HALL RENDER
KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

MARCH 31, 2011

BREAKING NEWS: CMS ISSUES ITS PROPOSED RULE FOR ACCOUNTABLE CARE ORGANIZATIONS

This installment of Hall Render's Health Law Broadcast series on health care reform is designed to provide you with the insight, analysis and practical suggestions with respect to the various reform initiatives that will affect your organization.

BACKGROUND

Introduction. On March 31, 2011, approximately one year from the date the Patient Protection and Affordable Care Act ("Affordable Care Act") was enacted, the Centers for Medicare and Medicaid Services ("CMS") issued its proposed rule (the "Proposed Rule") outlining the framework for implementation of Accountable Care Organizations ("ACOs"). The Proposed Rule is expected to be published in the Federal Register on April 7, 2011, and provides for a public comment period of 60 days. The Proposed Rule, though lengthy, is indeed instructive for hospitals, certain other providers, physicians, and/or other practitioners as they strive to develop new patient care models that facilitate patient-centric, quality, cost-effective care, coordinated along the patient care continuum.

In developing the Shared Savings Program, CMS worked closely with other federal government agencies to ensure a coordinated approach in the implementation of the Shared Savings Program. Accordingly, along with the Proposed Rule, several other agencies issued related concurrent notices/statements, including the Office of the Inspector General ("OIG"), the Internal Revenue Service ("IRS"), and the Federal Trade Commission and Department of Justice (collectively, the "Antitrust Agencies").

The following is a select overview of the Proposed Rule. More detailed analysis of certain provisions of the Proposed Rule will follow.

Statutory Basis for the Medicare Shared Savings Program. By way of background, Section 3022 of the Affordable Care Act required the Secretary of Health and Human Services ("HHS") to establish the Medicare Shared Savings Program ("Shared Savings Program") intended to encourage the development of ACOs. Section 3022 of the Affordable Care Act amended Title XVIII of the Social Security Act (the "Act") (42 U.S.C. 1395 et seq.) by adding new Section 1899 to establish a Shared Savings Program. Section 1899 sets forth the types of groups of providers of services and suppliers with established mechanisms for shared governance that are eligible to participate as ACOs under the Program, as well as requirements that eligible groups must meet in order to participate.

Overview and Intent of the Medicare Shared Savings Program. Pursuant to the Affordable Care Act, the intent of the Shared Savings Program is to (i) promote accountability for a population of Medicare beneficiaries, (ii) improve the coordination of fee for service ("FFS") items and services, (iii) encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and (iv) incent higher value care. The Proposed Rule establishes the requirements for ACOs to take responsibility for improving the quality of care while lowering costs, in return for a share of the resulting savings. In addition to establishing a shared savings model that rewards quality and financial performance, the program holds ACOs accountable for excess expenditures by establishing a (initially optional) two-sided risk model which requires repayment of losses to CMS. CMS believes that this represents a new approach for the Medicare FFS program, under which providers have traditionally had little financial incentive to coordinate care or to be financially accountable for the total costs and quality of the care provided.

PROVISIONS OF PROPOSED RULE

ORGANIZATION OF THE PROPOSED RULE.

This section is a road map of the proposed rule. More importantly, however, it defines an ACO, an ACO Participant and an ACO Provider/Supplier.

ACO. An ACO shall be a legal entity recognized and authorized under applicable State law, identified by a Taxpayer Identification Number ("TIN"), and comprised of an eligible group (as defined later in the proposed rule) of ACO participants that work together to manage and coordinate care for Medicare FFS beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process.

ACO Participant. An ACO participant is a Medicare-enrolled provider of service and/or a supplier and identified by a TIN.

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

ACO Provider/Supplier. An ACO Provider/Supplier is a provider of services and/or supplier that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.

ELIGIBILITY AND GOVERNANCE.

Eligible Entities. CMS contemplated the addition of federally qualified health centers ("FQHCs") and Rural Health Centers ("RHCs") to the list of groups eligible to participate as ACOs. However, due to the absence of the data elements required for assignment of beneficiaries, it is not possible for FQHCs and RHCs to participate in the Shared Savings Program by forming their own ACOs. It is, however, possible for them to join as an ACO participant in an ACO containing one or more of the statutory organizations eligible to form an ACO and upon which assignment can be made consistent with the statute and the assignment methodology proposed in this proposed rule. The assignment of beneficiaries to ACOs in which FQHCs and RHCs are participating would have to be based solely on data from the other eligible ACO participants upon whom assignment can be based. Additionally, CMS determined that billing procedures (where a critical access hospital ("CAH") submits bills for both the facility and the professional services to its Medicare fiscal intermediary or its Medicare Part A/B MAC) used by CAHs does provide for the type of data needed in an ACO.

Thus, CMS has added CAHs, which use the specified billing method, to the list of the four groups specifically identified in the Act (ACO professionals in group practice arrangements; Networks of individual practices of ACO professionals; Partnerships or joint venture arrangements between hospitals and ACO professionals; and Hospitals employing ACO professionals) that would have the opportunity to form ACOs independently.

Legal Structure and Governance. Operationally, an ACO's legal structure must provide both the basis for its shared governance as well as the mechanism for it to receive and distribute shared savings payments to ACO participants and providers/suppliers.

