have been assigned to an ACO based on the ACO participants' TINs identified at the start of the agreement period. The payments taken into account include individual beneficiary identifiable payments made under a pilot, demonstration, or time-limited programs. This benchmark would be updated annually during the three-year agreement period, based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

In an attempt to minimize variation from catastrophically large claims, CMS will cut an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile, as determined for each benchmark year and for each subsequent performance year. The actual benchmark will be the weighted average of the three years' averages, after trending and risk adjusting, with the greatest weight assigned to the most recent year.

It is important to note that CMS indicates in the final rule that it intends "to revisit use of a benchmarking methodology based on the ACO's assigned population in future rule making, as soon as practicable, once [it] gain[s] more experience with this benchmarking approach through the Pioneer Model."²⁵

How Beneficiaries are Assigned to Establish a Benchmark

Beneficiaries will be assigned to an ACO for benchmark purposes in the same way that beneficiaries are assigned to an ACO for other purposes. Specifically, CMS will use the claims records of the ACO participants to determine a list of beneficiaries who received a plurality of their primary care services from an ACO in each of the prior three most recent, available years.

²⁵ 76 Fed. Reg. 67802, 67914 (Nov. 2, 2011).

Obtaining an Initial Benchmark – Trending Forward Prior Years’ Experiences

CMS will establish an initial expenditure benchmark by trending forward the most recent three years of per-beneficiary expenditures using the national growth rates per-beneficiary expenditures for Parts A and B services. For example, CMS will use 2009, 2010, and 2011 claims year data to set the benchmark for an ACO starting its agreement period January 1, 2012. The 2009 and 2010 data will be trended forward using a factor so that all benchmark dollars would be in 2011 dollars. Further, when trending forward expenditures, CMS will use separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. Using the national growth index, CMS will trend the expenditures to determine a benchmark for year three in a dollar amount. This dollar amount would then be adjusted, as described above, to reflect benchmark year three risk-adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the three years used to establish the benchmark stated in benchmark year three (“BY3”) risk and expenditure amounts.

CMS will weight the most recent year of the benchmark, BY3, at 60 percent; will weight benchmark year two (“BY2”) at 30 percent; and will weight benchmark year one (“BY1”) at 10 percent.

Adjusting the Benchmark

Adjusting for “Beneficiary Characteristics.” CMS will adjust benchmark expenditures by employing the CMS-Hierarchical Condition Category (“CMS-HCC”) model used in the Medicare Advantage program. The CMS-HCC model uses demographic variables in addition to beneficiaries’ prior year diagnoses to develop risk scores that then are applied to current year expenditures. Each year, CMS will adjust expenditures to account for changes in severity and case mix for beneficiaries “newly assigned” to an ACO and for beneficiaries “continuously assigned” to an ACO. First, CMS will annually update an ACO’s CMS-HCC prospective risk scores to adjust for changes in severity and case mix in the newly assigned population. Second, CMS will annually recalculate the ACO’s CMS-HCC prospective risk score for continuously assigned beneficiaries. If continuously assigned beneficiaries show a lower risk score, CMS will adjust benchmark expenditures accordingly. However, if continuously assigned beneficiaries show no decline in their CMS-HCC scores, the continuously assigned beneficiary population will be adjusted by demographic factors only. Each performance year, an ACO’s updated benchmark will be restated to account for the risk profile of assigned beneficiaries.

Other Adjustments. CMS will remove indirect medical education (“IME”) and disproportionate share hospital (“DSH”) payments from per capita costs included in the benchmark for an ACO. However, CMS will not remove geographic payment adjustments from the calculation of benchmark expenditures. Further, certain incentive payments, if made from the Medicare Trust Fund for Parts A and B services on behalf of a Medicare beneficiary assigned to an ACO, would be counted in both the computation of actual expenditures and benchmark expenditures for Part A and B costs.

Updating the Benchmark During the Agreement Period. The initial benchmark will be updated in the second and third years of an ACO’s agreement period. The initial benchmark would be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS’s Office of the Actuary. However, in updating the benchmark, CMS will calculate separate cost categories for different populations of Medicare beneficiaries.

Shared Savings

Minimum Savings Rate

The final rule establishes a minimum savings rate (“MSR”) that must be exceeded in order for an ACO to qualify for shared savings. The MSR is intended to give CMS some assurances that the ACO’s performance is a result of its interventions, not normal variation. The MSR, in combination with the savings rate, discussed further below, will determine whether an ACO will receive shared savings (if it meets the quality performance standards and otherwise maintains its eligibility to participate in the Shared Savings Program).

The minimum savings rate is a percentage of the benchmark that ACO expenditure savings must exceed in order for an ACO to qualify for shared savings in any given year. ACOs in the one-sided payment model that have smaller populations, resulting in greater variation in expenditures, will have a larger MSR. ACOs in the one-sided payment model that have larger populations, and therefore have less variation in expenditures, have a smaller MSR. The MSR percentage is based on a statistical confidence interval ranging from 90 percent for small ACOs to 99 percent for larger ACOs. The confidence interval reflects at what point CMS can be sure that the savings are real, not the result of a fluke or randomness. A chart reflecting the MSR proposal for the one-sided payment model is set forth in the final rule, and is provided below.

Number of Beneficiaries	MSR (low-end of assigned beneficiaries)	MSR (high-end of assigned beneficiaries)
5,000-5,999	3.9%	3.6%
6,000-6,999	3.6%	3.4%
7,000-7,999	3.4%	3.2%
8,000-8,999	3.2%	3.1%
9,000-9,999	3.1%	3.0%
10,000-14,999	3.0%	2.7%
15,000-19,999	2.7%	2.5%
20,000-49,999	2.5%	2.2%
50,000-59,999	2.2%	2.0%
60,000+	2.0%	

Under the two-sided approach, CMS has adopted a flat, 2 percent minimum savings rate.

Net Sharing Rate

In the proposed rule, CMS indicated that ACOs would only share in savings in excess of a certain threshold in Track 1. In the final rule, CMS declined to implement this proposal, and under § 435.604 of the final rule, if an ACO meets or exceeds the MSR, ACOs participating in either Track 1 or Track 2 will share on first dollar savings. “Sharing on first dollar savings” means that an ACO will share on *all* savings below the ACO’s updated benchmark.

