Client Advisory

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Government Issues Eagerly Awaited Proposed ACO Regulations

At long last, the oft-delayed Proposed Rule for Accountable Care Organizations (the Proposed Rule) has been issued with only nine months remaining before the Medicare Shared Savings Program is implemented on January 1, 2012. The question now is whether there will be a sufficient number of ACO applicants around the country standing in line to manage the health care needs of an expected 5,000,000 Medicare beneficiaries.

The Proposed Rule, along with a new statement on antitrust enforcement and possible waivers of certain federal laws, such as Stark and the Anti-Kickback Statute, reflects considerable thought and unprecedented coordination between CMS, the Federal Trade Commission, the Department of Justice, the Office of the Inspector General and the IRS (the Agencies). However, more questions have been raised than necessarily answered. CMS and the other Agencies are actively seeking comments on many of the key standards that are still in flux and which need to be finalized before a potential ACO participant can make a truly informed decision on whether to submit a certification application to CMS.

Examples of the unresolved standards include issues and questions relating to the shared savings methodologies, especially the two-sided risk model; the full extent of the final waivers; and the identification of the final quality benchmarks and how performance results will be collected and reported. There are also important questions associated with the ACO leadership, governance and management requirements that, for all practical purposes, will necessitate the establishment of a new legal entity as opposed to the utilization of an existing corporation, partnership or LLC. Moreover, the start-up costs and infrastructure required to comply with the Proposed Rule would appear to favor well-capitalized health care systems and payors over small physician groups and standalone provider facilities.

Despite these challenges, providers will feel compelled to review the provisions of the Proposed Rule and standards. The Executive Summary below and the more detailed analysis that follows are intended to assist potential ACO participants in their deliberations.

EXECUTIVE SUMMARY

Eligibility

ACOs can and will take many different forms and encompass different provider groups, including:

- ACO professionals (defined as an ACO provider/supplier who is either a doctor of medicine or osteopathy, or a practitioner as defined in the Patient Protection and Affordable Care Act (the Act), including physician assistants, nurse practitioners and clinical nurse specialists) in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals (defined as acute care hospitals paid under the hospital inpatient prospective payment system) and ACO professionals
- Hospitals employing ACO professionals
- Providers or suppliers otherwise recognized under the Act that are not ACO professionals
- Certain critical access hospitals

Legal Structure

- An ACO's structure must be one recognized and authorized to conduct business under state law (e.g., corporation, partnership, LLC, foundation).
- An ACO must be able to receive and distribute shared savings.
- An ACO can be an existing legal entity, if it otherwise meets all other requirements.
- An ACO must have a tax identification number.
- An ACO need not be enrolled in Medicare Program, but each ACO participant must be so enrolled.

Governance

- An ACO's governing body must have a board of directors that has adequate legal, management and executive authority to implement and enforce all requirements under the Act, including the promotion of evidence-based medicine and patient engagement, reporting on quality and cost measures, and the coordination of care.
- The governing body must be comprised of ACO participants or their designated representatives.
- The governing body must include Medicare beneficiary representatives who are served by the ACO.
- At least 75% control of an ACO's board of directors must be held by ACO participants.
- Each ACO participant must have proportionate control over governing body decision making.

Management

- An ACO must be managed by an executive, officer, manager or general partner under the control of the ACO governing body.
- Clinical management must be through a full-time senior-level medical director.

Quality Assurance and Process Improvement

- A physician-directed quality assurance and process improvement committee must oversee an ongoing action-oriented quality assurance and improvement program.
- Internal performance standards for quality of care and services, cost-effectiveness and other standards must be adopted and implemented.
- ACO participants must be held accountable for meeting performance standards.
- ACO participants must make a meaningful commitment either through financial investment or meaningful investment of time and effort.
- An ACO must have data collection and evaluation infrastructure, such as information technology.

Compliance Plan

- An ACO must have a compliance plan that meets specific requirements which are standard within the health care industry, including a compliance official who is not the in-house general counsel.

Patient-Centeredness Criteria

- An ACO must meet patient-centeredness criteria specified by CMS.

Assignment of Medicare Beneficiaries to ACOs

- Medicare fee-for-service beneficiaries are assigned to an ACO based on their utilization of primary care services by a primary care physician who is an ACO provider/supplier during the performance year for which savings are determined.
- Beneficiary assignment does not in any way diminish or restrict the rights of beneficiaries to exercise free choice in determining where to receive health care services, including a provider who is not a participant in the assigned ACO.

Sufficient Number of Primary Care Providers and Beneficiaries

- An ACO must have a sufficient number of primary care physicians to treat at least 5,000 Medicare patients and must maintain an assigned beneficiary population of at least 5,000 such patients.

Distribution of Savings

- ACOs will be required to provide in their application a description of the criteria to be employed for distribution of shared savings among ACO participants and how such savings will be used to align with the aims of better care for individuals, better health for patient populations, and lower growth of expenditures.

Three-Year Agreement with CMS

- ACOs will be required to enter into a three-year agreement with CMS.

CMS Monitoring, Termination, Audits and Record Retention

- CMS will monitor the compliance of ACOs with all requirements, conduct investigations as may be necessary, collect any and all information relevant to assessing performance, and may terminate an ACO based on 16 specified grounds set forth in the Proposed Rule.

Quality and Other Reporting Requirements

- The Proposed Rule identifies 65 quality measures. The required benchmarks are still to be identified, but an ACO and its participants must meet all of the quality performance standards in order to be eligible for shared savings.
- Measures are divided into five domains:
  - Patient/caregiver experience (7 measures)
  - Care coordination (16 measures)
  - Patient safety (2 measures)
  - Preventative health (9 measures)
  - At-risk population/frail elderly health (31 measures relating to diabetes, heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disorder and frail elderly)
- Where an ACO fails to meet minimum attainment levels for one or more domains, fails to report all required measures or provides inaccurate or incomplete recording, the ACO agreement will be terminated under certain conditions.
- An ACO must submit quality measures data to CMS in order to monitor and determine whether it has achieved minimal compliance with required benchmarks.
- The level of compliance with these benchmarks will affect the percentage of savings that the ACO will be entitled to receive and distribute to its participants.

Shared Savings Determination

- CMS has proposed a hybrid approach for structuring the Shared Savings Program that would allow an ACO to choose between two tracks. This is intended to provide an entry point for organizations that have less experience in "at risk" (e.g., HMO) arrangements, while providing more experience with population management before transitioning to a full risk model.
- Track 1 (one-sided model): Shared savings would be reconciled annually for the first two years of the three-year arrangement using a one-sided shared saving approach. ACOs would not be responsible for any portion of the losses above the expenditure target until the third year. Thereafter, ACOs would participate in the two-sided model, sharing in losses as well as savings.
- Track 2 (two-sided model): The two-sided model is for ACOs ready to share in losses for all three years of the agreement. These ACOs would be eligible for higher sharing rates than under the one-sided model.
- For a more detailed description of the shared savings methodology, see Section III below.

Proposed Statement of Antitrust Enforcement

- ACOs that are certified by CMS and therefore must meet various clinical integration, legal and governance structural requirements, will be viewed by the FTC/DOJ as bona fide arrangements intended to improve quality and reduce costs.
- Consequently, the Agencies will apply a "Rule of Reason" as opposed to the "Per Se" analysis to ACOs when negotiating payor contracts in the commercial market, which will allow the ACO to identify community benefits achieved through the ACO to offset any anti-competitive effects of its operations and practices.