- **Legal Entity** - The ACO's legal entity may be structured in a variety of ways, including: a corporation, partnership, limited liability company, foundation, or other entity permitted by State law. If an existing legal entity meets the eligibility requirements to be an ACO, as described in the proposed rule, it may operate as an ACO, as long as it is recognized under applicable State law and is capable of receiving and distributing shared savings, repaying shared losses, and performing the other ACO functions identified in the statute and regulations, including the requirement for shared governance for ACO participants. Each ACO would be required to certify that it is recognized as a legal entity under State law and authorized by the State to conduct its business in each State in which it operates.
- **Governance** - An ACO must establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO. A governing body may be 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, and that has the authority to execute the statutory functions of an ACO.
- **Composition of the Governing Body** - ACOs should be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries. In order to be eligible for participation in the Shared Savings Program, the ACO participants must have at least 75 percent control of the ACO's governing body. CMS is proposing that ACOs be required to partner with community stakeholders as part of their application, and that ACOs provide for beneficiary involvement in their governing processes.

Leadership and Management Structure. ACOs should have a leadership and management structure that includes clinical and administrative systems. ACOs must meet the following criteria:

- The ACO's operations would be managed by an executive, officer, manager, or general partner, 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.
- Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present in that State.
- ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success.
- The ACO would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program.

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

- The ACO would develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, and lower growth in expenditures.
- The ACO would have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of care.

In order to determine an ACO's compliance with these requirements, as part of the application process, CMS lists the documents to be submitted by the ACO.

Accountability for Beneficiaries. An ACO executive who has the authority to bind the ACO must certify to the best of his or her knowledge, information, and belief that the ACO participants are willing to become accountable for, and to report to CMS on the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO. The certification would be included as part of the ACO's application and 3-year participation agreement.

Agreement Requirement. The ACO Agreement between CMS and the ACO will need to include the following terms and conditions:

- A certification of an executive of the ACO, who has the ability to bind the ACO, that to the best of his or her knowledge, information, and belief, the ACO participants agree to the requirements set forth in the 3-year agreement between the ACO and CMS, sign a 3-year participation agreement and submit the signed agreement to CMS.
- Require an ACO to give CMS 60 days advance written notice of the ACO's intention to terminate its agreement to participate in the Shared Savings Program.
- If an ACO completes its 3-year agreement successfully, CMS will refund in full any portion of shared savings withheld during the course of the 3-year agreement period that is not needed to offset losses.
- In the event an ACO's 3-year agreement is terminated before the completion of the 3 years, CMS will retain any portion of shared savings withheld.
- All ACOs, ACO participants, and ACO providers/suppliers with direct or indirect obligations under the Shared Savings Program shall be subject to the requirements of the agreement between the ACO and CMS and that all certifications submitted on behalf of the ACO in connection with the Shared Savings Program application, agreement, shared savings distribution, or otherwise, extend to all parties with obligations to which the particular certification applies.

Distribution of Savings. The distribution of shared savings will be made to the ACO TIN directly, which such TIN could be associated with an entity that is a non-Medicare-enrolled entity. CMS states that it intends to require the ACO to include in its application for an ACO, how the ACO plans to use potential shared savings to meet the goals of the program.

Sufficient Number of Primary Care Providers and Beneficiaries. Beneficiaries will be assigned to an ACO on the basis of primary care services rendered by physicians with primary care specializations in general practice, internal medicine, family practice, and geriatric medicine. This algorithm will also be used to assign beneficiaries during the baseline years in order to establish a historical per capita cost benchmark against which the ACO would be evaluated during each year of the agreement period. An ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the 3-year benchmarking period using the ACO participant TINs exceeds the 5,000 threshold for each year. The number of assigned beneficiaries could fall below the 5,000 level due to either significant events, or in those instances where the actual number of beneficiaries is close to 5,000 as a result of normal fluctuations in patient populations. If the ACO falls below the 5,000, the ACO will be given a warning and put on a corrective plan and remain eligible for shared savings for the performance year for which a warning was issued. If the ACO's assigned population has not returned to at least 5,000 by the end of the second performance year, then that ACO's agreement will be terminated and the ACO would not be eligible to share in savings for the second performance year.

Required Reporting on Participating ACO Professionals. Entities applying to participate in the Shared Savings Program must provide not only the TINs of the ACO and the ACO participants, but also a list of national provider identifiers (NPIs) associated with the ACO providers/suppliers, which would separately identify the physicians that provide primary care. In addition, an ACO will be required to

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

maintain, update, and annually report to CMS the TINs of its ACO participants and the NPIs associated with the ACO providers/suppliers.

Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, and Coordination of Care. CMS decided on an option that simply requires documentation of an ACO's plans to "define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies," and not require any more specific criteria for these requirements.

- **Processes to Promote Evidence-Based Medicine** - Evidence-based medicine seeks to assess the strength of evidence of the risks and benefits of treatments (including lack of treatment) and diagnostic tests, and applies this evidence to the processes of medical decision-making and treatment. The ACO would be required to describe the evidenced-based guidelines it intends to establish, implement, and periodically update.
- **Processes to Promote Patient Engagement** - The term "patient engagement" is the active participation of patients and their families in the process of making medical decisions. The ACO would be required to describe, in its application, the patient engagement processes it intends to establish, implement, and periodically update.
- **Processes to Report on Quality and Cost Measures** - As part of the application, the ACO would describe its process to report internally on quality and cost measures, and how it intends to use that process to respond to the needs of its Medicare population and to make modifications in its care delivery.
- **Processes to Promote Coordination of Care**- Coordination of care involves strategies to promote, improve, and assess integration and consistency of care across primary care physicians, specialists, and acute and post-acute providers and suppliers, including methods to manage care throughout an episode of care and during transitions between providers. ACOs would be prohibited from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

