

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 352-G
200 Independence Avenue, SW
Washington, DC 20201



Office of Media Affairs

MEDICARE FACT SHEET

FOR IMMEDIATE RELEASE
Mar. 31, 2011

Contact: CMS Office of Media Affairs
(202) 690-6145

Federal agencies address legal issues regarding Accountable Care Organizations

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), proposed new rules under the Affordable Care Act to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients through Accountable Care Organizations (ACOs). ACOs create incentives for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Medicare Shared Savings Program will reward ACOs that lower growth in health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary.

Accountable Care Organizations require health care providers to work closely and share information – and share in the savings achieved through providing more efficient care. To do so, providers may need to address certain legal or tax issues. This fact sheet describes the proposals to ensure that ACOs provide high quality care, while not violating Federal law. There will be a 60 day public comment period on both the proposed rules and these proposals. CMS encourages all interested members of the public, including providers, suppliers, and Medicare beneficiaries to submit comments so that CMS can consider them as it develops final regulations on the program.

The HHS Centers for Medicare & Medicaid Services (CMS) has worked closely with agencies across the Federal government to ensure a coordinated and aligned inter- and intra-agency effort to address these legal and tax implications. In particular, CMS, the HHS Office of Inspector General (OIG), the Federal Trade Commission (FTC), the Antitrust Division of the Department of Justice (DOJ), and the Internal Revenue Service (IRS) have released three documents in conjunction with the proposed ACO rules on which they seek comment:

1. A joint CMS and OIG Notice and Solicitation of Public Comments on Waivers in Connection with Sections 1899 and 1115A of the Social Security Act.

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2. An IRS notice, Notice 2011-20, requesting comments regarding the need for guidance on participation by tax-exempt organizations in the Medicare Shared Savings Program through ACOs.
3. A joint FTC and DOJ Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Antitrust Policy Statement).

Notice and Solicitation of Public Comments on Waivers in Connection with Sections 1899 and 1115A of the Social Security Act:

Sections 1899 and 1115A give the Secretary of Health and Human Services authority to waive certain fraud and abuse laws as necessary to achieve the goals of each section, respectively. In conjunction with the issuance by CMS of the proposed rule that would establish ACOs, CMS and the Health and Human Services Office of Inspector General (OIG) issued a joint notice with comment period outlining proposals for waivers of certain federal laws - the physician self-referral law, the anti-kickback statute, and the civil monetary penalty law - for the Shared Savings Program. CMS and OIG have also solicited comments on further waiver design considerations for the Shared Savings Program and Innovation Center.

The Laws Addressed in the Notice: The joint CMS and OIG notice and solicitation of public comments addresses the application of the following federal laws to ACOs participating in the Shared Savings Program:

- The Physician Self-Referral Law (Section 1877(a) of the Social Security Act (the “Act”)), which 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.
- The Federal anti-kickback statute (Section 1128B(b) of the Act), which 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 Federal health care program, as defined in section 1128B of the Act.
- The civil monetary penalties law (Section 1128A(b)(1) and (2) of the Act) that prohibits a hospital from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare and Medicaid beneficiaries under the physician’s direct care (the CMP).

What Waivers are CMS and the OIG Proposing? The agencies have outlined proposals to waive the laws listed above in three circumstances (as further detailed in the notice and solicitation of public comments):

- The distribution of Program's shared savings payments received by an ACO to or among qualified ACO participants and ACO providers/suppliers described in the notice with comment period.
- An ACO's distribution of Program's shared savings payments to other individuals or entities for activities necessary for and directly related to the ACO's participation in the Shared Savings Program.
- For the anti-kickback statute and CMP *only*, certain financial relationships that are necessary for and directly related to the ACO's participation in the Shared Savings Program *and* fully comply with an exception to the physician self-referral law.

These waivers would cover shared savings earned during the agreement period with CMS and, as applicable, financial relationships existing during the agreement period. The notice and solicitation of public comment explains the conditions that would apply to the waivers in more detail.

Solicitation of Comments: CMS and OIG solicit public comments on a list of topics regarding other waiver design considerations. For example, the notice solicits comment on exercising the waiver authority to address start-up costs, continuing operating expenses, non-shared savings relationships between ACO members or outside entities, and special considerations relating to two-sided risk. CMS and OIG ask specific questions about each of these topics and others in hopes of eliciting detailed information from the public.

The notice also solicits comments on the best way to exercise the separate waiver authority under Section 1115A of the Act, which applies to the Innovation Center.

For more information on this document, please contact:

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Notice Addressing Federal Tax Issues Affecting Tax-Exempt Organizations:

With the issuance of the Medicare Shared Savings Program's proposed rule, the IRS anticipates that tax-exempt organizations (such as hospitals and other health care organizations) will be participating in the Program through ACOs. Accordingly, the IRS has issued a notice, Notice 2011-20, soliciting comments as to whether its existing guidance is sufficient for those tax-exempt organizations planning to participate in the Program through ACOs and, if not, what additional guidance is needed.