- In order to be in the proposed antitrust Safety Zone, independent ACO participants that provide the same "common service" (e.g., cardiology, gastroenterology) must have a combined share of 30% or less in each common service in each participant's Primary Service Area (PSA) whenever two or more ACO participants provide that service to patients from that PSA which means that Agencies will not investigate or intervene, barring extraordinary circumstances.
- The PSA for each common service is defined as "the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients for that service."
- Hospital and surgery center participation in an ACO must be nonexclusive in order to fall within the Safety Zone.
- The Safety Zone applies to physicians or other providers irrespective of whether they are exclusive or nonexclusive to the ACO.
- For a more detailed description of the calculation methodology for PSA shares, see Section V below.
- See also discussion of rural exception, dominant provider limitation and mandatory review of ACOs that exceed the 50% PSA share threshold.

Fraud and Abuse Waivers

CMS and the Office of the Inspector General have proposed three types of waivers and have solicited comments on additional waivers and waiver criteria:

- Stark Law waiver for distribution of shared savings received by an ACO from CMS under the Shared Savings Program to or among ACO participants, and ACO providers/suppliers, and for activities necessary for and directly related to ACO's participation in the Shared Savings Program
- Anti-Kickback Statute waiver for the same savings distribution and activities as described in the Stark Law waiver plus a waiver for any financial relationships between or among such described parties necessary and directly related to participation in the Shared Savings Program
- Gainsharing Civil Monetary Penalty waiver for savings distribution under the Shared Savings Program from a hospital to a physician, subject to specified conditions, and for financial relationships among the ACO, ACO participants and ACO providers/suppliers directly related to participation in the Shared Savings Program

IRS Notice 2011-20

- The IRS has solicited comments on sufficiency of existing IRS guidance for tax-exempt entities participating in the Shared Savings Program.

PROVISIONS OF THE PROPOSED RULE

I. Eligibility and Governance

A. Eligible Entities

- The following ACO participants (providers and suppliers as defined in the Affordable Care Act (the Act) and identified by a taxpayer identification number (TIN)) are eligible, separately or in combination, to form ACOs that may participate in the Shared Savings Program:
  - ACO professionals (defined as an ACO provider/supplier who is either a doctor of medicine or osteopathy, or a practitioner as defined in the Act, including physician assistants, nurse practitioners and clinical nurse specialists) in group practice arrangements
  - Networks of individual practices of ACO professionals
  - Partnerships or joint venture arrangements between hospitals (defined as acute care hospitals paid under the hospital inpatient prospective payment system) and ACO professionals
  - Hospitals employing ACO professionals
  - Providers or suppliers otherwise recognized under the Act that are not ACO professionals
  - Certain critical access hospitals

- ACO applicants must provide the TINs of the ACO and ACO participants and the national provider identifiers (NPIs) associated with the ACO's providers/suppliers. Such information must be maintained, updated and annually reported to CMS.

B. Legal Structure

- An ACO must be formed as a legal entity that is recognized and authorized under applicable state law, such as a corporation, partnership, limited liability company, foundation or any other permitted entity.
- An ACO must certify 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.
- The legal entity must be constituted such that it can receive and distribute shared savings, repay shared losses and establish, report and ensure provider compliance with health care quality criteria, including quality performance standards.
- An ACO must have a TIN. The ACO need not be enrolled in the Medicare program, but each ACO participant must be so enrolled.
- There is no requirement that existing legal entities, appropriately recognized under state law, must form a new entity to participate in the Shared Savings Program. If an existing legal entity meets the eligibility requirements to be an ACO, it may so qualify. One such example identified in the preamble of the Proposed Rule is a hospital employing ACO professionals. However, CMS acknowledges the difficulties that such a hospital ACO presents and specifically invites comment on whether every ACO should be required to be formed as a distinct legal entity.

C. Governance

- An ACO must establish and maintain a governing body with adequate authority to execute the functions of the ACO, including, but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.
- The governing body must have and possess broad responsibility for the ACO's administrative, fiduciary and clinical operations.
- The governing body must comprise the following:
  - ACO participants or their designated representatives; and
  - Medicare beneficiary representative(s) served by the ACO who (along with immediate family members) do not have a conflict of interest with the ACO.
- At least 75% control of the ACO's governing body must be held by ACO participants.
- Each ACO participant must choose an appropriate representative from within its organization to represent it on the governing body and each ACO participant must have proportionate control over governing body decision making.
- The governing body of an ACO must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent entities, such as several independent physician practice groups.

D. Management

- An ACO's operations must be managed by an executive, officer, manager or general partner whose appointment and removal are under the control of the ACO'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 must be managed by a full-time senior-level medical director who is physically present on a regular basis in an established ACO location, and who is a board-certified physician and licensed in the state in which the ACO operates.

E. Quality Assurance and Process Improvement

- A physician-directed quality assurance and process improvement committee must oversee an ongoing action-oriented quality assurance and improvement program.
- The quality assurance program must establish internal performance standards for quality of care and services, cost-effectiveness, and process and outcome improvements, and hold the ACO's providers/suppliers accountable for meeting the performance standards.

- ACO participants and ACO providers/suppliers must have a meaningful commitment to the ACO's clinical integration program, such as by a meaningful financial investment in the ACO or a meaningful investment of time and effort.
- An ACO must implement evidence-based medical practice or clinical guidelines and processes. ACO participants and providers/suppliers must agree to comply with these guidelines and processes and be subject to performance evaluations and remedial actions, including expulsion from the ACO.
- An ACO must have an infrastructure, such as information technology, that enables it to collect and evaluate data and provide feedback to ACO participants and ACO providers/suppliers.

F. Compliance Plan

- An ACO must have a compliance plan that satisfies specified requirements which are standard for the health care industry, including a designated compliance official who is not the in-house legal counsel.

G. Processes to Promote Evidence-Based Medicine, Patient Engagement and Coordination of Care, and to Report on Quality and Cost Measures

- An ACO must have processes to promote evidence-based medicine, patient engagement and coordination of care, and to report on quality and cost measures. It must provide documentation in its application describing such processes and reporting procedures.

H. Patient-Centeredness Criteria

- An ACO must meet patient-centeredness criteria specified by CMS.
- The Proposed Rule specifies processes and features that will cause CMS to consider the ACO to be patient-centered, including, for example, patient involvement in governance and a mechanism for coordination of care.

I. Data Sharing with ACOs

- CMS will share both aggregate data and beneficiary identifiable data with ACOs. The aggregate data reports will be shared at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark and each quarter thereafter during the agreement period. The aggregate data will include financial performance, quality performance scores, aggregated metrics on the assigned beneficiary population and utilization data.
- Sharing of beneficiary-specific data with an ACO will be subject to the right of each assigned beneficiary to opt out of the claims data sharing, except for four data points (beneficiary name, beneficiary date of birth, beneficiary sex and beneficiary health insurance claim number).
- Prior to receiving any beneficiary identifiable data, an ACO must enter into a data use agreement with CMS.

J. Assignment of Medicare Beneficiaries to ACOs

- Medicare fee-for-service beneficiaries are assigned to an ACO based on their utilization of primary care services by a primary care physician who is an ACO provider/supplier during the performance year for which shared savings are determined. CMS will employ the following assignment methodology:
  - for each ACO, identification of all primary care physicians who were ACO participants during the performance year;
  - at the end of each performance year, determination of all beneficiaries who received services from an ACO's primary care physicians;
  - determination of the total allowed charges for primary care services that each of the identified beneficiaries received from any provider or supplier during the performance year;
  - for each beneficiary, computation of the allowed charges for primary care services provided by the primary care physicians in each ACO; and
  - assignment of a beneficiary to an ACO if the beneficiary has received a plurality of his or her primary care services, as determined by the sum of allowed charges for those services, from identified primary care physicians who are ACO participants.