Patient Centeredness Criteria. CMS outlines eight areas, which ACOs will need to address to demonstrate patient-centeredness. Some of these areas include: individualized care, beneficiary access to their own medical records, assessment of beneficiary and caregiver and/or family experience of care, smooth transitions among providers, patient involvement in ACO governance, process for evaluating health needs of the ACO's assigned population, systems to identify high-risk individuals, and processes for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

- **Beneficiary Experience of Care Survey** - ACOs shall have a beneficiary experience of care survey in place, specifically the Clinician and Group CAHPS survey, and be required to collect and report on measures of beneficiaries' experience of care, and to submit their plan on how they will promote, assess, and continually improve in weak areas identified by the survey.
- **Patient Involvement in Governance** - The ACO will be required to demonstrate a partnership with Medicare FFS beneficiaries by having representation by a Medicare beneficiary serviced by the ACO, in the ACO governing body. However, CMS requests comments on the possible use of a Medicare beneficiary advisory panel or committee in promoting the goal of engaging patients in ACO governance.
- **Evaluation of Population Health Needs and Consideration of Diversity** - With an eye towards the need to consider diversity in its patient populations, ACOs are required to describe, in their application, their process for evaluating the health needs of their Medicare population, including consideration of diversity, and a plan to address the needs of their Medicare population.
- **Implementation of Individualized Care Plans and Integration of Community Resources** - ACOs must have systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations. The plan must be tailored to: (1) the beneficiary's health and psychosocial needs; (2) account for beneficiary preferences and values; and (3) identify community and other resources to support the beneficiary in following the plan.

ACO Marketing Guidelines. In order to avoid beneficiaries from being misled into thinking that they may only receive services or only certain services from the other participating ACO providers/suppliers, CMS requires that all ACO marketing materials, communications, and activities related to the ACO and its participation in the Shared Savings Program, such as mailings, telephone calls or community events, that are used to educate, solicit, notify, or contact Medicare beneficiaries or providers/suppliers regarding the ACO and its participation in the Shared Savings Program, be approved by CMS before use. This approval requirement is extended to any revisions of such materials.

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

Program Integrity Requirements. CMS proposed the following program integrity criteria to protect the Shared Savings Program from fraud and abuse.

- **Compliance Plans** - An ACO must have a compliance plan with the following elements: (i) a designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body; (ii) mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance; (iii) a method for employees or contractors of the ACO or ACO providers/suppliers to report suspected problems related to the ACO; (iv) compliance training of the ACO's employees and contractors; and (v) a requirement to report suspected violations of law to an appropriate law enforcement agency.
- **Compliance with Program Requirements** - Although the ACO may have relationships with other entities, the ACO maintains ultimate responsibility for compliance with all terms and conditions of its agreement with CMS. All contracts or arrangements between or among the ACO, its ACO participants and ACO providers/suppliers, and other entities furnishing services related to ACO activities require compliance with the obligations under the 3-year agreement. An executive, who has the ability to legally bind the ACO, must make a written request for payment of the shared savings in a document that certifies the ACO's compliance with program requirements.
- **Conflicts of Interest** - ACO governing bodies must have a conflicts of interest policy that applies to members of the governing body.
- **Screening of ACO Applicants** - ACOs will not be subject to the existing screening for enrolling in Medicare, but will be screened for integrity history, including any history of program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.
- **Prohibition on Certain Required Referrals and Cost Shifting** - To address the risk of inappropriate cost-shifting within Medicare and other Federal health care programs, CMS is considering prohibiting ACOs and their ACO participants from conditioning participation in the ACO on referrals of Federal health care program business that the ACO or its ACO participants know or should know is being provided to beneficiaries who are not assigned to the ACO.

ESTABLISHING THE 3-YEAR AGREEMENT WITH THE SECRETARY.

Options for Start Date of the Performance Year. The timing of the application process for an ACO's participation in the Shared Savings Program and its start date will be as follows:

- ACO applications must be submitted by a deadline established by CMS;
- CMS will review the applications and approve applications from eligible organizations prior to the end of the calendar year;
- The requisite 3-year agreement period will begin on January 1 following approval of an application; and
- The ACO's performance periods under the agreement will begin on January 1 of each respective year during the agreement period.

Timing and Process for Evaluating Shared Savings. An ACO's eligibility to receive a payment for shared savings will be based upon an analysis of the claims submitted by providers and suppliers for services and supplies furnished to beneficiaries assigned to the ACO. Due to the lags inherent in the claims reporting and payment processes, all Medicare service and expenditure data have a defined claims run-out period. A "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. In an effort to accurately determine the per capita expenditures associated with each respective ACO, a 6-month claims run-out will be used to calculate the benchmark and per capita expenditures for the performance year. This longer 6-month period allows for more accurate and complete utilization and expenditure data used to determine the ACO's eligibility to receive shared savings.

Data Sharing. So that ACOs have the ability to understand the totality of care provided to beneficiaries assigned to them, including those services and supplies beneficiaries receive from providers and suppliers outside its organization, ACOs will have an opportunity to request CMS claims data on their potentially assigned beneficiary population.

Sharing Aggregate Data. CMS shall make aggregated Medicare data available to ACOs so as to identify priority areas of care upon which to focus for improvement. The Medicare data and other data provided to ACOs will include:

- aggregated metrics on the assigned beneficiary population;

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

- beneficiary utilization data at the start of the agreement period based on historical data used to calculate the benchmark;
- yearly financial and quality performance reports; and
- quarterly aggregate data reports to ACOs based upon the most recent 12 months of data from potentially assigned beneficiaries.