Tax Issues Addressed in the Notice: A tax-exempt organization must ensure that its participation in the Shared Savings Program through an ACO will not result in its net earnings inuring to the benefit of "insiders" with respect to the organization or in its being operated for the benefit of private parties, such as other participants in the ACO. Whether prohibited inurement or impermissible private benefit has occurred is determined on a case-by-case basis, based on all the facts and circumstances. The notice describes the proposed CMS regulation and oversight of the Shared Savings Program and identifies certain circumstances in which, in light of the CMS regulation and oversight, the IRS expects that a tax-exempt organization's participation in the Shared Savings Program through an ACO generally would not result in prohibited inurement or impermissible private benefit to the private party ACO participants.

In addition, because Congress created the Shared Savings Program to lessen the government's burden associated with providing Medicare benefits, the IRS expects that Program payments received by a tax-exempt organization from an ACO that complies with all Program requirements generally would not result in unrelated business taxable income.

Solicitation of Comments: The IRS is soliciting comments regarding whether additional guidance is needed to facilitate participation by tax-exempt organizations in the Shared Savings Program through ACOs. The IRS is also soliciting comments concerning whether guidance is needed regarding the tax implications for tax-exempt organizations participating in activities unrelated to the Program, including shared savings arrangements with commercial health insurance payers, through an ACO. In particular, comments should describe the activities a tax-exempt organization might expect to participate in through an ACO, identify how such non-Program activities might further exempt purposes and explain what criteria, requirements, and safeguards would ensure the furtherance of these exempt purposes.

For more information on this document, please contact:

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Proposed Antitrust Policy Statement Regarding ACO Participation in the Medicare Shared Savings Program:

The DOJ and FTC have worked together to facilitate the creation of ACOs by giving providers the clear and practical guidance they need to form innovative, integrated health care delivery systems without running afoul of the antitrust laws. Accordingly, DOJ and FTC have issued a joint Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (“Antitrust Policy Statement”).

Antitrust Agency Review of ACOs: The proposed Antitrust Policy Statement applies to collaborations, not including mergers, among otherwise independent providers formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate, in the Medicare Shared Savings Program. DOJ and FTC will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Program.

Safety Zone: The Antitrust Policy Statement describes a Safety Zone for certain ACOs that participate in the Shared Savings Program. ACOs that fall within the Safety Zone are highly unlikely to raise significant competitive concerns and the Antitrust Agencies will not challenge ACOs that fall within the Safety Zone, absent extraordinary circumstances. To fall within the Safety Zone, independent ACO participants that provide a common service must have a combined share of 30 percent or less for each common service in each participant’s Primary Service Area (“PSA”), wherever two or more ACO participants provide that service to patients from that PSA.

Mandatory Antitrust Review: An ACO applicant that has a share above 50 percent for any common service that two or more independent ACO participants provide to patients in the same PSA is required to obtain a letter from one of the Antitrust Agencies advising that the reviewing Agency has no present intent to challenge or recommend challenging the ACO.

- If DOJ or FTC advises it is likely to challenge or recommend challenging an ACO if it proceeds, the ACO as proposed will be ineligible to participate in the Shared Savings Program.
- DOJ and FTC have committed to provide a 90-day expedited review of ACOs that exceed the 50 percent PSA share threshold. The reviewing Agency, therefore, must receive all of the required documents and information at least 90 days before the last day on which CMS has stated that it will accept applications to participate in the Shared Savings Program for the relevant calendar year.

Additional Antitrust Guidance: ACOs that are outside the Safety Zone and below the 50 percent mandatory review threshold that do not impede the functioning of a competitive market and that engage in pro-competitive activities will not raise competitive concerns and may participate in the Shared Savings Program without Antitrust Agency review.

- An ACO that desires further antitrust certainty can seek an expedited review from one of the Antitrust Agencies, similar to the mandatory review for ACOs above the 50 percent threshold. The reviewing Agency will complete the review within 90 days of receiving all of the necessary documents and information and will inform the ACO of the outcome of the review.
- In addition, the Antitrust Policy Statement identifies five types of conduct that an ACO can avoid to reduce significantly the likelihood of antitrust concern.

For more information about this document, contact:

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The proposed rule and joint CMS/OIG notice are posted at:

www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1#special

They will appear in the **XX**, 2011 issue of the *Federal Register*.

Comments on the proposed rule will be accepted until **XX**, 2011. CMS will respond to all comments in a final rule to be issued later this year. Comments on the joint CMS/OIG notice will be accepted until **XX**, 2011.

The Proposed Antitrust Policy Statement is posted at: www.ftc.gov/opp/aco/. Comments on the Proposed Antitrust Policy Statement will be accepted until **XX**, 2011.

The IRS Notice 2011-20 will be posted at: www.irs.gov/pub/irs-drop/n-11-20.pdf.

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Summary of proposed rule provisions for Accountable Care Organizations under the Medicare Shared Savings Program

Overview

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), proposed new rules under the Affordable Care Act to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients through Accountable Care Organizations (ACOs). ACOs create incentives for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Medicare Shared Savings Program will reward ACOs that lower growth in health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary.

In developing the proposed rule, CMS has worked closely with agencies across the Federal government to ensure a coordinated and aligned inter- and intra-agency effort to facilitate implementation of the Medicare Shared Savings Program (Shared Savings Program).