- Such beneficiary assignment in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

K. Sufficient Number of Primary Care Providers and Beneficiaries

- For eligibility purposes, an ACO will 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 three-year benchmarking period using the ACO participant TINs exceeds the 5,000-beneficiary threshold for each year.
- If an ACO's assigned population falls below 5,000 during the course of the agreement period, CMS will issue a warning and place the ACO on a corrective action plan. The ACO will remain eligible for shared savings for the performance year for which the warning was issued.
- If the ACO fails to have more than 5,000 beneficiaries by completion of the next performance year, the ACO's participation agreement will be terminated and the ACO will not be eligible to share in savings for that year.

L. Distribution of Savings

- Any shared savings payments will be made directly to an ACO as identified by its TIN.
- ACOs will be required to provide in their application a description of the criteria to be employed for distribution of shared savings among ACO participants and providers/suppliers, and how any shared savings will be used to align with the aims of better care for individuals, better health for populations and lower growth in expenditures.

M. Three-Year Agreement with CMS

- ACO applications will need to be submitted by a deadline established by CMS. Applications will be reviewed and approved prior to the end of the calendar year.
- The requisite three-year agreement will begin on January 1 following approval of an application.
- An ACO's performance will begin on January 1 of each respective year during the agreement period.

N. Significant Changes to the ACO During Agreement Period

- During the three-year agreement, an ACO may remove, but not add, ACO participants, althought it may remove or add ACO providers/suppliers. ACOs must notify CMS at least 30 days prior to any significant change.
- A significant change occurs when an ACO is unable to fulfill its three-year agreement due to:
  - deviation from its approved application, such as a reorganization of the ACO's legal structure or other changes in eligibility;
  - a material change as defined in Section 425.14 of the Proposed Rule (Termination, Suspension, and Repayment of Shared Savings); or
  - government-required reorganization as a result of fraud or antitrust concerns.
- CMS will review an ACO's notification and make one of the following determinations:
  - the ACO may continue to operate under the new structure with savings calculations for the performance year based upon the updated list of ACO participants;
  - the ACO structure is so different from the initially approved ACO that it must submit a new application and, if applicable, undergo an antitrust review;
  - the ACO is materially different from the initially approved ACO because of the inclusion of additional ACO providers/suppliers such that the ACO must obtain an antitrust review and a letter from the reviewing Agency stating that it has no present intent to challenge the ACO. An ACO's failure to request an antitrust review in a timely manner shall be deemed to constitute voluntary termination of its three-year agreement;
  - the ACO no longer meets the eligibility criteria for the Shared Savings Program and its three-year agreement must be terminated; or
  - CMS and the ACO may mutually decide to terminate the agreement.

O. New Program Standards Established During the Three-Year Agreement Period

- ACOs will be subject to all statutory changes. ACOs also will be subject to all regulatory changes, except:
  - eligibility requirements concerning the structure and governance of ACOs;
  - calculation of sharing rate; and
  - beneficiary assignment.
- Where changes in law or regulations require an ACO to change its processes pertaining to design, delivery and quality of care, or to planned distribution of shared savings, the ACO must submit to CMS for review and approval a supplement to the ACO's original application detailing how it will address key changes in processes resulting from these modifications.
- If an ACO cannot effectuate the changes needed to conform to the regulatory modifications, it will be terminated from the Shared Savings Program.

P. CMS Monitoring During Three-Year Agreement

- CMS will employ a range of methods similar to those developed for purposes of Medicare Advantage and Medicare's prescription drug program to monitor and assess the performance of ACOs.
- The goals of this monitoring activity will be to:
  - identify ACOs that may be avoiding at-risk beneficiaries;
  - ensure that ACOs continue to meet specified eligibility requirements; and
  - ensure that ACOs are properly notifying beneficiaries regarding sharing of claims data and providing opportunities to opt out of such data sharing arrangements.
- These methods may include, without limitation, analysis of financial and quality data reported by ACOs, site visits, analysis of complaints and audits.
- If CMS suspects cases of beneficiary avoidance, it may request further investigation and follow-up with the beneficiary or the ACO and its ACO providers/suppliers.
- If CMS finds beneficiary avoidance, it may require the ACO to submit a corrective action plan (CAP) and implement the plan as approved by CMS.
- While under the CAP, the ACO's shared savings payments will be suspended.
- The ACO will be reevaluated during and after the CAP implementation period, and if CMS determines that the ACO continued to avoid at-risk beneficiaries during or after the CAP, the ACO's participation in the Shared Shavings Program may be terminated.
- CMS will review submission of quality measurement data by ACOs and may request additional documentation from ACOs, ACO participants or ACO providers/suppliers to determine whether ACOs are meeting quality performance standards.
- Prior to terminating an ACO, CMS may take a variety of actions, including, without limitation:
  - issuing an initial warning with subsequent reevaluation the following year;
  - requesting required data with an explanation as to why the ACO did not timely submit the data; and
  - subjecting the ACO to a CAP during which time the ACO's performance will be monitored.
- If the ACO exhibits a pattern of inaccurate or incomplete reporting, fails to make timely corrections following notice to resubmit or fails to demonstrate improved performance upon completion of the CAP, CMS may terminate the ACO from the Shared Savings Program.

Q. ACO Termination, Reapplication and Reconsideration

- The Proposed Rule sets forth 16 grounds for termination of an ACO agreement, including the failures noted above.
- If an ACO is terminated from the Shared Savings Program, it may apply to reenter only under the two-sided model and only after the end of its original three-year agreement period. The ACO must also demonstrate that it has corrected the deficiencies that caused its termination and has processes in place to ensure future compliance.

- If an ACO decides to terminate its agreement, it must notify CMS, its ACO participants and ACO providers/suppliers within 60 days. In turn, the ACO participants and providers/suppliers must notify the ACO's beneficiaries in a timely manner.
- If an ACO agreement is terminated for any reason before the end of the three-year agreement period, the ACO forfeits its mandatory 25% withholding of any shared savings.
- The Proposed Rule creates an administrative process by which ACOs may request review of CMS determinations, such as the denial of a Shared Savings Program application or the termination of an ACO agreement, for reasons other than those exempted by statute.
- The Proposed Rule proposes a process similar to that used by the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies competitive bidding program and the Medicare Advantage Part C and D programs. An ACO may appeal initial determinations by requesting a reconsideration review by a CMS reconsideration official.
- Upon completion of this review, if any of the parties disagree with the recommendation of the reconsideration official, the decision can be further appealed to an independent CMS official who was not involved in the initial determination or the reconsideration review process.
- The independent CMS official will then conduct an on-the-record review of the reconsideration official's recommendation. This review is final and binding.
- An ACO appealing a termination decision will be able to continue to participate in the Shared Savings Program during the review process, but if the termination decision is upheld, the termination is effective as of the date of the initial notice of termination.
- If CMS's initial determination to terminate the ACO is reversed, the ACO will be reinstated into the Shared Savings Program, retroactively back to the date of termination. Notably, this administrative process cannot be used to appeal determinations deemed unreviewable either by the Affordable Care Act or CMS's final rule.

R. Audits and Record Retention

- An ACO must agree, and must require its ACO participants, ACO providers/suppliers and contracted entities performing services or functions on behalf of the ACO to agree, that HHS, the Comptroller General, the OIG or their designees have the right to audit, inspect and evaluate any books, contracts, records, documents and other evidence pertaining to the ACO's activities under the Shared Savings Program. These same ACO parties must maintain such records for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation or inspection, whichever is later, unless there is a special reason to maintain such records for a longer period of time.
- Regardless of any arrangements between or among the ACO parties, the ACO bears ultimate responsibility for fully complying with all the terms and conditions of its agreement with CMS, including this record retention requirement.