Identification of Historically Assigned Beneficiaries. CMS will disclose to the ACO the name, date of birth (DOB), sex and Health Insurance Claim Number (HIC) of the ACO's historically assigned beneficiary population, in an effort to allow the ACO to benefit from understanding which of their fee-for-service beneficiaries were used to generate the aggregated data reports. The disclosure of this protected health information ("PHI") is permitted under the HIPAA Privacy Rule, because the disclosure is for "health care operations" purposes, and would constitute the minimum data necessary to accomplish the Shared Savings Program goals of the ACO.

Sharing Beneficiary Identifiable Claims Data. CMS will share beneficiary identifiable claims data with the ACOs upon request from the ACO, either at the time of application, or upon the receipt by CMS of a formal request for data during the agreement period. ACOs will be required to enter into a Data Use Agreement ("DUA") prior to receipt of any beneficiary identifiable claims data. Under the DUA, the ACO would be prohibited from sharing the Medicare claims data, provided through the Shared Savings Program, with anyone outside the ACO. ACOs will only be allowed to request beneficiary identifiable claims data for beneficiaries who have 1) visited a primary care participating provider during the performance year, and 2) have not chosen to opt-out of claims data sharing.

- ***Legal Authority to Provide Beneficiary Identifiable Data to ACOs*** - The disclosure of patient information is allowed under the current privacy laws. The proposed disclosure of Part A and B claims data would be permitted by the HIPAA Privacy Rule provisions governing disclosures for "health care operations." Although the Part D data rule did not expressly address the question of whether Part D data could be shared with external entities for purposes other than research, CMS believes that the release of Part D claims data to ACOs for the purpose of supporting care coordination, quality improvement, and performance measurement activities, would be consistent with the purposes outlined in the Part D data rule. Thus, CMS will provide the ACO with data elements such as: beneficiary ID, prescriber ID, drug service date, drug product service ID, and indication if the drug is on the formulary.
- ***Beneficiary Opportunity to Opt Out of Claims Data Sharing*** - As part of its broader activities to notify patients at the point of care that their provider or supplier is participating in an ACO, the ACO must also inform beneficiaries of its ability to request claims data about them if they do not object. The beneficiaries will be provided the ability to opt-out of sharing their protected health information with the ACO.

New Program Standards Established During 3-Year Agreement Period. Although an ACO enters into a 3-year agreement with CMS, during the 3-year period, it will be subject to complying with future changes in regulation with the exception of the following program areas:

- eligibility requirements concerning the structure and governance of ACOs;
- calculation of sharing rate; and
- beneficiary assignment.

Failure by an ACO to effectuate the required changes will result in the ACO being placed on a corrective action plan, and, if after being given an opportunity to act upon the corrective action plan the ACO still fails to come into compliance, it would be terminated from the program.

Managing Significant Changes to the ACO During the Agreement Period. During the 3-year agreement, an the ACO may not add ACO participants; however the ACO may remove ACO participants (TINs) or add/subtract ACO providers/suppliers (NPIs). The ACO is required to notify CMS when such significant changes occur so that it may approve the new structure. The review by CMS could result in one of five actions:

- The ACO may continue with savings calculations for the performance year based upon the updated list of ACO participants and ACO providers/suppliers;
- The ACO must start over as a new ACO with a new 3-year agreement;
- The ACO is so materially different from the initially approved ACO that the ACO must obtain approval from a reviewing Antitrust Agency before it can continue in the program;

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

- The remaining ACO structure no longer meets the eligibility criteria for the program, and the ACO would no longer be able to participate in the program; or
- CMS and the ACO may mutually decide to terminate the agreement.

Future Participation of Previously Terminated Program Participants. In its application for an ACO, the applicant must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the program under the same or a different name, and specify whether it was terminated or withdrew voluntarily from the program. If an ACO was terminated, it may not begin another 3-year agreement period until the original agreement period has lapsed. An ACO may not reapply to participate in the Shared Savings Program if it previously experienced a net loss during its first 3-year agreement period.

ASSIGNMENT OF MEDICARE FEE-FOR-SERVICE BENEFICIARIES.

One of the more anticipated aspects of the proposed regulations relates to how beneficiaries will be assigned to an ACO. The proposed regulations make it clear that while an ACO professional may include a number of different type of providers, the Shared Savings Program must consider only a beneficiary's utilization of primary care services by ACO professionals who are physicians. CMS outlines four elements that are used to take into consideration beneficiary assignment to an ACO:

- An operational definition of an ACO;
- A definition of primary care of services;
- A determination concerning whether to assign beneficiaries respectively or retrospectively during a given year; and
- A determination concerning the proportion of primary care services necessary to assign them to an ACO.

CMS comments that assignment in "no way implies any limits, restrictions, or diminishment of the rights" of Medicare beneficiaries to exercise complete freedom of choice.