This fact sheet describes the proposals addressing the proposals for what ACOs are, how they can be created, and other general topics. CMS has posted separate fact sheets on its web site to address in greater detail specific aspects of the proposed rule, such as the quality measures and performance scoring.

There will be a 60 day public comment period on this proposed rule. CMS encourages all interested members of the public, including providers, suppliers, and Medicare beneficiaries to submit comments so that CMS can consider them as it develops final regulations on the program.

Background:

Section 3022 of the Affordable Care Act, added a new section 1899 to the Social Security Act (the Act) that requires the Secretary to establish the Shared Savings Program by January 1, 2012. This program is intended to encourage providers of services and suppliers (e.g., physicians, hospitals and others involved in patient care) to create a new type of health care entity, which the statute calls an “Accountable Care Organization (ACO)” that agrees to be held accountable for improving the health and experience of care for individuals and improving the health of populations while reducing the rate of growth in health care spending. Studies have shown that better care often costs less, because coordinated care helps to ensure that the patient receives the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors.

ACOs and the Medicare Beneficiary:

An ACO provides an opportunity for Medicare beneficiaries to receive high quality evidence-based health care that eliminates waste and reduces excessive costs through improved care delivery. However, , there would be significant differences between ACOs, as described in the proposed rule and the private managed care plans offered under the Medicare Advantage program. Beneficiaries would not enroll in a specific ACO. Instead the proposed rule calls for Medicare to take a retrospective look at the beneficiary’s use of services to determine whether a particular ACO should be credited with improving care and reducing expenditures. This means that an ACO would have an incentive to improve the quality of care for all patients seen by its member providers and suppliers.

The proposed rule would require providers participating in an ACO to notify the beneficiary that they are participating in an ACO, and that the provider will be eligible for additional Medicare payments for improving the quality of care the beneficiary receives while reducing overall costs or may be financially responsible to Medicare for failing to provide efficient, cost-effective care. The beneficiary may then choose to receive services from the provider or seek care from another provider that is not part of the ACO.

The proposed rule would also require each provider in an ACO to notify the beneficiary that the beneficiary’s claims data may be shared with the ACO. This data sharing is intended to make it easier to coordinate the beneficiary’s care; however, the provider may not require a beneficiary to obtain services from another provider or supplier in the same ACO. The provider must give the beneficiary the opportunity to opt-out of those data sharing arrangements. For Medicare beneficiaries who choose not to opt-out of the data sharing arrangements, the proposed rule

would limit data sharing to the purposes of the Shared Savings Program and would require compliance with applicable privacy rules and regulations, including the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Proposed eligibility requirements for an ACO:

Under the proposed rule, an ACO refers to a group of providers and suppliers of services (e.g., hospitals, physicians, and others involved in patient care) that will work together to coordinate care for the Medicare fee-for-service beneficiaries they serve. The goal of an ACO is to deliver seamless, high quality care for Medicare beneficiaries, instead of the fragmented care that has so often been part of fee-for-service health care. The ACO would be a patient-centered organization where the patient and providers are true partners in care decisions.

The Affordable Care Act specifies that an ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ACO professionals (i.e., physicians and hospitals meeting the statutory definition) in group practice arrangements,
- Networks of individual practices of ACO professionals,
- Partnerships or joint ventures arrangements between hospitals and ACO professionals, or
- Hospitals employing ACO professionals.
- Other Medicare providers and suppliers as determined by the Secretary

In the proposed rule, the Secretary has used her discretion to add certain critical access hospitals as eligible to participate in the Shared Savings Program.

The statute also requires each ACO to establish a governing body representing ACO providers of services and suppliers and Medicare beneficiaries. The proposed rule would make each ACO responsible for routine self-assessment, monitoring and reporting of the care it delivers.

To participate in the Shared Savings Program, the proposed rule would require an ACO to complete an application providing the information requested by CMS, including how the ACO plans to deliver high quality care at lower costs for the beneficiaries it serves. As proposed, the

ACO must agree to accept responsibility for at least 5,000 beneficiaries. If the application is approved, the ACO must sign an agreement with CMS to participate in the Shared Savings Program for a period of three years. An ACO will not be automatically accepted into the Shared Savings Program.

The proposed rule outlines a monitoring plan that includes analyzing claims and specific financial and quality data as well as the quarterly and annual aggregated reports, performing site visits, and performing beneficiary surveys.

Under the proposed rule, there are a number of circumstances under which CMS may terminate the agreement with an ACO, including avoidance of at risk beneficiaries and failure to meet the quality performance standards.

Tying payment to improved care at lower cost:

Under the proposed rule, Medicare would continue to pay individual providers and suppliers for specific items and services as it currently does under the fee-for-service payment systems. The proposed rule would require CMS to develop a benchmark for savings to be achieved by each ACO if the ACO is to receive shared savings, or be held liable for losses. Additionally, an ACO would be accountable for meeting or exceeding the quality performance standards to be eligible to receive any shared savings.