Comments and Recommendations

- The Proposed Rule proposes that existing entities, as well as newly formed distinct ACO entities, can qualify to participate in the Shared Savings Program. CMS acknowledges the difficulties that an existing entity presents, particularly in terms of the ability to monitor and audit compliance with all the program requirements. CMS has specifically requested comment on this issue.
- Providers interested in participating in an ACO need to quickly establish legal governance and management structures consistent with state law in order to be prepared to submit their applications to CMS for review and certification.
- Entities seeking to qualify for participation in the Shared Savings Program will need to quickly determine their ACO participants. Of particular note in this regard, during an ACO's three-year agreement with CMS, it may remove, but not add, ACO participants, meaning that the maximum number of ACO participants will be frozen during such three-year period. This restriction would seem to make little sense except where it may impact a mandatory review by the FTC/DOJ if an ACO's market share in a PSA exceeds 50%. We expect that there will be comments regarding this restriction.
- While the Proposed Rule provides for the flexibility of a certified ACO to alter its structure during its three-year CMS agreement (other than the addition of ACO participants), such restructuring will be a significant change, requiring prior notification to CMS, review by CMS, and a range of possible CMS determinations, including the required submission of a new application and antitrust review or termination of its CMS agreement.

II. Quality and Other Reporting Requirements

- Consistent with the overall purpose of the Affordable Care Act, the intent of the Shared Savings Program is to achieve high-quality health care for patients in a cost-effective manner. As part of CMS's goal to provide better care for individuals, defined as "safe, effective, patient-centered, timely, efficient, and equitable," the regulations propose:
  - measures to assess the quality of care furnished by an ACO;
  - requirements for data submission by ACOs;
  - quality performance standards;
  - incorporation of reporting requirements under the Physician Quality Reporting System; and
  - requirements for public reporting by ACOs.
- ACOs that do not meet quality performance thresholds for all measures would not be eligible for shared savings, regardless of how much per capita costs were reduced.

A. Proposed Quality Measures for ACO Quality Performance Standard

- The Proposed Rule proposes 65 quality measures that must be reported to CMS based on data submitted by ACOs, which must meet applicable performance criteria for all three years. (See pp. 19571–19591 of the April 7, 2011, Federal Register.)
- In year one, an ACO must provide full and accurate measures reporting with respect to all 65 measures.
- In years two and three and thereafter, the quality performance standard will be based on a measures scale with a minimum attainment level described in the Proposed Rule.
- Measures are divided into five domains:
  - Patient/caregiver experience (7 measures)
  - Care coordination (16 measures)
  - Patient safety (2 measures)
  - Preventative health (9 measures)
  - At-risk population/frail elderly health (31 measures relating to diabetes, heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disorder and frail elderly)

B. Impact of Failure to Comply

- Where an ACO fails to meet the minimum attainment level for one or more domains, the ACO would receive a warning and a requirement to reevaluate the following year. If the ACO continues to underperform on the quality performance standard in the following year, the ACO agreement will be terminated.
- If an ACO fails to report one or more measures, a written request would be sent to the ACO requiring the submission of the required data and a reasonable explanation for the delay in reporting. If the ACO continues to fail to report without a reasonable explanation, the ACO agreement will be immediately terminated.
- ACOs that exhibit a pattern of inaccurate or incomplete recording or failure to make timely corrections following a notice to resubmit may be terminated from the Shared Savings Program and would be disqualified from sharing in savings in each year in which they underperform.
- Measures are expected to evolve over time to include other highly prevalent patient conditions as well as additional measures for hospital-based care and quality measures for care furnished in other settings such as home health services and nursing homes.

C. Requirements for Quality Measures Data Submission by ACOs

- CMS proposes to make available a CMS-specified data collection tool and a survey tool for the 65 identified measures, although some are already being reported through methods such as the Physician Quality Reporting System, eRx, HITECH program data and Hospital Compare.
- The expectation is that the random sample for measures reported must consist of at least 411 assigned beneficiaries per measures set for each domain.

- The government retains the right to validate data entered into the system and to audit for compliance. Failure to report quality measure data accurately, completely and timely or to timely track such data may subject an ACO to termination or other sanctions.
- Assuming compliance with all other requirements, an ACO that obtains the total potential points for all five domains within the quality performance standard will share in 60% of the savings generated under the two-sided model, versus 50% under the one-sided model.
- The first year only requires complete and accurate reporting of all quality measures. Thereafter, savings will vary based on an ACO's actual performance on measures as compared with identified benchmarks.

D. Public Reporting

- The Proposed Rule describes CMS's intent to report the following to the general public:
  - Providers and suppliers participating in an ACO
  - Parties sharing in the governance of an ACO
  - Quality performance standards scores
  - General information on how an ACO shares savings with its members.
  - A description of how savings are spent and invested in services, infrastructure, etc.

Comments and Recommendations

- Compliance with these quality performance standards will be mandated in order to remain eligible for the Shared Savings Program and will affect the percentage of savings that can be shared among ACO participants.
- Compliance may also have a direct or indirect impact on provider responsibilities under accreditation standards, doctrine of corporate negligence and related civil liability theories, and DOJ/OIG expectations on board responsibility for delivering quality health care services, which could trigger False Claims Act exposure.
- ACOs and participating providers therefore need to incorporate these quality metrics and standards—minimally at the ACO entity level, but possibly at the local provider level as well (e.g., participating hospitals, physician groups, ASCs).
- Standards need to be developed that track the 65 measures, and ensure that they are communicated to providers and then monitored for compliance.
- Providers need to receive periodic reports regarding their individual and comparative performances.
- Remedial action plans need to be developed that are designed to assist providers in meeting standards but can include the ability to suspend or terminate participation, at least at the ACO entity level, and possibly at the local provider level.
- Performance results should be taken into consideration at the time of appointment, reappointment and contract renewal, and some internal administrative process/fair hearing for participants who are excluded should be provided.
- It is important that an ACO evaluate its processes and procedures, reports, analyses, etc., so as to maximize available confidentiality and immunity protections under state and federal law (e.g., participation in a Patient Safety Organization under Patient Safety Act of 2005).

III. Shared Savings Determination

A. Background: Two Risk Models

CMS has proposed a hybrid approach for structuring the Shared Savings Program that would allow ACOs to choose between two tracks. This is intended to provide an entry point for organizations that have less experience in "at risk" (e.g., HMO) arrangements, while providing more experienced ACOs an opportunity to receive greater reward for greater risk.

- **Track 1 (one-sided model):** Shared savings would be reconciled annually for the first two of the three-year arrangement. ACOs would not be responsible for any portion of the losses above the expenditure target until the third year. Thereafter, ACOs would participate in the two-sided model.

- **Track 2 (two-sided model):** This model is for ACOs ready to share in losses for all three years of the agreement period. ACOs would be eligible for higher sharing rates than those available under the one-sided model.