Operational definition. According to CMS, the two data sources available to identify specific providers of services and suppliers that would participate in an ACO include the National Provider Identifier (NPI) and the provider's tax identification number (TIN). CMS explains that using TINs, in its opinion, provides the most direct link between the beneficiary and the practice providing primary care services. For this reason, CMS proposes to identify an ACO operationally as a collection of Medicare enrolled TINs, which may include the combined TINs from ACO professionals that form the ACO. CMS also proposes that ACO professionals who are primary care physicians within a respective TIN on which the beneficiary assignment is based, will be exclusive to one ACO agreement. Non-primary care physicians and other providers who participate in an ACO are not restricted from participation in a single ACO. CMS notes that this exclusivity restriction is intended to address ACOs developing "excessive market power, especially in areas with shortages of physicians." NPIs will also be utilized for monitoring an ACO's activities with regard to quality and other ACO activities.

Definition of primary care services. CMS proposes to define primary care services for purposes of beneficiary assignment to physicians who are defined to be primary care providers, which include internal medicine, general practice, family practice, and geriatric. These physician determinations are based on indentified HCPCS codes described in Section 5501 of the Affordable Care Act. CMS recognizes that defining primary care services in this way may make it difficult to form ACOs in regions with primary care shortages.

Assignment prospectively or retrospectively. CMS seems to have incorporated provider input regarding the concern that it is important to be able to profile a population in order to address specific population needs, while at the same time recognizing the value of ACOs being informed of their expected assigned population. CMS proposes to utilize an approach of retrospective beneficiary assignment that would occur at the end of a performance year based on utilization data.

Proportion of primary care services. This element relates to the Program requirement that beneficiaries be assigned "on their utilization of primary care services." CMS has proposed that utilization of primary care services be based upon a plurality of allowed charges. This was the method utilized in the Physician Group Practice Demonstration Project.

Beneficiary notification. CMS comments on the value of beneficiaries having the ability to exercise free choice and at the same time forging relationships that are in their best interests. Therefore, CMS proposes to develop a communications plan that would serve to educate them about the Program, the possibility of being assigned to an ACO, and other information regarding how their health information may be shared

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

within an ACO. CMS proposes that beneficiary notification would come from the ACO directly.

QUALITY AND OTHER REPORTING REQUIREMENTS.

A theme throughout the Affordable Care Act, including the Shared Savings Program, are the goals of improving care for individuals and improving the health for populations. To accomplish these goals, CMS proposes a number of measures to assess the quality of care furnished by an ACO and outlines requirements for how data will be submitted by ACOs. Closely related to these measures are what quality performance standards ACOs will be held to and what reporting requirements will be imposed with regard to an ACO's performance. To this end, CMS proposes that an ACO will be considered to have met a quality performance standard if it has reported the required quality measures and also meets the applicable performance criteria for each of the three performance years of an ACO's minimum obligation.

Quality Measures. For 2012, CMS proposes 65 performance measures that are categorized into 5 domains: patient/caregiver experience, care coordination, patient safety, preventative health, and at high-risk population/frail elderly health. Many of these measures are commonly known, as they either have received National Quality Forum endorsement or are used in other CMS quality programs. Following 2012, CMS will propose additional or different measures in future proposed rule making. CMS specifically requests comment on whether the list of proposed measures should be narrowed or whether they should be excluded for scoring purposes and utilized for monitoring only.

Data submission. The requirements for submitting quality measurement data will be familiar to providers who participate in the Physician Quality Reporting System, Hospital Compare and other CMS data reporting programs. CMS recognizes, however, that certain quality measures that will come from claims submission, such as the care coordination measures, do not squarely fit with existing claims processing systems. To address this gap, CMS proposes to make available its GPRO data collection and survey tool to ACOs. The GPRO tool was utilized by a number of large group practices and other providers as part of Physician Quality Reporting System in 2010. CMS also outlines proposed requirements for how it will address random sampling of measures and how it will perform periodic audits on data submission.

Certified EHR Technology. CMS highlights its use of quality measures that are currently included in its EHR Incentive Program as CMS' goal is to require 50% of an ACO's primary care providers to be meaningful EHR users as defined under the meaningful use regulations.

Quality Performance Standards. In order to be eligible for shared savings, ACOs must meet the quality performance goals for the proposed 65 measures. CMS proposes to use what is called a performance score approach for establishing the quality standards. In its words, "the performance score approach rewards ACOs for better quality with larger percentages of shared savings." As a brief description, CMS will score the performance on each measure and combine the scores into a score for each domain. The percentage of points then earned for each domain will be aggregated based upon a described weighting methodology to arrive at a single percentage that will be applied the ACOs sharing rate. CMS intends to set the quality performance standard for the first year of the program at the reporting level and adjust it higher in subsequent years. A shared savings percentage of 50 or 60% will be determined by the ACO's choice of a one or two-sided risk model as described above. There is ample discussion within the proposed rule regarding whether CMS should alternatively adopt a blended approach.

Public Reporting. Following the premise that public reporting of an ACO's performance would improve a beneficiary's ability to make informed decisions, while at the same time assisting the ACO to improve its quality and efficiency, CMS proposes that the following information be transparent to the public: 1) providers and suppliers participating in an ACO; 2) parties sharing in the governance of the ACO; 3) quality of performance standard scores; and 4) general information on how the ACO shares savings with its members.

As an interesting component to this public reporting requirement, CMS also proposes that ACO participants be identified who have joint ventures between ACO professionals and hospitals. CMS does indicate, though, that public reporting may be limited to the extent it is not administratively feasible.

SHARED SAVINGS DETERMINATION.