Cap on Shared Savings

The final rule establishes a shared savings payment limit of 10 percent of an ACO’s updated benchmark for the one-sided model. For the two-sided model, CMS establishes a payment limit of 15 percent of an ACO’s updated benchmark.

Shared Losses

The shared losses methodology of the final rule parallels the shared savings methodology. Specifically, the shared losses methodology includes: “a formula for calculating shared losses based on the final sharing rate, use of a MLR to protect against losses resulting from random variation and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay.”²⁶

²⁶ 76 Fed. Reg. 67802, 67936 (Nov. 2, 2011).

Minimum Loss Rate

Similar to shared savings, CMS finalized a minimum loss rate for purposes of computing shared losses when an ACO's actual expenditure exceeds its benchmark. An ACO will not be responsible for shared losses unless its expenditures exceed the minimum loss rate ("MLR"). The MLR is intended to protect "ACOs against being held accountable for losses that result from random variation as opposed to their performance."²⁷ CMS sets the MLR at 2 percent of the updated benchmark.

Shared Loss Rate

If an ACO's actual expenditures are 2 percent or more above its update benchmark, the ACO must share in losses on a first dollar basis. Under the final rule, an ACO experiencing losses would be responsible for sharing in losses based on the inverse of its final sharing rate based on quality performance. However, in the final rule, CMS caps the shared loss rate at 60 percent in order to be consistent with the maximum possible shared savings rate.

The example below elucidates how losses would be shared:

- An ACO's actual expenditures exceed the benchmark by \$1 million. (Presume, for this example, that the \$1 million excess expenditures exceeds the MLR.)
- The ACO has achieved a sharing rate of 45 percent, based on quality performance.
- The ACO is responsible for losses based on the inverse of its final sharing rate, based on quality performance. Therefore, in this example, the ACO is responsible for 55 percent of its losses.
- The ACO will be responsible for \$550,000 in shared losses.

Cap on Shared Losses

CMS adopted a maximum shared loss cap, meaning that the shared losses that an ACO might be required to return to the Medicare program under the two-sided model could not exceed a designated percentage of an ACO's benchmark in any performance year. CMS finalized a phased-in shared loss cap of: 5 percent in the first year of the Shared Savings Program; 7.5 percent in the second year of the Program; and 10 percent in the third year of the Program. Because ACOs that participate in the one-sided payment model will not be responsible for shared losses, no cap applies to them.

²⁷ *Id.*

Ensuring ACO Repayment of Shared Losses

CMS proposed a flat 25 percent withholding rate, on an annual basis, to any shared savings achieved by an ACO. CMS intended for this withholding rate to serve as assurance that an ACO would repay any shared losses it incurred in the future. In the final rule, CMS declined to finalize its proposal requiring a withhold of shared savings.

CMS also proposed that an ACO demonstrate that it established a self-executing method for repaying losses to the Medicare program should it face losses that exceeded CMS's prior withholding. Instead, the final rule allows ACOs "flexibility" to determine how they will repay future, potential losses, and how that repayment methodology would apply to various ACO participants. CMS requires that an ACO participating in the two-sided model submit documentation that it is capable of repaying losses by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit, or establishing another repayment mechanism that will ensure its ability to repay the Medicare program. An ACO participating in the two-sided model must submit information regarding its ability to repay losses to the Medicare program with its application and then again on an annual basis.

CMS adopted a requirement mandating that an ACO have reserves sufficient to ensure repayment of potential losses equal to at least 1 percent of per capita Medicare FFS Parts A and B expenditures for its assigned beneficiaries during the most recent performance year or benchmark year. To the extent an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, it will not carry an ACO's losses forward to subsequent performance years.

Timing of Repayment

In the proposed rule, CMS proposed to require that an ACO repay losses within 30 days after it is notified of those losses. Under the final rule, if an ACO incurs shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

Determining First-Year Performance for ACOs Beginning in 2012

Because the start dates for 2012 are April 1 and July 1, the first performance "year" for ACOs beginning participation in the Shared Savings Program in 2012 is 21 months and 18 months, respectively. ACOs that commence participation in the Shared Savings Program in 2012 will have the option of receiving an interim payment based on the ACO's first 12 months of participation. ACOs that wish to receive an interim payment must indicate such on the Shared Savings Program Application.

A final reconciliation will occur at the end of the first performance year, and ACOs participating in both the one-sided model and two-sided model must assure CMS of their ability to make repayments of any monies owed during reconciliation. For example, CMS may determine that

an ACO's interim payment overpaid the ACO for shared savings, and therefore, the ACO would owe CMS the difference after reconciliation.

Analysis and Potential Issues for Applicants

- Providers and suppliers forming an ACO should carefully consider whether to participate in the one-sided payment model or the two-sided payment model. Smaller, less sophisticated ACOs should opt for the one-sided payment model, whereas larger, more sophisticated ACOs experienced with capitated payment models may wish to consider the two-sided payment model.
- ACOs that operate in areas that have a growth rate above the growth rate in national per capita expenditures might be disadvantaged by CMS proposing to update the benchmarks by the annual growth rate in national per capita expenditures. On the other hand, ACOs that operate in areas that have a growth rate below the national per capita expenditures might benefit from this.
- Recognizing that developing a successful ACO will require a significant investment and that ACOs are not guaranteed to achieve savings, CMS made a number of concessions in the final rule. For example, allowing ACOs to participate in the Shared Savings Program under a shared-savings-only model makes participation more attractive to smaller and new ACOs. CMS declining to implement the automatic withholding of 25 percent of shared savings, which could have created cash flow problems for some ACOs, was another significant concession.
- CMS notes in the preamble of the final rule that it will further clarify operational questions about repayment through the application process and other program instructions. Stay tuned.
- CMS also remarks that certain fraud and abuse laws may be implicated by the division of liability for shared losses among ACO participants, unless the fraud and abuse laws have been waived. It is important for an ACO to work with legal counsel to determine how to share both savings and losses in a way that either falls under the waivers created for the Shared Savings Programs, or in a way that otherwise complies with the fraud and abuse laws.

Additional Program Requirements and Beneficiary Protections

Beneficiary Protections

ACO participants must post signs in their facilities indicating their participation in the Shared Savings Program. In addition, in ACO settings where FFS beneficiaries are receiving primary care services, ACO participants must make a standardized, CMS-developed written notice available to FFS beneficiaries that they serve. Further, as described above, ACOs may choose to provide beneficiaries with notification of their participation in the Shared Savings Program.