B. Shared Savings Methodology

The Proposed Rule includes the following determinations about the design of the shared savings methodology:

- **Establishing an Expenditure Benchmark, Which Involves the Following Four Factors**
  - Determining the patient population for whom the benchmark is calculated
    - Option 1: The benchmark would be based on expenditures of beneficiaries who would have been assigned to an ACO in each of the three years prior to the start of the ACO's agreement period using the ACO participants' TINs.
    - Option 2: The benchmark would be based on the populations of specific beneficiaries who are actually assigned to an ACO during the agreement period. CMS considered, but is not proposing this option.
    - CMS has solicited comments on both options, particularly as to how each approach might affect the willingness of ACOs to participate in the Shared Savings Program, create incentives for ACOs to seek or avoid certain kinds of beneficiaries, and impact Medicare beneficiaries
  - Determining adjustments for beneficiary characteristics such as demographic factors or health status
    - CMS has noted that under a shared savings model, the realization of savings against a benchmark could be a function of: (a) reduced expenditure growth as a result of greater quality and efficiency in delivering services, or (b) changes in the characteristics of the beneficiaries who are under the care of the ACO.
    - CMS considered two options for risk adjusting the average per capita expenditures to reflect beneficiary characteristics: (a) consider only patient demographic factors (age, sex, Medicaid status and the basis for Medicare entitlement), or (b) incorporate diagnostic information, specifically, the CMS-HCC prospective risk adjustment model used under the Medicare Advantage program.
    - CMS proposes to employ the second option, noting that the CMS-HCC model predicts health care expenditures more accurately than the demographic-only model, as it accounts for variation in case complexity and severity.
    - CMS proposes to calculate a single benchmark risk score for each ACO, which would be applied throughout the agreement period to the annual assigned patient populations per capita expenditures for assigned beneficiaries. The benchmark risk score would be calculated by applying the CMS-HCC model to the assigned beneficiary population attributed in each year of the three-year benchmark.
    - However, CMS also proposes that changes in the assigned beneficiary population risk score from the three-year benchmark period during the performance year not be incorporated. This is intended to protect the program from costs due to greater diagnosis coding intensity in the ACOs.
    - CMS has solicited comments on this proposal, including alternative approaches such as using the Medicare Advantage "new enrollee" demographic risk adjustment model for risk adjusting, or applying a coding intensity cap on annual growth in the risk scores on an ACO's assigned beneficiary population.
    - CMS intends to audit ACOs, especially those with high levels of risk score growth.
  - Determining whether other adjustments to the three-year benchmark are warranted
    - CMS considered adjusting the benchmark to avoid potentially disadvantaging certain types of providers, such as hospitals receiving Medicare disproportionate share hospital (DSH) adjustments, teaching hospitals that receive indirect medical education (IME) payments and ACOs located in high-cost or low-cost areas.
    - CMS does not propose to remove IME and DSH payments from the per capita costs included in the benchmark for an ACO, but has asked for comments on the issue. CMS is particularly interested in receiving comments on how including or excluding these payments in the benchmark might affect access to medically necessary services provided at teaching/DSH hospitals.
    - CMS also is proposing not to remove geographic payment adjustments from the calculation of the benchmark expenditures, but does propose excluding Medicare expenditures or savings for incentive payments and penalties under section 1848 of the Affordable Care Act for value-based purchasing initiatives.

- Trending the benchmark forward
  - CMS considered two options for trending forward the most recent three years of per beneficiary expenditures for Medicare Parts A and B services in order to estimate the benchmark for each ACO.
  - The first option is to trend the expenditures forward using growth rates in expenditures for Medicare Parts A and B services for fee-for-service (FFS) beneficiaries.
  - The second option is to trend these expenditures forward using a flat dollar amount equivalent to the absolute amount of growth in per capita expenditures for Medicare Parts A and B under the FFS program.
  - For purposes of the initial expenditure benchmark, CMS proposes to employ the first option. In addition, CMS proposes to employ the national (rather than local) growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the fixed benchmark.
  - CMS is seeking comments on this proposal and on alternatives to using a national growth rate.
  - CMS is proposing to update the benchmark *during* the agreement period by the projected absolute amount of growth in national per capita expenditures.
  - CMS is seeking comments on this proposal and on an alternative it has considered (i.e., by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/state projected absolute amount of growth in per capita expenditures).

- **Determining the Savings Amount and Establishing an Appropriate Minimum Savings Rate**
  - The Proposed Rule requires CMS to specify a minimum savings rate (MSR) to give some assurance that an ACO's performance does not simply reflect normal variation.
  - For the one-sided model, CMS proposes to set the confidence interval to 90% for ACOs with 5,000 beneficiaries, resulting in an MSR of 3.9%.
  - For ACOs with 20,000 and 50,000 beneficiaries, CMS proposes to set the confidence interval to 95% and 99%, respectively, resulting in MSRs of 2.5% and 2.2%.
  - As ACO size increases, CMS proposes blending the MSRs between the two neighboring confidence intervals, resulting in a variable MSR, as shown in Table 6 of the Proposed Rule. (See p. 19612 of the April 7, 2011, Federal Register.)
  - In determining the amount of savings an ACO could be eligible to receive, CMS considered permitting the ACO to share on the first dollar of savings once the MSR was exceeded. However, because of concerns that this could result in sharing on unearned savings rather than on redesigned care processes, CMS also considered limiting the savings by requiring ACOs to exceed the MSR and share only those savings in excess of the MSR.
  - After considering these options, CMS proposed a third method: to require ACOs to exceed the MSR to be eligible for savings, but only share savings in excess of a certain threshold.
  - In addition, unless exempted (i.e., smaller ACOs), those ACOs that exceed the MSR would be eligible to share in net savings above a 2% threshold, calculated as 2% of its benchmark. The sharing rate (50% of the earned quality performance sharing rate, plus an additional 2.5% increase for including Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) in the ACO, for the one-sided model) would be applied to net savings above this 2% threshold to determine the shared savings amount.
  - CMS is seeking comments on methods to provide preference to ACOs that serve a large dual-eligible population or that enter and maintain similar arrangements with other payors.

- **Determining Caps on the Total Amount of Shared Savings.**
  - CMS proposes a payment limit of 7.5% of an ACO's benchmark for the first two years of the agreement under the one-sided model, and 10% of an ACO's benchmark for the third year and for all three years of the agreement for ACOs that elect the two-sided model.
  - CMS has solicited comments on whether the limit should be higher—for example, 10 percent for all ACOs—and on whether differential limits should be established based on an ACO's readiness.

Comments and Recommendations

- ACO participants with limited experience with risk-based models may wish to consider the one-sided model. The two-sided model offers greater potential savings rewards in exchange for taking on the risk of potential losses.
- ACOs should be running calculations and otherwise assessing their financial impact, especially if leaning toward the two-sided model.
- In designing the shared savings methodology, CMS appears to be open to a variety of alternative approaches. During the regulatory comment period, prospective participants should consider suggesting alternatives to CMS that might better suit their needs.

IV. Two-Sided Model

A. Background

CMS is proposing that ACOs may choose to operate under a two-sided model for the entire three-year agreement period, under which they would be accountable for losses in addition to sharing in the savings. Because of the higher risk involved, such ACOs would be eligible for a higher rate of savings than ACOs in the one-sided model.

B. Elements of the Two-Sided Model

- CMS proposed to use the same elements for the two-sided model that it proposed for the one-sided model, with modifications and additions necessary for and unique to the two-sided model, including eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data-sharing provisions, monitoring for avoidance of at-risk beneficiaries, and transparency requirements. (See pp. 19618–19 of the April 7, 2011, Federal Register.)
- CMS also proposes to add some requirements for the two-sided model to provide greater assurance of an ACO's ability to repay the Medicare program if it should incur losses.
- CMS seeks comments on the sufficiency of its proposed monitoring procedures as well as other potential areas and mechanisms for monitoring ACOs which choose to participate in the two-sided model.
- CMS also requests comments on whether additional eligibility requirements are necessary to ensure that ACOs participating in the two-sided model are capable of repaying the Medicare program for losses in excess of their benchmarks.