Given there are many questions by providers whether the investment and effort in developing and participating in an ACO will be worthwhile, the determination for actual shared savings that are attainable is on everyone's mind. But in addition to shared savings, CMS is authorized to utilize other payment models. Relying in part on comments that CMS received in response to its November 2010 solicitation, CMS is proposing to adopt a hybrid approach to the proposed payment models that will combine the elements of a pure shared savings model and a risk-based option. CMS sees the hybrid approach as benefiting organizations with less experience with risk models (physician organizations and smaller ACOs) by having a perhaps easier way to access the Shared Savings Program without the downside associated

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

with sharing and losses. This hybrid approach would entail ACOs having an option between two tracks:

- Track 1 - this option allows for ACOs to reconcile the shared savings on an annual basis for the first two years using a pure shared savings approach and transitioning in the third year during which the ACO would agree to share in losses and savings generated by their operations.
- Track 2 - ACOs with more experience at managing populations and who are ready to share in the losses with a greater upside in savings, may elect to enter a risk-based model for the entire three years of its agreement. ACOs choosing Track 2 would be eligible for higher sharing rates.

Expenditure Benchmark. Recall that an ACO is eligible for shared savings "if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percents specified by the secretary below the applicable benchmark...." CMS describes in the proposed rule how it proposes to establish the expenditure benchmark by: 1) comparing the benchmark to assigned beneficiary per capita data, 2) then establish the minimum savings rate, and 3) then determine what the required sharing cap will be on the total amount of shared savings paid to an ACO.

Minimum Savings Rate. With a goal of the Shared Savings Program being to encourage and reward ACOs for coordinating the care for assigned beneficiaries in a way that also manages the growth of Medicare expenditures, CMS recognizes that normal variations may result in cost savings in the absence of any intentional effort by an ACO. With this in mind, CMS intends to establish a minimum savings rate to provide some assurance that the ACO's performance "is a result of its interventions, not normal variations." In establishing this minimum savings rate, CMS comments that its goal is to achieve a balance between the advantages of providing incentives and "prudent stewardship of the Medicare trust funds." So because CMS is obligated to take into consideration the number of fee-for-service beneficiaries assigned to an ACO, CMS proposes to assign minimum savings rates for Track 1 ACOs based upon the number of assigned beneficiaries to the ACO. These rates range from 2.0% to 3.9% depending upon a number of variables.

Net Sharing Rate. For determining the net sharing rate, CMS proposes to share savings beyond a specified threshold with ACOs that exceed their minimum savings rate. CMS also recognizes that certain ACOs that care for underserved populations or which may be smaller "physician-driven" ACOs may have various challenges in developing an ACO. To address this concern CMS proposes to exempt ACOs with less than ten thousand (10,000) assigned beneficiaries that are either comprised of only ACO professionals in a group practice arrangement or networks of individual practices; or 75% or more of the ACOs assigned beneficiaries reside in counties outside a Metropolitan Statistical Area; or 50% or more of the ACOs assigned beneficiaries were assigned to the ACO on the basis of primary care services received from a Method II billing Critical Access Hospital; or 50% or more of the beneficiaries assigned to the ACO had at least one encounter with an ACO participating Federally Qualified Health Center or Rural Health Center in the most recent year in which complete claims data is available. CMS also proposes an increase in the savings rate that may be available if the ACO utilizing a pure shared savings model includes a Federally Quality Health Center or Rural Health Center.

Withholding of Savings. As a safeguard against ACOs failing to fulfill a three (3) year obligation, CMS is proposing to impose a flat 25% withholding rate to be applied annually to any earned performance payment. This withhold is intended to offset future losses. At the end of each agreement period, any positive balance would be returned to the ACO or otherwise forfeited if the ACO fails to complete its three (3) year agreement.

Payment Limit. In response to the requirement that CMS establish limits on the total amounts that can be paid to an ACO, CMS proposes to establish the payment limit of 7.5% of an ACO's benchmark for the first two (2) years of its agreement under a pure shared savings model. For those ACO's that adopt the two-sided or at-risk model, CMS proposes a payment limit of 10%, which would also apply to the third year for ACOs that choose the one-sided, pure shared savings model.

MONITORING AND TERMINATION OF ACOS.

Much of the delay for the Shared Savings Program proposed rule was speculated to be about concerns with building appropriate safeguards against abuse and addressing concerns by various federal agencies who have jurisdiction over ACO issues. Of CMS' concerns is that ACOs may avoid certain patients in order to avoid increasing costs that may disqualify them from receiving shared savings. To address this concern and to deal with ACOs that do not meet quality performance standards, CMS proposes to both monitor and terminate those ACOs that fail to perform. CMS outlines the available methods for monitoring an ACO, which include an analysis of submitted data and aggregated

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

reports, site visits, assessments and related investigations after receipt of a complaint, and various audit tools.

The basic approach CMS proposes to take with regard to terminating an ACO agreement would involve: 1) providing a warning notice of a specific performance concern, 2) requesting or the opportunity to submit a corrective action plan, or 3) placing the ACO on a special monitoring plan. CMS outlines a number of specific reasons in which it would be compelled to terminate an ACO ranging from a failure to meet performance standards to an inability to demonstrate that an ACO has adequate resources in place to repay losses and to maintain resources for the agreement. CMS is seeking comment on these and other actions that may be appropriate before terminating an agreement with an ACO.

COORDINATION WITH OTHER AGENCIES.