Under the proposed rule, CMS suggested that ACOs and ACO participants would be required to notify beneficiaries if they terminated participation in the Shared Savings Program. CMS has declined to finalize this proposal in the final rule.

Marketing Materials

The final rule allows ACOs to use marketing materials five days after filing them with CMS if the ACO certifies that the marketing materials comply with the applicable marketing requirements and guidelines. However, CMS may disapprove the marketing materials or activities at any time after the initial five-day review period. Further, all marketing materials: (1) must use template language when available; (2) must comply with the prohibition regarding certain beneficiary inducements; (3) must not be used in a discriminatory manner or for discriminatory purposes; (4) must not be inaccurate or misleading; and (5) must be provided in “plain language” that complies with the Plain Writing Act of 2010. Finally, if an ACO fails to adhere to the marketing materials requirements, it may be placed under corrective action or terminated.

Program Monitoring

CMS finalized its proposal to monitor and assess ACOs and their participating providers/suppliers. CMS will utilize a number of different measures to monitor ACOs, including: (1) analysis of specific financial and quality measurement data reported by ACOs, as well as aggregated annual and quarterly reports; (2) site visits; (3) analysis of beneficiary and provider complaints; and (4) audits. CMS will monitor ACOs for several, specific activities: (1) avoidance of at-risk beneficiaries; (2) compliance with quality performance standards; (3) changes to ACO eligibility requirements; (4) ACO marketing materials and activities; and (5) notification of the provider and supplier’s role in the ACO, and the ability for beneficiaries to opt-out of sharing claims data.

CMS will use the monitoring measures previously outlined to identify patterns suggestive of the avoidance of at-risk beneficiaries. If CMS finds anything to hint that an ACO and its suppliers/providers are avoiding at-risk beneficiaries, CMS may follow up with the beneficiary. If CMS determines that an ACO, its ACO participants, any ACO providers/suppliers, or any contracted entities performing functions or services on behalf of the ACO, avoids at-risk

beneficiaries, the ACO will be required to submit a corrective action plan (“CAP”) and implement the CAP as approved by CMS. An ACO will not be eligible to receive shared savings during the probation period, and the ACO will not be eligible to receive shared savings for the performance period attributable to the time the ACO was under the CAP. CMS will re-evaluate the ACO during and after CAP implementation to ensure it is not still avoiding at-risk beneficiaries. If an ACO continues to avoid at-risk beneficiaries during or after the CAP, it may be terminated. In addition, CMS retains the right to immediately terminate an ACO in certain situations.

Actions Prior to Termination

CMS could take several actions prior to terminating an ACO. CMS could: (1) provide a warning to the ACO regarding the specific performance at issue; (2) request a corrective action plan from the ACO; or (3) place the ACO on a special monitoring plan.

Termination

CMS could terminate an agreement with an ACO if the ACO, the ACO participants, the ACO providers/suppliers, or contracted entities performing services or functions on behalf of the ACO: (1) avoid at-risk beneficiaries; (2) fail to meet quality performance standards; (3) fail to completely and accurately report information or fail to make timely corrections to reported information; (4) are not in compliance with eligibility requirements or have fallen out of compliance with the requirements; (5) are unable to effectuate any required regulatory changes; (6) are not in compliance with requirements to notify beneficiaries of ACO provider/supplier participation in an ACO; (7) engage in material noncompliance or show a pattern of noncompliance with respect to public reporting and other CMS reporting requirements; (8) fail to submit or implement a CAP or fail to demonstrate improved performance after implementation of CAP; (9) violate the physician self-referral prohibition, civil monetary penalties, anti-kickback statute, or other applicable antitrust and antifraud laws; (10) submit to CMS false, inaccurate, or incomplete data or information; (11) use marketing materials that are not approved by CMS; (12) fail to maintain at least 5,000 beneficiaries; (13) fail to offer beneficiaries the option to opt-out of sharing claims information; (14) limit or restrict beneficiaries’ medical records or summaries of care from other providers/suppliers within and outside of the Shared Savings Program; (15) improperly use or disclose claims information received from CMS in violation of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, or the data use agreement; or (16) fail to demonstrate that the ACO has adequate resources in place to repay losses and maintain those resources for the agreement period. Finally, under the final rule, CMS retains the right to terminate an ACO's agreement immediately for violations it determines are more serious.

Except for the prohibitions on reconsideration and appeals noted in the section directly below, an ACO that is terminated from the Shared Savings Program can seek administrative reconsideration of its termination. However, if an ACO is terminated, it may not re-apply to the Shared Savings Program until the end of its original three-year agreement period.

Reconsideration Review Process

The final rule severely limits reconsideration, appeals, or other administrative or judicial review. In fact, the final rule stipulates that there is *no* reconsideration, appeals, or other administrative or judicial review of the following determinations: (1) specification of quality and performance standards; (2) the assessment of the quality of care furnished by an ACO; (3) the assignment of Medicare beneficiaries; (4) the determination of whether an ACO is eligible for shared savings; (5) the percent of shared savings specified by the Secretary and the limit on the total amount of shared savings; and (6) the termination of an ACO for failure to meet the quality performance standards. For appeals of administrative decisions not restricted by the above prohibitions, Subpart I of the final rule outlines the Shared Savings Program’s reconsideration review process.

Provision of Aggregate and Beneficiary Identifiable Data

Sharing Aggregate Data

CMS will provide ACOs with aggregate data reports that will include: (1) aggregated metrics on the assigned beneficiary population; and (2) utilization and expenditure data for the Medicare beneficiaries used to calculate the ACO’s benchmark. CMS will provide ACOs with these aggregate data reports at the start of the agreement period and on a quarterly basis. In addition, at the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS will provide, upon the ACO’s request, the following information regarding preliminary prospectively assigned beneficiaries whose data was used to generate the aggregate data reports: (1) beneficiary name; (2) date of birth; (3) health insurance claim number (“HICN”); and (4) sex.