C. Quality Performance Measurement and Scoring

- To incentivize ACOs to participate in the two-sided model, CMS proposes a higher shared savings rate: 60% percent versus 50% for the one-sided model.
- As with the one-sided model, CMS proposes to set the quality performance standard at full and accurate reporting for the first year. If an ACO meets this standard, it would receive the maximum savings rate of 60% for quality performance.
- CMS also proposes to reconcile ACOs using the same methodology it proposes to employ for the first two years of the one-sided methodology.
- CMS considered two alternative approaches to incorporating the quality performance standard proposed for the one-sided model into the two-sided model:
  - take a threshold approach to measuring quality performance for the purpose of determining the amount of shared savings or losses; or
  - blend the proposed option with the first alternative by permitting ACOs to increase their savings with higher quality scores, but use a threshold approach to calculate losses.
- CMS seeks comment on these alternative approaches as well as the proposed approach.

D. Shared Savings Methodology

- CMS proposes to adopt the same methodology for determining shared savings for the two-sided model as proposed for the one-sided model, but with some modifications. Specifically, CMS proposes that ACOs participating in the two-sided model would:
  - be eligible for increased incentive payments for the same quality measures and for including FQHCs and/or RHCs as ACO participants;
  - have a fixed, versus variable, MSR and a fixed minimum loss rate of 2%, and would share the gross savings on the first dollar exceeding the MSR; and
  - share responsibility for expenditures in excess of the benchmark based on quality performance and inclusion of FQHCs/RHCs.
- Minimum Savings Rate
  - CMS proposes to use a fixed 2% MSR for the two-sided model, regardless of size, as opposed to the variable rate proposed for the one-sided model.
  - CMS believes that a fixed rate would: (a) attract more organizations to participate in this model, and (b) provide greater protection to the Medicare program by allowing ACOs to accept the risk of repaying Medicare for its losses.
- Additional Shared Savings
  - CMS proposes to increase the share of savings for ACOs participating in the two-sided model that include FQHCs/RHCs as ACO participants.
  - To reward such ACOs for taking on the risk of the two-sided model, CMS proposes to award a sliding scale increase of up to 5% for including FQHCs/RHCs as ACO participants, compared to the maximum 2.5% increase proposed for the one-sided model.
- Net Sharing Rate
  - CMS proposes that ACOs participating in the two-sided model would be eligible for shared savings upon the first dollar of savings generated in excess of the MSR.

E. Calculating Sharing in Losses

- To calculate the shared losses for the two-sided model, CMS proposes to utilize a methodology similar to that proposed for the one-sided model, including a minimum loss rate, a shared loss cap and an adjustment to the shared loss percentage based on an ACO's quality performance and inclusion of FQHCs/RHCs.
- According to CMS, these factors would operate as *decreases* in an ACO's shared loss rate, while such factors would operate as *increases* to the shared savings rate.
- CMS proposes to multiply an ACO's total losses by 1 minus the shared savings rate (e.g., 1 minus 65% for ACOs including FQHCs/RHCs, resulting in ACO responsibility for 35% of the losses).
- ACOs would be required to share the expenditures starting with the first dollar in excess of the minimum loss rate.

F. Maximum Shared Savings and Shared Loss Caps

- CMS proposes to implement a maximum shared loss cap for the first three-year period, with a cap of 5% in the first year, 7.5% in the second year and 10% in the third year; ACOs would not be responsible for losses in excess of these annual caps.
- CMS also proposes that ACOs participating in the one-sided model that transition to the two-sided model in the third year would be subject to the 5% cap on losses.
- In addition, CMS is proposing a higher maximum shared savings cap for the two-sided model than for the one-sided model: 10% versus 7.5%.

G. Ensuring ACO Repayment of Shared Losses:

- To ensure that ACOs participating in the two-sided model are capable of repaying the costs in excess of their benchmark, CMS is proposing to require that ACOs establish a "self-executing method" for repaying the Medicare program for its shared losses by indicating that funds may be recouped from the ACO's participants, obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit or establishing another repayment mechanism.
- CMS also proposes that an ACO's repayment mechanism must be able to ensure the repayment of losses that are at least equivalent to 1% of the per capita expenditures for its assigned beneficiaries based on data from the most recent year available.
- Finally, CMS proposes that an ACO would be required to submit detailed documentation of its repayment methodology in its application for approval by CMS.
- CMS seeks comments on its proposed methodology for ensuring that ACOs have the capacity to repay potential losses, as well as other methodologies it considered and discussed in the rulemaking.
- CMS also invites alternative suggestions for ensuring that ACOs have an appropriate amount to repay potential losses, assuring that such losses can be recouped, the process for recouping losses from ACOs and the amount of funds that ACOs in a risk-bearing model should be required to have available.

H. Future Participation of Underperforming Organizations

- CMS is proposing that ACOs that incur losses in all of the first three years will not be able to reapply to participate in the Shared Savings Program.
- CMS seeks comment on whether such exclusion would create disincentives to forming an ACO.

Comments and Recommendations

- Potential ACO participants will need to determine whether they are capable of handling the risk of losses under the two-sided model, and whether the opportunity for higher rewards is worth the risk of incurring potential losses.
- ACOs intending to participate in the two-sided model will need to establish a "self-executing method" that they may utilize to repay the Medicare program.
- ACOs will also need to establish a repayment mechanism that will ensure their ability to repay losses that are at least equivalent to 1% of the per capita expenditures for its assigned beneficiaries.

V. FTC and DOJ's Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program

A. Background

The FTC and DOJ's Proposed Statement addresses a concern expressed by physicians, hospitals and other health care providers regarding how the FTC and DOJ would evaluate the impact of ACOs participating in the Shared Savings Program and their expected interaction and negotiation with commercial payors in light of existing enforcement standards as reflected in the Statements of Antitrust Enforcement Policy in Health Care (1996), the revised Horizontal Merger Guidelines (2010), other related antitrust guidelines and the relevant advisory opinions issued by the FTC (collectively, the Antitrust Standards). In particular, providers are seeking additional flexibility so as to promote and support collaborations among otherwise competing providers, as well as additional clarity on whether ACOs would be presumed to be "clinically integrated" in light of the requirements for certification set forth under the Affordable Care Act.

B. Summary of Proposed Statement

- The Proposed Statement applies to collaborations among otherwise independent providers and provider groups formed after March 23, 2010, that participate in the Shared Savings Program.
- "Collaboration" is defined as a "set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in economic activity, and the resulting economic activity."
- In light of the degree of clinical integration that must be achieved in order for an ACO to be certified by CMS, in addition to other requirements such as the establishment of a formal legal and governance structure, ACOs are "reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the cost, of providing medical and other health care services to their participants' joint efforts."
- Consequently, the Agencies will apply a "Rule of Reason" as opposed to the "Per Se" analysis to an ACO in the commercial market if it "uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Shared Savings Program."
- The Rule of Reason treatment will apply to an ACO for the duration of its participation in the Shared Savings Program, which will allow the ACO to introduce and the Agencies to consider various community benefits and other factors to offset actual or perceived anti-competitive effects of the ACO's operations and practices.

C. Antitrust Safety Zone for ACOs

- Independent ACO participants that provide the same "common service" must have a combined share of 30% or less in each common service in each participant's primary service area (PSA) whenever two or more ACO participants provide that service to patients from that PSA.
- The PSA for each service is defined as "the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients for that service."
- Hospitals or surgicenters participating in an ACO must be nonexclusive to the ACO in order to fall within the Safety Zone irrespective of its PSA share.
- An ACO may still enter into exclusive arrangements, but it would not qualify for the Safety Zone.
- "Nonexclusive" means that the hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payors.
- The Safety Zone applies to physicians and other providers irrespective of whether they are exclusive or nonexclusive to an ACO.
- The Safety Zone only applies to ACOs participating in the Shared Savings Program. Otherwise, providers must comply with more restrictive Antitrust Standards.
- Failure to fall within the Safety Zone does not mean that the ACO arrangement is in violation of the Antitrust Standards and laws.