The proposed rule would establish quality performance measures and a methodology for linking quality and financial performance that will set a high bar on delivering coordinated and patient-centered care by ACOs, and emphasize continuous improvement around the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. The proposed rule would require the ACO to have in place procedures and processes to promote evidence-based medicine and beneficiary engagement in their care. The proposed rule would require ACOs to report quality measures to CMS and give timely feedback to providers. CMS expects that ACOs will invest continually in the workforce and in team-based care. To assure program transparency, the proposed rule would require ACOs to publicly report certain aspects of their performance and operations.

Under the proposed rule, an ACO that meets the program's quality performance standards would be eligible to receive a share of the savings it generates below a specific expenditure benchmark that would be set by CMS for each ACO. The proposed rule would also hold ACOs accountable for downside risk by requiring ACOs to repay Medicare for a portion of losses (expenditures above its benchmark). To provide an entry point for organizations with varied levels of experience with and willingness to take on risk, the proposed rule would allow an ACO to choose one of two program tracks. The first track would allow an ACO to operate on a shared

savings only track for the first two years, but would then require the ACO to assume the risk for shared losses in the third year. The second track would allow ACOs to share in savings and risk liability for losses beginning in their first performance year, in return for a higher share of any savings it generates.

The Shared Savings Program NPRM will appear in the XX, 2011 issue of the *Federal Register*. CMS will accept comments on the proposed rule until XX, and will respond to them in a final rule to be issued later this year. The Shared Savings Program will begin operating on January 1, 2012.

For more information, please see:

www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1

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What Providers Need to Know:

Accountable Care Organizations

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), proposed new rules under the Affordable Care Act to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients through Accountable Care Organizations (ACOs). ACOs create incentives for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Medicare Shared Savings Program will reward ACOs that lower growth in health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary.

Under the proposal, ACOs – teams of doctors, hospitals and other health care providers working together – would coordinate and improve care for patients with Original Medicare – Medicare Parts A and B. ACOs would have to meet high quality standards to ensure patients are happy with the care they receive and have better health outcomes. And if ACOs can help save money by getting patients the right care at the right time, they can share in those savings with Medicare. As proposed, ACOs could also have to pay back Medicare for failing to provide efficient, cost-effective care. The new program would begin on January 1, 2012.

This fact sheet describes the proposals to ensure that ACOs provide high-quality care, including proposed quality measures, and a proposed method for scoring the performance of the ACO for purposes of the Medicare Shared Savings Program. There will be a 60 day public comment period on this proposed rule. CMS encourages all interested members of the public, including providers, suppliers, and Medicare beneficiaries to submit comments so that CMS can consider them as it develops final regulations on the program.

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What is an ACO?

Under the proposed rule, an ACO refers to a group of providers and suppliers of services (e.g., hospitals, physicians, and others involved in patient care) that will work together to coordinate care for the patients they serve in Original Medicare. The goal of an ACO is to deliver seamless, high-quality care for Medicare beneficiaries, instead of the fragmented care that often results from different providers receiving different, disconnected payments. The ACO would be a patient-centered organization where the patient and providers are partners in care decisions.

The Affordable Care Act specifies that an ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ACO professionals (i.e., physicians and hospitals meeting the statutory definition) in group practice arrangements,
- Networks of individual practices of ACO professionals,
- Partnerships or joint ventures arrangements between hospitals and ACO professionals, or
- Hospitals employing ACO professionals.
- Other Medicare providers and suppliers as determined by the Secretary

In the proposed rule, the Secretary has made clear that certain critical access hospitals are eligible to participate in the Shared Savings Program.

How Could Providers Participate?

To participate in the Shared Savings Program, providers must form or join an Accountable Care Organization (ACO) and apply to CMS. An existing ACO will *not* be automatically accepted into the Shared Savings Program. If accepted, they would serve at least 5,000 Medicare patients and agree to participate in the program for three years. Medicare providers who join an ACO that participates in the Program would continue to receive payment under Original Medicare fee-for-service (FFS) rules.

The statute also requires each ACO to establish a governing body representing ACO providers of services, suppliers, and Medicare beneficiaries. The ACO would be responsible for monitoring

and reporting of the care it delivers. The proposed rule outlines a monitoring and reporting plan that includes analyzing claims and specific financial and quality data, producing quarterly and annual aggregated reports, performing site visits, and conducting beneficiary surveys.

How Would Shared Savings Work?

Under the proposed rule, Medicare would continue to pay individual providers and suppliers for specific items and services as it currently does under the Original Medicare payment systems. CMS would also develop a benchmark for each ACO against which ACO performance is measured to assess whether it qualifies to receive shared savings, or be held accountable for losses. The benchmark is an estimate of what the total Medicare fee-for-service Parts A and B expenditures for ACO beneficiaries would otherwise have been in the absence of the ACO, even if all of those services would not have been provided by providers in the ACO. The benchmark would take into account beneficiary characteristics and other factors that may affect the need for health care services. This benchmark would be updated for each performance year within the three-year performance period.

CMS is proposing to implement both a one-sided risk model (sharing of savings only for the first two years and sharing of savings and losses in the third year) and a two-sided risk model (sharing of savings and losses for all three years), allowing the ACO to opt for one or the other models. CMS believes this approach would have the advantage of providing an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model, while also providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides a greater share of savings, but at the risk of repaying Medicare a portion of any losses.