Beneficiary-Identifiable Claims Data

ACOs have the opportunity to request certain beneficiary-identifiable claims data on a monthly basis, in compliance with applicable laws. These data sets will be limited to the minimum data necessary for the ACO to effectively coordinate care of its patient population. If an ACO wishes to receive beneficiary-identifiable claims data, it must sign a Data Use Agreement (“DUA”) and submit a formal request for data. The ACO must explain how it will use the data to evaluate the performance of ACO participants, suppliers, and providers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of the assigned beneficiary population. The ACO may request the data during its application process or on a monthly basis during the agreement period. CMS believes that more complete

beneficiary-identifiable information will enable practitioners in an ACO to better coordinate and target care strategies toward the individual beneficiaries who may ultimately be assigned to them.

Consistent with statutory and regulatory restrictions, CMS will not disclose data related to patient records by federally conducted or assisted substance abuse programs, except as expressly authorized.

Data Use Agreement

Before receiving any beneficiary-identifiable data, ACOs must enter into a DUA with CMS. Under the DUA, the ACO is prohibited from sharing the Medicare claims data provided to it with any entity outside of the ACO, and would also be prohibited from using or disclosing data in a manner that violates the HIPAA Privacy Rule. If an ACO does not comply with the DUA, it would result in the ACO no longer being eligible to receive data, and may also lead to termination from the MSSP, or additional sanctions and penalties available under law.

Beneficiary Opt-Out

CMS will allow Medicare beneficiaries to opt-out of sharing their protected health information with an ACO. ACOs will only have access to beneficiary-identifiable claims data for beneficiaries that have chosen not to opt-out of claims data sharing. An ACO can gain access to beneficiary claims data in two ways, both requiring the ACO to inform a Medicare beneficiary that it may request personal health information as part of the MSSP and then allowing that beneficiary a “meaningful opportunity” to opt-out of sharing his or her data. First, an ACO can obtain access to protected health information for beneficiaries who (1) are listed as preliminary, prospectively assigned patients; (2) have received from the ACO a written, advance notification requesting data sharing; and (3) have not chosen to opt-out of claims data sharing within 30 days after the advance notification is sent. Beneficiaries who receive advance notification in this manner must also be given an opportunity to opt-out of further claims data sharing during their first primary care visit. Alternatively, an ACO can obtain access to protected health information for beneficiaries who have (1) visited a primary care provider participating in the ACO during the performance year; (2) been informed about how the ACO intends to use beneficiary claims data; and (3) not chosen to opt-out of claims data sharing.

If a beneficiary declines to have its claims data shared with the ACO, this does not preclude physicians from sharing protected health information as allowed under HIPAA. For example, a referring primary care physician may provide protected health information to a specialist for treatment purposes.

Public Reporting and Transparency

Several aspects of an ACO's operation and performance must be publicly reported: (1) providers and suppliers participating in the ACO; (2) each member of the ACO governing body; (3) quality performance standard scores; (4) general information on how an ACO shares savings with its members; (5) the name and location of the ACO; (6) the primary contact of the ACO; and (7) the ACO's organizational information. Each ACO is responsible for making this information available to the public in a standardized format that CMS will publish through subregulatory guidance. Additionally, quality measures reported using the Group Practice Reporting Option ("GPRO") web interface will be reported on Physician Compare in the same way it is for group practices that report under the Physician Quality Reporting System.

Analysis and Potential Issues for Applicants

- The necessity of a robust health information exchange infrastructure and effective communication among ACO participants and the ACO's neighboring health care providers to convert large volumes of claims data into actionable information and assist in accessing data in "real-time" may present a fundamental challenge to effective participation in the MSSP for smaller, unintegrated health care providers.
- Pursuant to a DUA an ACO must sign in order to receive beneficiary-identifiable data, ACOs must establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the beneficiary-identifiable claims data and comply with HIPAA and the Privacy Act. Steps that an ACO may take to ensure it protects the confidentiality of the beneficiary-identifiable claims data and complies with HIPAA and the Privacy Act include: (1) controlling who has access to the data provided by CMS; (2) developing and communicating clear policies and procedures regarding the protection of the data; (3) implementing network security measures such as a network firewall; (4) implementing security protections for individual, desktop computers; (5) regularly screening for viruses and malware; (6) developing and initiating safeguards for remote access to the data provided by CMS.
- To request claims data about individual beneficiaries, an ACO must develop appropriate forms to: (1) inform Medicare beneficiaries that it may request personal health information from CMS for the purposes of the MSSP; and (2) explain that Medicare beneficiaries can decline data sharing. ACOs should work with legal counsel to develop forms that meet the requirements of the MSSP, as well as federal and state privacy laws. Further, ACOs should develop and implement policies and procedures to ensure that each beneficiary receives a notification and has the opportunity to opt-out of this data sharing. Finally, an ACO should document that it has provided beneficiaries with this form.

CMS/OIG Interim Final Rule—Waivers

Introduction

Concurrent with the publication of the Medicare Shared Savings Program’s final rule, the Centers for Medicare & Medicaid Services (“CMS”) and the Department of Health and Human Services Office of Inspector General (“OIG”) published an [interim final rule with comment period](#) establishing certain waivers of federal fraud and abuse laws.²⁸

Overview

In response to public comments outlining a wide variety of arrangements that might develop in order for successful participation in the Medicare Shared Savings Program, CMS and the OIG expanded upon the waivers proposed in their April 7, 2011 notice with comment period. The interim final rule includes five waivers: (1) an “ACO pre-participation” waiver (new in the interim final rule); (2) an “ACO participation” (new in the interim final rule); (3) a “shared savings distributions” waiver (modified from April 7, 2011 notice); (4) a “compliance with the Physician Self-Referral Law” waiver (modified from April 7, 2011 notice); and (5) a “patient incentive” waiver (new in the interim final rule). CMS and the OIG believe that the “ACO pre-participation” and the “ACO participation” waivers will cover many of the arrangements developed pursuant to the Shared Savings Program, but elected to make the “shared savings distributions” waiver and “compliance with the Physician Self-Referral Law” waiver available because “some parties may find these two [waivers] more suitable to their particular needs.”²⁹

In the interim final rule, CMS and the OIG explain that the waivers are intended to be self-implementing—meaning that parties that wish to utilize a waiver do not need to take action apart from the actions required by the respective waiver’s conditions. Specifically, parties wishing to utilize a waiver do not need to submit an application to CMS or the OIG.