In developing the Shared Savings Program and in response to stakeholder concerns, CMS worked with other interested federal agencies to facilitate participation in the Shared Savings Program and to ensure a coordinated approach in the implementation of the program. As a result, three documents were issued contemporaneously with this Proposed Rule: (i) a joint CMS and OIG document entitled, "Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center," addressing proposed waivers fraud and abuse laws; (ii) an IRS notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Shared Savings Program; and (iii) a proposed Antitrust Policy Statement issued by the Antitrust Agencies. In addition, CMS proposes to preserve the benefits of competition for Medicare beneficiaries by precluding newly formed ACOs with market power from participating in the Shared Savings Program.

Waivers of CMP, Anti-Kickback, and Stark Laws. Certain arrangements between and among ACOs, ACO participants, owners, and providers/suppliers, and third parties may implicate the civil monetary penalties ("CMP") laws, the federal Anti-Kickback Statute, and/or the physician self-referral prohibition (referred to as the "Stark Law"). Section 1899(f) of the Act authorized the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Program. Accordingly, CMS and OIG jointly published a separate "Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center" (the "Proposed Waivers"), which describes and solicits public input regarding possible waivers of the application of certain CMP law provisions, the Anti-Kickback Statute, and the Stark Law. Notably, CMS and OIG assert that that many exceptions and safe harbors already exist that might apply to ACO arrangements, depending on the circumstances.

Stark Law. The federal Stark Law prohibits physicians from making referrals for Medicare "designated health services" (including hospital services) to entities with which they (or their immediate family members) have a financial relationship, unless an exception applies, and prohibits the entity from billing Medicare for services rendered as a result of a prohibited referral. Violations of the statute may result in civil monetary penalties and liability under the False Claims Act.

The Secretary would waive application of the Stark Law to distributions of shared savings received by an ACO under the Medicare Shared Savings Program:

- To or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; and
- For activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program.

The proposal would purportedly protect financial relationships created by the distribution of shared savings within the ACO, as well as financial relationships created by a distribution of shared savings outside the ACO, but only if the distribution outside the ACO relates closely to the requirements for an ACO under Section 1899 of the Act. Distributions of shared savings dollars to referring physicians outside the ACO would not be protected unless those physicians are being compensated (using shared savings) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. Other financial relationships with referring physicians outside the ACO would need to meet an existing exception under the Stark Law (e.g., the fair market value, personal services, or indirect compensation exceptions).

Anti-Kickback Statute. The Anti-Kickback Statute provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under any of the federal health care programs. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the Statute may also result in the imposition of CMPs, program exclusion, and liability under the False Claims Act. Certain practices that meet all of the

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

conditions of a statutory exception or regulatory safe harbor are not subject to prosecution or sanctions under the Statute.

CMS and OIG have proposed to waive application of the provisions of the Anti-Kickback Statute in the following two scenarios:

- Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (i) to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (ii) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program.
- Any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Stark Law and fully complies with an exception under Stark.

Similar to the Stark waiver, other financial arrangements outside the ACO would need to fit in a safe harbor or otherwise comply with the Anti-Kickback Statute. With respect to the reference to Stark in the second bullet, CMS and OIG note that ordinarily, compliance with an exception to Stark does not provide immunity under Anti-Kickback Statute; however, in light of the specific safeguards proposed to be incorporated in the Medicare Shared Savings Program and the waiver authority, CMS and OIG have proposed a limited exception to this general rule. Failure to qualify for one of the proposed waivers under the Anti-Kickback Statute would not mean that an arrangement is automatically illegal, but the arrangement would nevertheless need to comply with the Statute.

CMP Laws. Sections 1128A(b)(1) and (2) of the Act (the "Gainsharing CMPs") apply to certain payment arrangements between hospitals and physicians, including arrangements commonly referred to as "gainsharing" arrangements. A hospital is prohibited from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. Violations may result in penalties of up to $2,000 per patient covered by the payments.

The Secretary would waive application of the provisions of the Gainsharing CMPs in the following two scenarios:

- Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program in circumstances where the distributions are made from a hospital to a physician, provided that (i) the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and (ii) the hospital and physician are ACO participants or ACO providers/suppliers, or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.
- Any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Stark Law and fully complies with Stark exception.

Duration of Waivers. The waivers related to the distribution of shared savings would apply to the distributions of shared savings earned by the ACO during the term of the agreement to participate in the Medicare Shared Savings Program, even if the actual distributions occur after the expiration of the agreement. The Anti-Kickback Statute and Gainsharing CMP waivers for arrangements that comply with an existing Stark exception would apply during the term of the ACO's agreement to participate in the Medicare Shared Savings Program.

Solicitation of Comments. CMS and OIG are also soliciting comments on the following topics:

- Arrangements related to establishing the ACO
- Arrangements between or among ACO participants and/or ACO providers/suppliers related to ongoing operations of the ACO and achieving ACO goals
- Arrangements between the ACO, its ACO participants, and/or its ACO providers/suppliers and outside individuals or entities
- Distributions of shared savings or similar payments received from private payors
- Other financial arrangements for which a waiver would be necessary
- Duration of waivers
- Additional safeguards

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

- Scope of proposed waivers
- Two-sided risk model
- Use of existing exception and safe harbor for electronic health records arrangements that are expected to occur after the sunset date of 2013 currently applicable to that exception and safe harbor
- Beneficiary inducements
- Timing of waivers

CMS expects that the waivers applicable to ACOs participating in the Shared Savings Program will be issued concurrently with the publication of the Shared Savings Program final rule. Because of the interplay between the final ACO regulations and the development of waivers necessary to carry out the provisions of the Shared Savings Program, commenters to the Proposed Rule should also consider commenting on the Proposed Waivers.