CMS is also proposing to establish a minimum sharing rate that would account for normal variations in health care spending. The minimum savings rate is a percentage of the benchmark that ACO expenditure savings must exceed in order for an ACO to qualify for shared savings in any given year. Under the proposed rule, ACOs in the one-sided risk program that have smaller populations (and having more variation in expenditures) would have a larger MSR and ACOs with larger populations (and having less variation in expenditures) have a smaller MSR. Under the two-sided approach, CMS is proposed a flat 2 percent minimum sharing rate.

If an ACO meets quality standards and achieves savings exceeding the minimum saving rate, the ACO would share in savings, based on the quality score of the ACO. The proposed rule would

provide for additional shared savings for ACOs that include beneficiaries who receive services from a Federally Qualified Health Center or Rural Health Clinic during the performance year.

ACOs that Participate in the Two-Sided Risk Model Can Obtain Greater Shared Savings

To qualify for shared savings, ACOs must meet certain quality and performance standards and have total per capita costs for assigned beneficiaries in the performance year to be both below the estimated updated benchmark and above the minimum savings rate. Once the ACO surpasses the minimum savings rate, it may share in savings if it is eligible to receive shared savings based on its quality performance score. To provide a greater incentive for ACOs to adopt the two-sided risk approach, the maximum sharing percentage is 60 percent for ACOs in the two-sided model compared to 50 percent in the one-sided model. In addition, under the two-sided model, ACOs would receive shared savings for the first dollar after the minimum savings rate is achieved. In contrast, under the one-sided model, ACOs would share on savings after a 2 percent threshold is met, with an exemption for small ACOs in rural or underserved communities. Under both models, an ACO would be eligible for a greater portion of shared savings the higher its quality and performance score.

The proposed rule also provides a methodology for determining shared losses for ACOs in the two-sided model (or year three of the one-sided model) if the per capita cost per beneficiary were more than 2 percent higher than the benchmark. As with shared savings, the amount of shared losses would be based in part on the ACO's quality performance score. Additionally, CMS is also proposing a shared loss cap of 5 percent of the benchmark in the first year of the Shared Savings Program, 7.5 percent in the second year, and 10 percent in the third year.

Participation in the First Program Year Allows for ACOs to Obtain the Maximum Sharing Rate if they Successfully Report Quality Measures

CMS is encouraging providers to participate in the Shared Savings Program in 2012 by setting the quality performance standard to reporting only. ACOs would be eligible for the maximum sharing rate (60 percent for the two-sided model and 50 percent for the one-sided model) if the ACO generates sufficient savings and successfully reports the required quality measures. This flexibility would allow newly formed ACOs a grace period as they start up their operations and learn to work together to better coordinate patient care.

The Proposed Quality Measurement is Aligned with Other CMS Quality Initiatives

CMS has proposed to measure quality of care using nationally recognized measures in five key domains: patient experience, care coordination, patient safety, preventive health, and at-risk population/frail elderly health. These measures are aligned with the measures in other CMS programs such as the Electronic Health Records (EHR) and Physician Quality Reporting System (PQRS). An ACO that successfully reports the quality measures required under the Shared Savings Program would be deemed eligible for the PQRS bonus.

ACOs may not participate, however, in any other shared savings program or demonstration under the Center for Medicare and Medicaid Innovation or Independence At Home Medical Practice pilot program to ensure that savings are not counted twice.

Existing Clinically Integrated Entities Need Not Form New Entities to Participate in the Shared Savings Program

If an ACO is already comprised of a self-contained financially and clinically integrated entity that has a pre-existing board of directors or other governing body, the ACO need not form a separate governing body or create a new legal entity. The existing entity, however, must be recognized under applicable State law, be capable of receiving and distributing shared savings and repaying shared losses, and meet the other ACO functions identified in the statute.

How ACOs Help Doctors Coordinate Care

Health care providers have reported that an important barrier to improving care coordination is lack of information. While they may know about the services they provide to the beneficiary, they don't know about other services provided to the beneficiary. To better treat patients and to coordinate their care, ACOs would be able to request claims information about their patient from CMS. Before doing so, ACOs must notify a beneficiary in writing that it would request the beneficiary's claims information from CMS. ACOs must allow beneficiaries to opt-out of having their claims information shared with the physician and the ACO. This opting out of having claims information shared, however, does not affect the patient's participation in the ACO or CMS's use of the patient's data for purposing of assessing quality or cost measures. This notification must happen the first time the ACO cares for the beneficiary.

Alignment of CMS Requirements and Other Federal Laws

CMS has worked closely with agencies across the Federal government to facilitate participation in the Shared Savings Program by coordinating federal fraud and abuse requirements, tax guidance, and antitrust considerations. In particular, the Federal Trade Commission and the Antitrust Division of the Department of Justice have proposed an antitrust policy statement that clarifies application of the antitrust laws to Medicare Shared Savings Program -approved ACOs that negotiate and contract with commercial payers. *See: Medicare Fact Sheet: Federal agencies address legal issues regarding Accountable Care Organizations*

The Shared Savings Program NPRM will appear in the XX, 2011 issue of the *Federal Register*. CMS will accept comments on the proposed rule until XX, and will respond to them in a final rule to be issued later this year. The Shared Savings Program will begin operating on January 1, 2012.