CMS and the OIG also note that they do not plan to codify the waivers in the Code of Federal Regulations, and instead intend to make the waiver text available on both the OIG’s and CMS’s websites. They plan to do this in order “to ensure that the waivers, if modified, remain consistent over time and across relevant laws.”³⁰

²⁸ 76 Fed. Reg. 67992 (Nov. 2, 2011).

²⁹ *Id.* at 67999.

³⁰ *Id.* at 67999.

Purpose

The stated purpose of the interim final rule is to “address application of these fraud and abuse laws [to ACOs] so that the laws do not unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs.”³¹ Specifically, the waivers intend “to promote a high degree of certainty, innovation, and variation in the development of ACOs to improve the quality of care, as well as economy and efficiency in the Medicare program.”³² In developing the waivers, CMS and the OIG attempted to balance the protection of the Medicare program and beneficiaries and the need for certainty, innovation, and flexibility in the Shared Savings Program. The Patient Protection and Affordable Care Act authorizes the Secretary to waive the fraud and abuse laws in order to carry out the purposes of the Shared Savings Program.³³

While the interim final rule became effective November 2, 2011, CMS and the OIG will accept comments related to the interim final rule until January 3, 2012. The interim final rule indicates that CMS and the OIG plan to closely monitor ACOs that commence participation in the Shared Savings Program through June 2013, and that CMS and the OIG intend to narrow the waivers established in the interim final rule *unless* “the Secretary determines that information gathered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive arrangements.”³⁴ In the interim final rule, CMS and the OIG seek comments regarding how to narrow the waivers established by the interim final rule. In addition, CMS and the OIG seek comments on additional categories of arrangements that should receive protection from the fraud and abuse laws, how those categories should be defined, and what limits, if any, should apply to the waivers.

Implicated Fraud and Abuse Laws

The proposed waivers directly implicate three different federal fraud and abuse laws: (1) the Anti-Kickback Statute (“AKS”); (2) the Stark Law, which prohibits certain physician self-referrals; and (3) the Civil Monetary Penalty Law (“CMPL”)—specifically the “gainsharing” and “beneficiary inducement” prohibitions.

³¹ *Id.* at 67993.

³² *Id.* at 68007.

³³ Social Security Act § 1899(f).

³⁴ *Id.* at 68008.

Established Waivers

Four of the five waivers explicitly protect arrangements involving an ACO, ACO participants, and ACO providers/suppliers currently participating and in good standing in the Shared Savings Program. However, the “pre-participation” waiver is available for start-up arrangements provided that the ACO “is making good faith efforts to form an ACO and to submit an application to participate in the Shared Savings Program, and all other conditions of the waiver are satisfied.”³⁵ With regard to duration, the waivers could apply to start-up arrangements that pre-date an ACO’s participation in the Shared Savings Program to shared savings distributions and other arrangements that post-date an ACO’s participation in the Shared Savings Program.

The waivers apply uniformly to each ACO, ACO participant, and ACO provider/supplier participating in the Shared Savings Program, and as defined by the Shared Savings Program’s regulations. Further, several waivers require that the arrangements are “reasonably related to the purposes of the Shared Savings Program.” CMS and the OIG modified the language proposed in the April 7, 2011 notice requiring arrangements be “necessary for and directly related to ACO purposes.” This modification allows for greater flexibility in arrangements that will meet this “reasonably related” standard.

The interim final rule lists the purposes of the Shared Savings Program, to which activities must be “reasonably related,” as the following:

- Promoting accountability for the quality, cost, and overall care for a Medicare population as described in the Shared Savings Program
- Managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO
- Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries³⁶

The interim final rule does not further explain what arrangements may be “reasonably related to the purposes of the Shared Savings Program,” but instead states, “[w]here a reasonable relationship exists, it should not be difficult for parties to articulate clearly the nexus between their arrangement and the purposes of the Shared Savings Program.”³⁷

³⁵ *Id.* at 68002.

³⁶ *Id.* at 68002.

³⁷ *Id.*

Pre-Participation Waiver

The “pre-participation” waiver waives application of the Stark Law, the gainsharing provisions of the CMPL, and the federal anti-kickback statute. The interim final rule limits this waiver to “start-up arrangements.” For clarity, the interim final rule includes a list of examples of what CMS and the OIG would consider to be start-up arrangements that could be included under the umbrella of the pre-participation waiver, if the waiver’s other conditions are met. The interim final rule’s list of examples includes: (1) infrastructure creation and provision; (2) network development and management, including the configuration of a correct ambulatory network and the restructuring of existing providers and suppliers to provide efficient care; (3) care coordination mechanisms, including care coordination processes across multiple organizations; (4) clinical management systems; (5) quality improvement mechanisms including a mechanism to improve patient experience of care; and (6) creation of governance and management structure; among other examples.³⁸

The interim final rule also specifies that arrangements that have purposes similar to the Shared Savings Program, but unrelated to the Shared Savings Program, do not qualify for a waiver. Importantly, however, CMS and the OIG state that arrangements that involve care for non-Medicare patients as well as Medicare beneficiaries are eligible for the waivers established pursuant to the Shared Savings Program.³⁹

The pre-participation waiver applies to start-up arrangements that pre-date an ACO’s participation agreement, provided that the arrangement meets the following conditions:

- The arrangement is undertaken by a party or parties acting with the good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a particular year (the “target year”), and to submit a completed application to participate in the Shared Savings Program for that year. The parties to the arrangement must include, at a minimum, the ACO or at least one ACO participant of the type eligible to form an ACO. The parties to the arrangement may not include drug and device manufacturers, distributors, durable medical equipment (DME) suppliers, or home health suppliers.
- The parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year, including taking diligent steps to meet the regulatory requirements related to an ACO’s governance, leadership, and management.

³⁸ *Id.* at 68003.

³⁹ *Id.* at 68002.

- The ACO's governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.
- The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement; the documentation of the authorization must be contemporaneous with the authorization; and the documentation of the diligent steps must be contemporaneous with the diligent steps. All such documentation must be retained for at least 10 years following completion of the arrangement (or, in the case of the diligent steps, for at least 10 years following the date the ACO submits its application, or the date the ACO submits its statement of reasons for failing to submit an application. The documentation must identify at least the following:
 1. A description of the arrangement, including all parties to the arrangement; the date of the arrangement; the purpose(s) of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.
 2. The date and manner of the governing body's authorization of the arrangement. The documentation of the authorization should include the basis for the determination by the ACO's governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.
 3. A description of the diligent steps taken to develop an ACO, including the timing of actions undertaken and the manner in which the actions relate to the development of an ACO that would be eligible for a participation agreement.
- The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.
- If an ACO does not submit an application for a participation agreement by the last available application due date for the target year, the ACO must submit a statement on or before the last available application due date for the target year, in a form and manner to be determined by the Secretary, describing the reasons it was unable to submit an application.⁴⁰

⁴⁰ *Id.* at 68000.