D. Calculation Methodology for PSA Shares of Common Services

- For physician services, first identify each service provided by at least two independent ACO participants as determined by the CMS Medicare Specialty Code.
  - "Primary care" is defined to include general practice, family practice, internal medicine and geriatric medicine as a single or common service.
- For inpatient facilities, a service is a Medicare Diagnostic Category.
- For outpatient facilities, a service is an outpatient category defined by CMS.
- Next, identify the PSA for each common service, for each participant (e.g., physician group, hospital, surgicenter) in the ACO. For each common service and for each participant, the PSA is defined as the lowest number of contiguous postal zip codes from which the participant draws at least 75% of its patients for that service.
- Finally, calculate the ACO's PSA share for each common service in each PSA in which at least two ACO participants serve patients for that service.

- Physician services: Calculate the ACO's shares of Medicare FFS-allowed charges during the most recent calendar year for which data are available.
- Outpatient services: Calculate the ACO's shares of Medicare FFS payments during the most recent calendar year for which data are available.
- Inpatient services: Calculate the ACO's shares of inpatient discharges using state-level all-payor hospital discharge data, where available. (See examples of PSA share calculations at page 13 of the Proposed Statement.)

E. Rural Exception

- Physicians: An ACO may include one physician per specialty for each rural county on a nonexclusive basis even if inclusion causes the ACO's share of any common service to exceed 30% in any ACO participant's PSA for that service.
- Hospitals: An ACO may include rural hospitals on a nonexclusive basis even if inclusion causes the ACO's share of any common service to exceed 30% in any ACO participant's PSA for that service.

F. Dominant Provider Limitation

- If an ACO includes a participant with a greater than 50% share in its PSA for any service that no other ACO participant provides to patients in the PSA, the "dominant provider" must be nonexclusive.
  - To remain in the Safety Zone, the dominant provider cannot require a commercial payor to contract exclusively with the ACO or otherwise restrict the commercial payor's ability to contract or deal with other ACOs or provider networks.

G. Mandatory Review of ACOs Exceeding 50% PSA Share Threshold

- An ACO exceeding the 50% PSA share threshold for any common service involving two or more independent participants cannot qualify for the rural exception unless it obtains a letter from the FTC or the DOJ stating that the reviewing Agency has "no present intention to challenge or recommend challenging the ACO under the antitrust laws."
- Under these circumstances, the Agencies will provide an expedited review of any request upon submission of the required documentation under CMS's final rule, which must be received by the reviewing Agency at least 90 days before the last day in which CMS will accept ACO applications for the relevant calendar year. (See pps. 9-10 in Proposed Statement for documentation requirements.)

H. ACOs Falling Below 50% Mandatory Review Threshold but Outside Safety Zone

- If an ACO falls into this category, it does not mean that the ACO is illegal, nor that it will be subjected to an Agency investigation.
- ACOs are not required to seek Agency review before seeking certification but can still request an expedited review.
- Providers in this category need to avoid the following types of conduct:
  - Preventing or discouraging commercial payors from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "guaranteed inclusion," "product participation," "price parity" or similar contractual clauses or provisions.
  - Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the commercial payor's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (e.g., an ACO may not require a purchaser to contract with *all* the hospitals in the same network as the hospital that belongs to the ACO).
  - With an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs and other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks.
  - Restricting a commercial payor's ability to make available to its health plan enrollees cost, quality, efficiency and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency and performance measures used in the Shared Savings Program.
  - Sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO.

Comments and Recommendations

- ACOs intending to seek CMS certification need to quickly determine which providers are going to participate, whether employed, affiliated, in a joint venture or under contract. ACOs needing to obtain an Agency review may have to submit request and documentation as early as August 2011.
- Market shares in each common service for each participant's PSA need to be determined.
  - Proposed methodology for calculating market shares is more of a proxy determination. If initial calculation puts an ACO outside the Safety Zone or beyond the 50% mandatory review threshold, the ACO can consider a more detailed market analysis for submission to the Agencies for their consideration.
- Determine whether an ACO falls within the Safety Zone in each area of common service in all applicable PSAs. If not, the ACO should reevaluate whether to reduce the number of participants, accept the risk of being outside Safety Zone or seek an expedited review.
- If an ACO intends to contract with commercial payors, it must maintain the same governance, leadership and other requirements for ACO certification when engaging in negotiations in order to take advantage of the proposed Safety Zone.
- Depending on the nature of the payor agreement, participating in "at risk" arrangements may be viewed as "financial integration," which also would trigger a Rule of Reason analysis.
- An ACO must be careful to avoid the high risk activity identified in this Advisory and in the Proposed Statement in order to mitigate against an Agency investigation, a private challenge or possible loss of ACO certification.

VI. Overlap with Other CMS Shared Savings Initiatives

A. Background

In order to prevent duplicative shared savings, the Proposed Rule expressly prohibits Medicare provider and supplier participants in other enumerated shared savings programs from participating in the ACO Shared Savings Program. The primary purpose of the prohibition "is to prevent a provider or supplier from being rewarded twice for achieving savings in the cost of care provided to the same beneficiary." However, in order to ensure that beneficiaries receive the highest quality of care possible, the prohibition will be tracked based on Medicare-enrolled TIN. Consequently, providers and suppliers will be allowed to submit claims under multiple TINs participating in different shared savings programs as long as the patient population is unique to each program.

B. Enumerated Programs Expressly Excluded under the Proposed Rule

- Independence at Home Medical Practice Pilot Program (Section 1866E of the Affordable Care Act)
- A model tested or expanded under Section 1115A of the Act that involves shared savings
- Any other Medicare initiative that involves shared savings
  - CMS will review and reject ACO applications if the ACO participants are participating in another Medicare initiative that involves shared savings payments.
  - A physician group practice (PGP) demonstration site applying for participation in the ACO Shared Savings Program will be required to complete a condensed application form.
- Although not expressly excluded under the Proposed Rule, CMS has determined that the following existing shared savings programs overlap with the ACO Shared Savings Program and are therefore precluded from participating in the ACO Shared Savings Program:
  - Independence at Home Medical Practice Demonstration Program, as established by Section 3024 of the Affordable Care Act
  - Medicare Health Care Quality Demonstration programs, as established by Section 646 of the Medicare Modernization Act
  - Medical home demonstrations with a shared savings element (currently only the multi-payor advanced primary care demonstration)
  - PGP transition demonstration

C. Programs Unlikely to Generate Duplicative Shared Savings

- State initiatives to provide health homes for Medicaid enrollees with chronic conditions as authorized under Section 2703 of the Affordable Care Act
- Programs to establish community health teams to support patient-centered medical homes under Section 3502 of the Affordable Care Act

Comments and Recommendations

- The Center for Medicare and Medicaid Innovation is seeking input on how it can best test different payment models that provide financial and technical assistance to groups of providers and suppliers that may wish to develop into ACOs.

VII. Proposed Waivers of Stark, Anti-Kickback Statute and Civil Monetary Penalty Law

A. Background

In the Proposed Rule, CMS briefly discusses waivers of the federal fraud and abuse laws (the physician self-referral law, the Anti-Kickback Statute and the Civil Monetary Penalty provision, sections 1877(a), 1128B(b)(1) and (2), and 1128A(b)(1) and (2), respectively). Detailed information regarding these critical waivers was published in a second document—CMS-1345-NC2—entitled "Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center" (the Notice). Despite being classified as a "notice with comment period," CMS and OIG actually proposed three types of waivers for the Shared Savings Program and sought comments on additional waivers and criteria for waivers that might be necessary to form and operate shared savings programs or delivery systems operating under the authority of CMS's Center for Medicare and Medicaid Innovation (the Innovation Center).