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Improving Quality of Care for Medicare Patients: Accountable Care Organizations

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), proposed new rules under the Affordable Care Act to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients through Accountable Care Organizations (ACOs). ACOs create incentives for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Medicare Shared Savings Program will reward ACOs that lower growth in health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary.

This fact sheet describes the proposals to ensure that ACOs provide high quality care, including proposed quality measures, and a proposed method for scoring the performance of the ACO for purposes of the Shared Savings Program. There will be a 60 day public comment period on this proposed rule. CMS encourages all interested members of the public, including providers, suppliers, and Medicare beneficiaries to submit comments so that CMS can consider them as it develops final regulations on the program.

Background:

The Medicare Shared Savings Program, which is to be implemented on January 1, 2012, is intended to encourage providers of services and suppliers (e.g., physicians, hospitals and others involved in patient care) to coordinate patient care and improve communications with each other to get each beneficiary the right care at the right time, and see that the care is provided right the first time. To accomplish this, the Act allows providers to create ACOs that will be held accountable for improving the health and experience of care for individuals, improving the health

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of populations, and reducing the rate of growth in health care spending. Studies show that better care often costs less, because coordinated care helps avoid unnecessary duplication of services and preventing medical errors.

Proposals For Assessing Quality Included in the ACO Proposed Rule:

Proposed Quality Measures: For 2012, CMS proposes to use a number of quality measures to establish the quality performance standard ACOs must meet in order to share in savings, provided they also meet the program's cost savings requirement. These 65 measures span five quality domains: Patient Experience of Care, Care Coordination, Patient Safety, Preventive Health, and At-Risk Population/Frail Elderly Health. The list of proposed measures is included in the appendix to this fact sheet.

CMS considered a broad array of process and outcome measures would help in assessing an ACO's success in delivering high-quality health care at both the individual and population levels. Several of the proposed quality measures align with those used in other CMS quality programs, such as the Physician Quality Reporting System, the Electronic Health Record (EHR) Incentive Program, and the Hospital Inpatient Quality Reporting Program. CMS also sought to align the proposed ACO quality measures with the National Quality Strategy and other Department of Health and Human Services priorities. CMS proposes that the measures would be reported to CMS through a combination of claims submission, data collection using a tool designed for clinical quality measure reporting, and surveys.

CMS is proposing to define the first quality performance period as beginning January 1, 2012 and ending December 31, 2012.

Proposed Quality Performance Scoring: As required by the Affordable Care Act, before an ACO can share in any savings created, it must demonstrate that it is delivering high quality care. Thus, a calculation of the quality performance standard will indicate whether an ACO has met the quality performance goals that would allow it to be considered eligible for shared savings. The proposed method for scoring the measures and determining the performance level that must be achieved to share in savings under the Shared Savings Program is described in the proposed rule.

CMS proposes that the performance on each measure will be scored on a linear points scale and roll up into 5 scores for each of the 5 domains. The percentage of points earned for each domain will be aggregated using an equal weighting method to arrive at a single percentage that will be applied to the maximum sharing rate for which the ACO is eligible.

For the first year of the Shared Savings Program, CMS proposes to set the quality performance standard at the reporting level. This means that during the first performance period, ACOs will be required to report the quality measures completely and accurately in order to share in savings. However, CMS proposes to still score quality in the first year for informational purposes and to help define the benchmarks for future program years. CMS proposes to set the quality performance standard at a higher level in subsequent years.

Proposed Incorporation of the Physician Quality Reporting System into the Shared Savings Program: The Affordable Care Act allows CMS to incorporate the Physician Quality Reporting System reporting requirements and incentive payments into the Shared Savings Program. ACO participant providers/suppliers who are also Physician Quality Reporting System eligible professionals may earn the Physician Quality Reporting System incentive as a group practice under the Shared Savings Program, by meeting its quality performance standard

The Shared Savings Program NPRM will appear in the XX, 2011 issue of the *Federal Register*. CMS will accept comments on the proposed rule until XX, and will respond to them in a final rule to be issued later this year. The Shared Savings Program will begin operating on January 1, 2012.