Participation Waiver

The “participation” waiver waives application of the Stark Law, the gainsharing provisions of the CMPL, and the federal anti-kickback statute. The duration of the waiver, for arrangements that meet all of the required conditions, is the start date of the participation agreement until six months following the earlier of: (1) the expiration of the participation agreement (including any renewals); or (2) the date on which the ACO voluntarily terminates its participation agreement. If an ACO is terminated from the Shared Savings Program, the waiver’s duration ends on the date of the termination notice. The participation waiver applies to any arrangement of an ACO, one or more of its ACO participants or its ACO providers/ suppliers, provided that the arrangement meets the following conditions:

- The ACO has entered into a participation agreement and remains in good standing under its participation agreement.
- The ACO meets the regulatory requirements related to its governance, leadership, and management.
- The ACO's governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.
- Both the arrangement and its authorization by the governing body are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, and the documentation of the authorization must be contemporaneous with the authorization. All such documentation must be retained for at least ten years following completion of the arrangement and promptly made available to the Secretary upon request. The documentation must identify at least the following:
 1. A description of the arrangement, including all parties to the arrangement; date of the arrangement; the purpose of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.
 2. The date and manner of the governing body's authorization of the arrangement. The documentation should include the basis for the determination by the ACO's governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.
- The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.⁴¹

⁴¹ *Id.* at 68001.

Shared Savings Distribution Waiver

The shared savings distribution waiver waives application of the Stark Law, the gainsharing provisions of the CMPL, and the federal anti-kickback statute with respect to distributions and use of shared savings earned by an ACO, if all of the following conditions are met:

- The ACO has entered into a participation agreement and remains in good standing under its participation agreement.
- The shared savings are earned by the ACO pursuant to the Shared Savings Program.
- The shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement.
- The shared savings are:
 1. Distributed to or among the ACO's ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or
 2. Used for activities that are reasonably related to the purposes of the Shared Savings Program.
- With respect to the waiver of the gainsharing provisions of the CMPL, payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.

Compliance with the Physician Self-Referral Law Waiver

This waiver waives application of the CMPL's gainsharing provisions and the federal anti-kickback statute to any financial relationships reasonably related to the purposes of the Shared Savings Program between or among the ACO, its participants, and its ACO providers/ suppliers that meet a Stark Law exception.

Waiver for Patient Incentives

The waiver for patient incentives waives application of the CMPL's beneficiary inducement provisions and the federal anti-kickback statute to any items or services provided by an ACO, its participants, or its ACO providers/suppliers for free or below fair market value if the following conditions are met:

- The ACO has entered into a participation agreement and remains in good standing under its participation agreement
- There is a reasonable connection between the items or services and the medical care of the beneficiary
- The items or services are in-kind
- The items or services:
 1. Are preventive care items or services; or
 2. Advance one or more of the following clinical goals:
 - a. Adherence to a treatment regime
 - b. Adherence to a drug regime
 - c. Adherence to a follow-up care plan; and/or
 - d. Management of a chronic disease or condition

Analysis and Potential Issues with Waivers

- Various waivers require specific and significant contemporaneous documentation and an “audit trail” that is maintained for 10 years. Potential ACOs, ACO participants, and ACO providers/suppliers should be diligent to ensure that the documentation requirements are met to prevent any technical violation of the waivers.
- CMS and the OIG will issue additional guidance regarding the public disclosure of arrangements, as required by the pre-participation and participation waivers in the interim final rule. However, until further guidance is provided, ACO parties utilizing these two waivers must post information: (1) identifying the parties to the arrangement; and (2) identifying the type of item, service, good, or facility provided under the arrangement on a public website belonging to the ACO, or the individual or entity forming the ACO, within 60 days of the date of the arrangement. There are additional requirements for this Internet disclosure, including specific identifying information. It is important to note, however, that the interim final rule states “such public disclosure shall not include the financial or economic terms of the arrangement.”
- CMS and the OIG significantly expanded the waivers proposed in its April 7, 2011 notice in the interim final rule. However, CMS and the OIG note their intent to limit the waivers in the future. Thus, ACOs, ACO participants, and ACO providers/suppliers should closely monitor any future modifications of the waivers to ensure that arrangements developed pursuant to the Shared Savings Program do not violate modified waivers.
- While the waiver for patient incentives waives the CMPL’s beneficiary inducement prohibitions and the federal anti-kickback statute for the provision of items or

services provided by an ACO, its participants, or its ACO providers/suppliers for free or below fair market value, the interim final rule's preamble notes that the Shared Savings Program regulations prohibits ACOs, ACO participants, and ACO providers/ suppliers, among others, from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from, or remaining in, an ACO. Further, the interim final rule's preamble notes that this waiver does not protect the provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries, an ACO, or its participants, providers/suppliers.

FTC/DOJ Final Antitrust Policy Statement

Overview

The ACO model has the potential of reducing competition and harming consumers through higher prices or lower quality of care through an ACO's accumulation and use of "market power." CMS describes its view of "market power" as "the ability of an ACO to reduce the quality of care furnished to Medicare beneficiaries and/or to raise prices or reduce the equality for commercial health plans and enrollees, thereby potentially increasing the providers' incentives to provide care for private enrollees of higher-paying health plans rather than for Medicare beneficiaries."⁴² In order to address these concerns and provide ACO participants with guidance to avoid anticompetitive behaviors, CMS and the antitrust agencies (the Department of Justice, "DOJ" and the Federal Trade Commission, "FTC") have developed coordinated [guidance](#) on antitrust enforcement policy for ACOs participating in the Shared Saving Program.