IRS Guidance Relating to Tax-Exempt Organizations. Nonprofit hospitals and other health care organizations recognized by the IRS as tax-exempt organizations are likely to participate in the development and operation of ACOs in the Shared Savings Program. Accordingly, the IRS has indicated that it will solicit public comment on whether existing guidance relating to the Internal Revenue Code provisions governing tax-exempt organizations is sufficient for those tax-exempt organizations planning to participate in the Shared Savings Program through ACOs, and if not, what additional guidance is needed. The IRS also intends to solicit comments concerning what guidance, if any, is necessary for tax-exempt organizations participating in ACOs that conduct activities unrelated to the Shared Savings Program.

Antitrust Policy Statement. Concurrently with the issuance of this Shared Savings Program proposed rule, the Antitrust Agencies have issued a proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program ("Antitrust Policy Statement").

The Antitrust Policy Statement sets forth an antitrust "Safety Zone" for certain ACOs. Specifically, the Antitrust Policy Statement provides that the Antitrust Agencies, absent extraordinary circumstances, will not challenge an ACO that otherwise meets the CMS criteria to participate in the Shared Savings Program if ACO participants that provide the same service ("common service") have a combined share of 30% or less of each common service in each ACO participant's Primary Service Area ("PSA") wherever two or more ACO participants provide that service to patients from that PSA. Also, under a "Rural Exception" set forth in the Antitrust Policy Statement, ACOs may qualify for the Safety Zone under certain circumstances even if their combined PSA share for common services would be greater than 30%. The Antitrust Policy Statement further provides that an ACO outside the Safety Zone may proceed without scrutiny by the Antitrust Agencies if its combined PSA share for each common service, wherever two or more ACO participants provide that service to patients from that PSA, is less than or equal to 50%. An ACO in this category is also highly unlikely to present competitive concerns if it avoids certain specified conduct. The Antitrust Policy Statement explains, however, that for ACOs that do not meet the Rural Exception, a combined PSA share for common services of more than 50% provides a valuable indication of an ACO's potential for competitive harm.

The Antitrust Policy Statement outlines a methodology by which ACOs can calculate their shares of common services (that is, the same services provided by two or more ACO participants) provided to patients from the same PSA. The "common services" consist of physician specialties, major diagnostic categories ("MDCs") for inpatient settings, and outpatient categories for outpatient settings.

Prohibition Against Shared Savings Program Participation by ACOs with Market Power. In light of the Antitrust Agency Policy Statement, CMS proposes that, except for an ACO that qualifies for the "Rural Exception" articulated in the Antitrust Policy Statement, an ACO with a PSA share above 50% for any common service that two or more ACO participants provide to patients from the same PSA must submit to CMS, as part of its Shared Savings Program application, a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging, the proposed ACO. Absent such a letter, the proposed ACO will not be eligible to participate in the Shared Savings Program. The procedures for obtaining such review are set forth in the Antitrust Policy Statement.

An ACO that is outside the Safety Zone and below the 50% mandatory review threshold and desires further certainty regarding the application of the antitrust laws to its formation and planned operation can seek an expedited review from the Antitrust Agencies, similar to the mandatory review described previously. Such an ACO will not be eligible to participate in the Shared Savings Program if the reviewing Antitrust Agency reviews the ACO and determines that it is likely to challenge or recommend challenging the ACO as anticompetitive.

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.

Finally, an ACO that falls within the Safety Zone would not be required to obtain an Antitrust Agency review as a condition of participation.

CMS provided the following chart to summarize the applicability of Antitrust Agency review/approval requirements:

ACO PSA Share	Review Process
	Safety Zone - No antitrust review necessary by the Antitrust Agencies
>30 percent and	*Expedited review, compliance with list of conduct restrictions, or proceed without antitrust assurances* - ACOs may: • Request an expedited review by the Antitrust Agencies and submit letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO, • Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of an antitrust investigation, or • Begin to operate and remain subject to antitrust investigation if it presents competitive concerns.
>50 percent	*Required expedited review* - ACO must seek review by the Antitrust Agencies to assess likelihood of pro-competitive and anti-competitive effects. ACO eligibility to participate in Shared Savings Program is contingent on the ACO's submission of a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO.

In the event of a material change in the composition of an ACO during the 3-year agreement period, the ACO must notify CMS of the change within 30 days and that the ACO must recalculate and report at that time their PSA shares, which may trigger mandatory review or re-review by the Antitrust Agencies.

OVERLAP WITH OTHER CMS SHARED SAVINGS INITIATIVES.

Section 1899 of the Act includes a provision that precludes duplication in participation in shared savings programs. Providers of services or suppliers thatparticipate in certain programs are not eligible to participate in the Shared Savings Program. Interested parties should check the CMS website for an updated list to ensure that they do not participate in another Medicare program or demonstration involving shared savings. However, in order to maintain flexibility for ACO providers/suppliers to participate concurrently in multiple shared savings programs, CMS did not extend this prohibition to individual providers and suppliers. Accordingly, an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program and another shared savings program if the patient population is unique to each program and if none of the relevant Medicare-enrolled TINs participate in both programs.

If you have questions or are interested in commenting on the Proposed Rule, please contact Brian Betner at bbetner@hallrender.com or 317.977.1466; Erin Drummy at edrummy@hallrender.com or 317.977.1470; or Tina Torossian at ctorossian@hallrender.com or 248.457.7806.

THIS IS AN ADVERTISEMENT
© 2002-2024. Hall, Render, Killian, Heath & Lyman, P.C. All Rights Reserved.