For more information, please see:

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**Proposed Quality Measures for Accountable Care Organizations
For First Year Of The Medicare Shared Savings Program**

Patient/Caregiver Experience Domain:

<u>1.</u>	<u>Clinician/Group CAHPS: Getting Timely Care, Appointments, and Information</u>
<u>2.</u>	<u>Clinician/Group CAHPS: How Well Your Doctors Communicate</u>
<u>3.</u>	<u>Clinician/Group CAHPS: Helpful, Courteous, Respectful Office Staff</u>
<u>4.</u>	<u>Clinician/Group CAHPS: Patients' Rating of Doctor</u>
<u>5.</u>	<u>Clinician/Group CAHPS: Health Promotion and Education</u>
<u>6.</u>	<u>Clinician/Group CAHPS: Shared Decision Making</u>
<u>7.</u>	<u>Medicare Advantage CAHPS: Health Status/Functional Status</u>

Care Coordination Domain:

<u>8.</u>	<u>Risk-Standardized, All Condition Readmission</u>
<u>9.</u>	<u>30 Day Post Discharge Physician Visit</u>
<u>10.</u>	<u>Medication Reconciliation</u>
<u>11.</u>	<u>Care Transition Measure:</u>

<u>12.</u>	<u>Ambulatory Sensitive Conditions Admissions: Diabetes, short-term complications</u>
<u>13.</u>	<u>Ambulatory Sensitive Conditions Admissions: Uncontrolled Diabetes</u>
<u>14.</u>	<u>Ambulatory Sensitive Conditions Admissions: Chronic obstructive pulmonary disease</u>
<u>15.</u>	<u>Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure</u>
<u>16.</u>	<u>Ambulatory Sensitive Conditions Admissions: Dehydration</u>
<u>17.</u>	<u>Ambulatory Sensitive Conditions Admissions: Bacterial pneumonia</u>
<u>18.</u>	<u>Ambulatory Sensitive Conditions Admissions: Urinary infections</u>
<u>19.</u>	<u>% All Physicians Meeting Stage 1 HITECH Meaningful Use Requirements</u>
<u>20.</u>	<u>% of PCPs Meeting Stage 1 HITECH Meaningful Use Requirements</u>
<u>21.</u>	<u>% of PCPs Using Clinical Decision Support</u>
<u>22.</u>	<u>% of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program</u>
<u>23.</u>	<u>Patient Registry Use</u>

Patient Safety Domain:

<u>24.</u>	<u>Health Care Acquired Conditions Composite:</u> <ul style="list-style-type: none">• <u>Foreign Object Retained After Surgery</u>• <u>Air Embolism</u>• <u>Blood Incompatibility</u>• <u>Pressure Ulcer, Stages III and IV</u>• <u>Falls and Trauma</u>• <u>Catheter-Associated UTI</u>• <u>Manifestations of Poor Glycemic Control</u>• <u>Central Line Associated Blood Stream Infection (CLABSI)</u>• <u>Surgical Site Infection</u>• <u>AHRQ Patient Safety Indicator (PSI) 90</u>• <u>Complication/Patient Safety for Selected Indicators (composite)</u><ul style="list-style-type: none">○ <u>Accidental puncture or laceration</u>○ <u>Iatrogenic pneumothorax</u>○ <u>Postoperative DVT or PE</u>○ <u>Postoperative wound dehiscence</u>○ <u>Decubitus ulcer</u>○ <u>Selected infections due to medical care (PSI 07: <u>Central Venous Catheter-related Bloodstream Infection</u>)</u>○ <u>Postoperative hip fracture</u>○ <u>Postoperative sepsis</u>
<u>25.</u>	<u>Health Care Acquired Conditions: CLABSI Bundle</u>

Preventive Health Domain:

26.	<u>Influenza Immunization</u>
27.	<u>Pneumococcal Vaccination</u>
28.	<u>Mammography Screening</u>
29.	<u>Colorectal Cancer Screening</u>
30.	<u>Cholesterol Management for Patients with Cardiovascular Conditions</u> •
31.	<u>Adult Weight Screening and Follow-up</u>
32.	<u>Blood Pressure Measurement</u>
33.	<u>Tobacco Use Assessment and Tobacco Cessation Intervention</u>
34.	<u>Depression Screening</u>

At-Risk Population/Frail Elderly Domain:

35.	At Risk Population - Diabetes	Diabetes Composite (All or Nothing Scoring): <ul style="list-style-type: none">• Hemoglobin A1c Control (<8%)• Low Density Lipoprotein (<100)• Blood Pressure <140/90• Tobacco Non Use• Aspirin Use
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36.	At Risk Population – Diabetes	Diabetes Mellitus: Hemoglobin A1c Control (<8%)
37.	At Risk Population – Diabetes	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus
38.	At Risk Population - Diabetes	Diabetes Mellitus: Tobacco Non Use
39.	At Risk Population - Diabetes	Diabetes Mellitus: Aspirin Use
40.	At Risk Population - Diabetes	Diabetes Mellitus: Hemoglobin A1c Poor Control (>9%)
41.	At Risk Population - Diabetes	Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus
42.	At Risk Population - Diabetes	Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients
43.	At Risk Population - Diabetes	Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients
44.	At Risk Population - Diabetes	Diabetes Mellitus: Foot Exam
45.	At Risk Population - Heart Failure	Heart Failure: Left Ventricular Function (LVF) Assessment
46.	At Risk Population - Heart Failure	Heart Failure: Left Ventricular Function (LVF) Testing
47.	At Risk Population - Heart Failure	Heart Failure: Weight Measurement
48.	At Risk Population - Heart Failure	Heart Failure: Patient Education