Three-Prong Approach

CMS has adopted a three-prong approach to guard against anticompetitive effects of the Shared Savings Program. First, the antitrust agencies, in coordination with CMS, will offer a voluntary expedited antitrust review to any newly formed ACO to assess whether the ACO is likely to present competitive concerns that could result in an antitrust challenge. Second, CMS will provide the antitrust agencies with aggregate claims data regarding allowable charges and fee-for-service payments to assist in monitoring an ACO's effect on competition. Third, CMS will rely on the existing enforcement processes of the antitrust agencies to evaluate anticompetitive concerns and to take enforcement action, when appropriate.

⁴² 76 Fed. Reg. 67841.

No Mandatory Review

One area of significant change in the final rule—reflected in the Antitrust Policy Statement—is how CMS will work with the DOJ and FTC to guard against anticompetitive harm. Under the proposed rule, if an ACO had greater than 50 percent of the primary service area share for any common service that two or more ACO participants provide, it would have been required to obtain an expedited antitrust review from the antitrust agencies confirming that the agencies have no present intent to challenge or to recommend challenge to the proposed ACO, and then submit this letter to CMS as part of its application to participate in the Shared Savings Program. CMS received many comments raising concerns about the timing and efficiency of the proposed mandatory review, as well as CMS’s legal ability to delegate such authority to the antitrust agencies. In the final rule, CMS declined to adopt the requirement for mandatory antitrust review of certain ACOs and opts for a voluntary process that it suggests will be less burdensome and avoid the legal issues raised by delegation of authority to the DOJ and FTC. Although the review process is now voluntary, an ACO with a significant market share in any common service—particularly those with a share greater than 50 percent—are well-advised to request expedited review.

Antitrust Safety Zone for ACOs Participating in the Shared Savings Program

In the Antitrust Policy Statement the DOJ and FTC affirm that each agency will not challenge ACOs that meet CMS eligibility criteria so long as they meet certain thresholds within an antitrust “safety zone.” The antitrust safety zone applies to ACO participants that provide the same service (a “common service”) and have a combined share of 30 percent or less of each common service in each participant’s primary service area, or “PSA,” wherever two or more ACO participants provide that service to patients from that PSA.⁴³ ACOs that fall within this safety zone can be reasonably confident that the antitrust agencies will not challenge their formation.

Rule of Reason Applied Outside the Safety Zone

The activities and formation of ACOs that do not fall within the safety zone will be evaluated by the antitrust agencies under the rule of reason analysis. A rule of reason analysis evaluates whether the collaboration is likely to have anticompetitive effects and, if so, whether the collaboration’s potential procompetitive efficiencies are likely to outweigh those effects. The

⁴³ An ACO that exceeds the 30 percent PSA share may still fall within the safety zone if it qualifies for a rural exception. The rural exception allows such an ACO to include one physician or physician group practice per specialty from each rural area on a non-exclusive basis and still fall within the safety zone, provided the physician’s or physician group practice’s primary office is in a zip code that is classified as “isolated rural” or “other small rural.”

greater the likely anticompetitive effects, the greater the likely efficiencies must be for the collaboration to pass muster under the antitrust laws. Although the rule of reason analysis lacks the kind of specificity desired by many health care providers and their counsel, the DOJ and FTC did acknowledge in the Antitrust Policy Statement that the eligibility requirements for the Medicare Shared Savings Program are generally consistent with the type of clinical integration the antitrust agencies have accepted in the past as procompetitive efficiencies that otherwise outweigh anticompetitive effects of collaborative collective bargaining with commercial insurers.

Conduct to Avoid

The Antitrust Policy Statement describes specific types of conduct that ACOs should avoid in order to reduce the potential for antitrust scrutiny, including:

- The use of certain anti-steering, anti-tiering, guaranteed inclusion, most favored nation, or similar contract provisions.
- Tying sales of the ACO's services to the private payer's purchase of other services from providers outside of the ACO, including those providers affiliated with an ACO participant.
- Contracting on an exclusive basis with ACO physicians, hospitals, ambulatory surgery centers ("ASCs"), or other providers that may prevent or discourage those providers from contracting with private payers outside of the ACO, either individually or through other ACOs or analogous collaborations.
- Restricting a private payer's ability to make available to its enrollees certain information about the ACO's cost, quality, and efficiency.

Analysis and Potential Issues with the Antitrust Policy Statement

- For those ACOs that fall outside the safety zone, the Antitrust Policy Statement leaves unanswered many questions about how the rule of reason might be applied in the context of ACOs and, in particular, the application of the rule of reason to collaborative collective bargaining with commercial insurers.
- While the Antitrust Policy Statement provides guidance on how the DOJ and FTC will monitor and enforce federal law, health care providers and suppliers have little guidance on how state authorities may apply state antitrust laws to ACOs and the collaborations between otherwise competing provider and suppliers.
- ACOs with shares in any PSA between 30 percent to 50 percent will face the difficult question of determining whether to spend the time and money necessary to obtain an expedited voluntary review. Given the views expressed

in the proposed policy statement, ACOs with shares in any PSA of greater than 50 percent should view an expedited voluntary review as a cheaper and less burdensome process than an investigation after the ACO is up and running.

- All ACOs must develop and implement firewalls to prevent the dissemination of competitively sensitive information between competitors. Even those ACOs within the safety zone are not exempt from antitrust scrutiny if there is evidence of collusion.
- All ACOs should develop and implement policies and procedures for avoiding potentially anticompetitive practices such as those described in the Antitrust Policy Statement.

IRS Fact Sheet

Overview

The IRS released [Notice 2011-20](#) when CMS published the proposed Shared Savings Program rule in April 2011. Notice 2011-20 provides an overview of how existing IRS guidance related to 501(c)(3), or charitable, organizations applies and relates to 501(c)(3) organizations participating in an ACO through the Medicare Shared Savings Program. The IRS released a [fact sheet](#) simultaneous to CMS's release of the Shared Savings Program's final rule that confirms that Notice 2011-20 reflects the IRS's expectations for charitable organizations participating in the Shared Savings Program and answers questions specific to charitable organizations wishing to participate in the Shared Savings Program. The following briefly summarizes Notice 2011-20 and the corresponding Fact Sheet.

Furthering Charitable Purposes and Factors to Avoid Inurement or Impermissible Private Benefit

Broadly speaking, a 501(c)(3) organization may participate in an ACO and not face adverse tax consequences if it continues to meet the requirements for tax exemption. Both Notice 2011-20 and the corresponding fact sheet emphasize that a charitable organization's participation in an ACO, as a general matter, will further the charitable purpose of the organization. More specifically, the IRS states, "any MSSP payments received by a tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government . . . as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP."⁴⁴ The IRS explains that CMS's oversight of the Shared Savings Program will ensure that an ACO serves the purpose of lessening the burdens of government.