Despite numerous opportunities for public input prior to the issuance of the Notice, CMS and OIG stated that no clear consensus emerged on the scope of the waivers necessary to carry out the Shared Savings Program.

Therefore, CMS and OIG stated that the Agencies were both proposing and soliciting comments (both generally and in response to the specific proposals) on waivers related to the Shared Savings Program. Given the nature of the underlying statutes, the proposed waivers of the physician self-referral law (often referred to as the "Stark Law") differ from the proposed waivers of the Anti-Kickback Statute and the Civil Monetary Penalty provision.

B. Proposed Waivers—Stark Law

- CMS and OIG proposed two waivers of section 1877(a) of the Social Security Act, which prohibits (1) a physician from making a referral for Medicare "designated health service" to an entity with which he or she (or an immediate family member) has a financial relationship unless an exception applies and is satisfied, and (2) an entity from billing Medicare for services rendered pursuant to a prohibited referral.
- The proposed Stark Law waivers would waive application of the provisions of section 1877(a) to distributions of shared savings received by an ACO from CMS under the 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 an ACO's participation in and operations under the Shared Savings Program.
- Essentially, the waivers would protect financial relationships created by the distribution of shared savings within the ACO, as well as financial relationships created by the distribution of shared savings outside the ACO if the distribution relates closely to the requirements for an ACO under section 1899 of the Social Security Act. The waivers would not protect other distributions of shared savings to referring physicians outside the ACO.
- The waivers would apply ONLY to distributions of shared savings.

C. Proposed Waivers—Anti-Kickback Statute

- The Anti-Kickback Statute provides for criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration intended to induce or reward the referral of business reimbursable under any of the federal health programs. Its reach is not limited to instances in which a physician is on the receiving end of the remuneration exchange.
- The proposed waivers of the Anti-Kickback Statute would apply to:
  - distributions of shared savings received by an ACO from CMS under the 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, or for activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program; and
  - any financial relationship between or among an ACO, its ACO participants and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program that implicates the Stark Law and fully complies with an exception to the Stark Law's referral and billing prohibitions.
- Generally, a financial relationship that is permissible under the Stark Law because it satisfies the requirements of an applicable exception does not automatically protect the parties from prosecution under the Anti-Kickback Statute. The proposed waiver would establish "automatic immunity" from liability under the Anti-Kickback Statute if the arrangement both (1) implicates the Stark Law and (2) satisfies an exception. Arrangements that do not implicate the Stark Law would remain subject to the Anti-Kickback Statute's prohibitions and penalties (unless they are eligible under the "distribution of shared savings" waiver).

D. Proposed Waivers—Civil Monetary Penalty Provision

- Section 1128A(b)(1) and (2) of the Social Security Act prohibits a hospital from making a payment to a physician to induce the physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. This law applies to gainsharing arrangements. In the Notice, CMS and the OIG refer to this law as the "Gainsharing CMP."
- The proposed waiver of the Gainsharing CMP would apply to:
  - Distributions of shared savings received by an ACO from CMS under the Shared Savings Program in circumstances where the distributions are made from a hospital to a physician, provided that:
    - the payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services; and
    - 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 an ACO, its participants and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program that implicates the Stark Law and fully complies with an exception to the Stark Law's referral and billing prohibitions.
- The proposed waiver of the Gainsharing CMP is significant for two reasons:
  - First, over the years, the OIG has consistently taken the position that the Gainsharing CMP's prohibitions apply even to the reduction or limitation of medically *unnecessary* services. By emphasizing the waiver's application to medically *necessary* items or services only in the specified circumstances, the OIG appears to propose waiving the Gainsharing CMP to instances of payments to reduce or limit medically unnecessary items or services, which is a departure from its historical position.
  - Second, as with the proposed waiver of the Anti-Kickback Statute, the proposed Gainsharing CMP waiver would establish "automatic immunity" from liability under that law if the arrangement both (a) implicates the Stark Law and (b) satisfies an exception.
- Arrangements that do not implicate the Stark Law would remain subject to the Gainsharing CMP's prohibitions and penalties (unless they are eligible under the "distribution of shared savings" waiver).

E. Duration of Proposed Waivers

- CMS and OIG stated, but did not specifically "propose," that waivers related to the distribution of shared savings would apply to the distribution of the shared savings earned by an ACO during the term of its agreement with CMS to participate in the Shared Savings Program. This would include distributions that occur after the expiration of the ACO participation agreement.
- The additional Anti-Kickback Statute and Gainsharing CMP waivers would apply only during the term of an ACO's agreement with CMS to participate in the Shared Savings Program.

F. Additional Waivers: Solicitation of Comments

- In addition to proposing the Stark Law, Anti-Kickback Statute and Gainsharing CMP waivers discussed above, CMS and OIG solicited comments, but made no proposals, regarding additional waivers that may be necessary to support beneficial ACO development under the Shared Savings Program.
- The Agencies also solicited comments regarding necessary safeguards to ensure that the Medicare program and its beneficiaries are protected from harms caused by fraud and abuse. Although industry stakeholders are encouraged to comment on any relevant issues, CMS and OIG specifically mentioned:
  - Arrangements related to establishing an 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 an ACO, its ACO participants and/or its ACO providers/suppliers and outside individuals or entities
  - Distribution of shared savings or similar payments received from private payors
  - Other financial arrangements for which a waiver would be necessary
  - The duration of waivers
  - The scope of the proposed waivers (distribution of shared savings and the additional Anti-Kickback Statue and Gainsharing CMP waivers)
  - Waivers that may be necessary for the two-sided risk model
  - The use of the existing Stark Law exception and the Anti-Kickback Statute safe harbor for the donation of electronic health records items and services
  - Waivers related to beneficiary inducements
  - The timing of final waivers
- Finally, CMS and OIG solicited comments on their separate waiver authority related to the Innovation Center and how the Agencies might best exercise their discretion to address demonstrations and pilot programs under section 1115A of the Social Security Act.
- Industry stakeholders wishing to comment on the CMS/OIG Notice should follow the same procedures and deadlines as those outlined in CMS's Proposed Rule.

VIII. IRS Notice: Tax-Exempt Hospitals Participating in ACOs

- The IRS issued Notice 2011-20 (the Notice) to address whether Section 501(c)(3) hospitals and other tax-exempt health care entities participating in the Shared Savings Program through an ACO may be affected by current limitations on such entities under the Internal Revenue Code. The IRS is soliciting comments on whether existing IRS guidance is sufficient for such tax-exempt entities planning to participate in the Shared Savings Program and what additional guidance may be needed.
- Generally, as indicated in the Notice, the IRS expects that a tax-exempt hospital's participation in ACO arrangements under the Shared Savings Program will not result in private inurement or benefit if the following factors are present:
  - The terms of the tax-exempt hospital's participation in the Shared Savings Program through an ACO 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 Shared Savings Program.
- The tax-exempt hospital's share of the economic benefits derived from the ACO (including its share of Shared Savings Program payments) is proportional to the benefits or contributions that the hospital provides to the ACO.
- The ownership interest received by the tax-exempt hospital, if any, 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 such ownership interest.
- The tax-exempt hospital's share of ACO losses (including its share of Shared Savings Program losses) does not exceed the share of ACO economic benefits to which the hospital is entitled.
- All contracts and transactions entered into by the tax-exempt hospital with the ACO and the ACO participants, and by the ACO with the ACO participants and other parties, are at fair market value.

Contact Us

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