49.	At Risk Population - Heart Failure	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
50.	At Risk Population - Heart Failure	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
51.	At Risk Population - Heart Failure	Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation
52.	At Risk Population – Coronary Artery Disease	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring <ul style="list-style-type: none">• Oral Antiplatelet Therapy Prescribed for Patients with CAD• Drug Therapy for Lowering LDL-Cholesterol• Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)• LDL Level <100 mg/dl• Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)

53.	At Risk Population – Coronary Artery Disease	<p>Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD</p> <p>Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed oral antiplatelet therapy.</p>
54.	At Risk Population – Coronary Artery Disease	<p>Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol</p> <p>Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed a lipid-lowering therapy (based on current ACC/AHA guidelines).</p> <p>The LDL-C treatment goal is <100 mg/dl. Persons with established coronary heart disease (CHD) who have a baseline LDL-C 130 mg/dl should be started on a cholesterol-lowering drug simultaneously with therapeutic lifestyle changes and control of non-lipid risk factors (National Cholesterol Education Program (NCEP).</p>
55.	At Risk Population – Coronary Artery Disease	<p>Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)</p>

56.	At Risk Population – Coronary Artery Disease	Coronary Artery Disease (CAD): LDL level < 100 mg/dl
57.	At Risk Population – Coronary Artery Disease	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)
58.	At Risk Population – Hypertension	Hypertension (HTN): Blood Pressure Control
59.	At Risk Population – Hypertension	Hypertension (HTN): Plan of Care
60.	At Risk Population – COPD	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation
61.	At Risk Population – COPD	Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received
62.	At Risk Population – COPD	Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy based on FEV1
63.	At Risk Population – Frail Elderly	Falls: Screening for Fall Risk
64.	At Risk Population – Frail Elderly	Osteoporosis Management in Women Who had a Fracture
65.	At Risk Population – Frail Elderly	Monthly INR for Beneficiaries on Warfarin

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Office of Media Affairs

MEDICARE FACT SHEET

FOR IMMEDIATE RELEASE
Mar. 31, 2011

Contact: CMS Office of Media Affairs
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Medicare Shared Savings Program: a new proposal to foster better, patient-centered care

What patients need to know about Accountable Care Organizations

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), proposed new rules under the Affordable Care Act to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients through Accountable Care Organizations (ACOs). ACOs create incentives for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Medicare Shared Savings Program will reward ACOs that lower growth in health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary.

By focusing on the needs of patients and linking payment rewards to outcomes, this delivery system reform, as part of the Affordable Care Act, will help improve the health of individuals and communities while lowering the cost of the system – up to an estimated \$960 million over three years in Medicare savings.

ACOs to Deliver Improved Care to Medicare Beneficiaries

The physicians, hospitals, and other providers participating in an ACO would work together to coordinate patient care and keep track of patients’ conditions and treatments, regardless of where the patient seeks care. The goal of the program is to prevent beneficiaries from retelling their story and medical history to each provider that cares for them.

ACO providers also would carefully coordinate their patients’ care as they move among physicians’ offices, hospitals, and lab and other facilities in an effort to eliminate duplication,

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medication errors, and mismanagement. In doing so, beneficiaries may save time and money when the ACO effectively coordinates the beneficiary's care because improved care coordination would reduce duplication and waste.

ACOs would be required to have in place processes to promote treatments and procedures based on the best medical evidence available in order to promote patient health. Beneficiaries would be able to obtain their regular Medicare fee-for service benefits, such as the annual wellness visit and relevant screening tests, from ACO providers.

ACOs to Provide Patients with More Health Care Quality Information

An ACO will publicly provide information about the quality of care the ACO providers deliver each year. ACOs also would track and report patient outcomes and experiences on over 60 different quality measures. In addition, beneficiaries obtaining care from ACOs would be surveyed annually about their experience with the ACO's providers. ACOs in turn would report publicly the different quality measures and survey results so that beneficiaries can have the information to better manage their own health care.

ACO Providers would Notify Beneficiaries of their Participation in an ACO

CMS is proposing to require ACO providers to notify beneficiaries, at the time they seek services, that the provider is participating in an ACO. The providers would offer beneficiaries information about the ACO including how the ACO would improve the care that they receive. Providers in an ACO also would be required to post signs in their facilities indicating their participation in an ACO and to make available written information about the ACO to Medicare beneficiaries.

Even if a beneficiary seeks care from a physician, hospital, or other facility that is a member of an ACO, the beneficiary would still be able to see or visit any provider they choose. An ACO would be prohibited from using managed care techniques such as limiting the beneficiary to certain providers, utilization management, or requiring prior authorization for services for Medicare beneficiaries.

Beneficiaries Can Opt Out of Sharing Personal Health Information with ACO Providers

To better coordinate care among ACO providers, an ACO would be able to request personal health information about the patient from CMS claims data. Before doing so, ACOs would be

required to provide written notice to beneficiaries during an office visit that it would request the beneficiary's personal health information from CMS. ACOs would be required to allow beneficiaries to opt-out of having their personal health information shared with the physician and the ACO.

The Shared Savings Program NPRM will appear in the XX, 2011 issue of the *Federal Register*. CMS will accept comments on the proposed rule until XX, and will respond to them in a final rule to be issued later this year. The Shared Savings Program will begin operating on January 1, 2012.

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