⁴⁴ IRS Notice 2011-20 (Mar. 31, 2011).

Notice 2011-20 and the corresponding Fact Sheet both repeatedly state that the IRS will determine whether prohibited inurement or impermissible private benefit has occurred, as part of a charitable organization's participation in the Shared Savings Program, on "a case-by-case basis, based on all of the facts and circumstances."⁴⁵ Because, as stated above, CMS will regulate and provide oversight for the Shared Savings Program, the IRS expects that it will not consider a tax-exempt organization's participation in the MSSP through an ACO to result in inurement or impermissible private benefit to an ACO participant. The IRS, in Notice 2011-20, set forth five factors it will use to determine if there is inurement or impermissible private benefit. However, the IRS clarified in its fact sheet that no one of the five factors, listed below, must be satisfied, in all circumstances, to avoid inurement or impermissible private benefit.

The following factors, taken from Notice 2011-20, should be considered during the structuring of an ACO that includes charitable organizations:

- The terms of the tax-exempt organization's participation in the MSSP through the ACO (including its share of MSSP payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm's length.
- CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP.
- The tax-exempt organization's share of economic benefits derived from the ACO (including its share of MSSP payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO, and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests.
- The tax-exempt organization's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.
- All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.⁴⁶

⁴⁵ IRS Notice 2011-20 (Mar. 31, 2011).

⁴⁶ IRS Notice 2011-20 (Mar. 31, 2011).

Can an ACO Qualify for Tax Exemption Under 501(c)(3)?

The IRS fact sheet related to tax-exempt organizations participating in the Medicare Shared Savings Program specifies that an ACO “engaged exclusively in Shared Savings Program activities could qualify for tax-exemption under §501(c)(3), as long as the ACO also meets all of the other requirements for tax-exemption under that section.”⁴⁷ The fact sheet further states, “Note, however, that an ACO that is treated as a partnership or is disregarded for federal tax purposes is not eligible to apply for tax-exempt status under §501(c)(3).”⁴⁸

Unrelated Business Income (“UBI) and Unrelated Business Income Tax (“UBIT”)

The IRS fact sheet specifies that a charitable organization’s share of an ACO’s shared savings payment from Medicare will generally not be subject to the unrelated business income tax. The Fact Sheet further explains that an ACO’s activities unrelated to the Shared Savings Program will not always generate unrelated business income for the charitable organizations participating in the ACO. If the activities unrelated to the Shared Savings Program are substantially related to a tax-exempt participant’s charitable purpose, it will not generate unrelated business income for the ACO’s charitable organization participant(s). The IRS fact sheet explains:

Whether an ACO’s activities that are not substantially related to a charitable purpose will generate UBI for its tax-exempt participants will depend on a variety of factors. For example, certain kinds of income from the ACO, including dividends and interest, may be excluded from UBI under one of the modifications described in § 512(b) of the Code. In addition, if the ACO is treated as a partnership, whether a tax-exempt partner of the ACO will have to include its share of income derived from an activity in UBI will depend on such factors as whether the activity constitutes a trade or business, is regularly carried on, or is specifically excluded from the definition of an unrelated trade or business under § 513 of the Code.⁴⁹

⁴⁷ IRS Fact Sheet 2011-11 (Oct. 20, 2011).

⁴⁸ *Id.*

⁴⁹ *Id.*

Non-Shared Savings Program Activities

The IRS will consider the “facts and circumstances” surrounding an ACO’s non-shared savings program activities in order to determine whether those activities will jeopardize the tax-exempt status of a charitable organization. The IRS explains that an ACO’s conduct of activities that do not further a charitable purpose will not jeopardize the tax-exempt status of one of its participants if the ACO’s activities are not attributed to that participant, or if they represent no more than an insubstantial part of the participant’s total activities. Further, non-shared savings program activities may not jeopardize the tax-exempt status of a charitable organization if they further a charitable purpose—for example, the fact sheet specifies that an ACO’s activities related to serving Medicaid or indigent populations might further the charitable purpose of relieving the poor and distressed or the underprivileged. The IRS fact sheet notes that if an ACO is treated as a partnership, the ACO and its tax-exempt participants should consult IRS guidance regarding joint ventures for examples of partnerships conducting activities that further a charitable purpose of a tax-exempt participant.⁵⁰

Analysis and Potential Issues with the IRS Guidance

- In its Notice 2011-20 and corresponding fact sheet, the IRS repeatedly notes that whether a tax-exempt organization will jeopardize its tax-exempt status by participating in an ACO will be determined on a case-by-case basis, depending on all the facts and circumstances. As a consequence, ACOs that include tax-exempt organizations should carefully structure their ACOs to avoid adverse tax consequences to the participating charitable organizations. The five factors listed in Notice 2011-20 will help provide guidance to an ACO that includes charitable organizations as it structures its ACO.
- Note that not every activity that promotes health furthers a charitable purpose under 501(c)(3). Therefore, an ACO participating in activities outside of the Shared Savings Program should carefully consider: (1) whether the activity would further a charitable purpose, and if not, (2) whether the activity is a substantial or an insubstantial part of its activities.
- As advised by the IRS, “tax-exempt participants in ACOs treated as partnerships that plan to engage in activities other than participation in the Shared Savings Program should consult IRS guidance regarding joint ventures.”⁵¹
- The IRS may release additional guidance regarding a tax-exempt organization’s participation in an ACO in the future—stay tuned.

⁵⁰ *Id.*

⁵¹ *Id.*

Conclusion

The Medicare Shared Savings Program, and similar efforts to establish alternative payment models at the federal and state level or in partnerships with commercial insurance, present both challenges and opportunities for the health care/life sciences industry. Reed Smith will be closely monitoring the regulatory guidance issued as a result of the Patient Protection and Affordable Care Act, and we will be reporting on major developments on our policy blog, www.healthindustrywashingtonwatch.com. We look forward to working with our clients to develop and implement strategies to respond to alternative payment models, including proposals related to ACOs and the Shared Savings Program. Please feel free to contact us if you have questions or if you need additional information.

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