Introduction

ACA MEDICARE SHARED SAVINGS PROGRAM (Section 1899 of the Social Security Act):

“For January 1, 2012, the Secretary of HHS must establish a shared savings program that promotes accountability for patient populations and coordinates items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.”
What is an ACO?

ACO Participants work together to manage and coordinate care for Medicare FFS beneficiaries

• Accountable for quality, cost and overall care

• If meet or exceed minimum savings rate, meet minimum quality performance standards & maintain eligibility in the program = eligible to receive payments for shared savings

• ACOs that operate under a two-sided model and meet or exceed a minimum loss rate must share losses with Medicare
Additional Requirements

- Minimum of 5,000 beneficiaries
- Identifiable governing body
- Leadership and management structure that includes clinical and administrative systems that align with the goals of the Shared Savings Program
- Defined processes to promote evidence-based medicine and beneficiary engagement
- Adequate primary care ACO professionals to treat the number of beneficiaries assigned to it
Who is Eligible?

A legal entity identified by a TIN/EIN, formed by one or more “ACO Participants”

• Physicians, PAs, NPs & clinical nurse specialists (“ACO professionals”) in group practices
• Networks of individual practices of ACO professionals
• Partnerships or jvs between hospitals and ACO professionals
• Hospitals employing ACO professionals
• CAHs under certain conditions
• RHCs / FQHCs
• Others that participate through an ACO formed by a participant above
Participation in Other Shared Savings Programs

- Not if the ACO includes an ACO participant that participates in the “independence at home medical practice” pilot program
- Not if any ACO participants participate in another Medicare initiative involving shared savings payments
- CMS will determine a method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs
- Advanced Payment Model – rural and small physician-owned entities and hospitals with insufficient capital; up to 50 entities will receive up-front payments to be recouped from future savings
Application Process

• Minimum 3 year participation agreement with CMS
• 2012 start dates - April 1 & July 1 (apps. starting 1/1)
• 2013 (and thereafter) start date – January 1
• All applications for ACOs formed after 3.23.10 will be shared with Antitrust Agencies

• Submission:
  • Documents sufficient to describe the ACO participants and their respective rights and obligations
  • Description of how the ACO will implement the patient-centeredness criteria
  • Documents evidencing the ACO’s organization and management structure (incl. evidence of the compliant governing body)
  • Copy of the ACO’s compliance plan
Application Process

Submission:
- Description of the plan to distribute savings and the use of the shared savings payments
- How the distribution plan will achieve the specific goals of the Shared Savings Program
- How the plan will achieve the triple aim
- Specify whether the ACO plans to participate in Track 1 or 2 (2-sided risk or 1 only)
- If applying for 2-sided model, evidence of ability to repay losses

Applications must be complete by the due date or will be denied
• ACOs are subject to all statutory changes during the term of their participation agreement; plus
• Regulatory changes except for:
  • Eligibility requirements concerning structure and governance
  • Calculation of the sharing rate
  • Beneficiary assignment
• Required to submit a supplement to its application explaining how it will accommodate change
• ACOs will be permitted to terminate if the change will impact its ability to continue
Termination

• CMS may terminate a participation agreement for failure to comply, but may implement a corrective action plan as an alternative

• ACOs may terminate with 60-days’ prior written notice

• ACOs will not share in any savings for the performance year during which it is terminated
Other Program Requirements

• No beneficiary inducements
• But, can provide “in-kind” items/services if reasonable connection with the medical care and the items/services are preventive
• May not:
  • Condition participation in the ACO on referrals of non-ACO beneficiaries
  • Require that beneficiaries be referred only to ACO participants (but doesn’t apply to employees/contractors except if the beneficiary expresses a preference or the referral isn’t in the beneficiary’s best interest)
• Marketing materials must be submitted to CMS for approval
• Must notify beneficiaries of ACO participation
• CMS will engage in on-going monitoring of the ACO for compliance, particularly any ACO avoidance of at-risk beneficiaries
Beneficiary Attribution

• Under the ACA the Secretary is to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their use of primary care services furnished by an ACO professional

• The Final Rule clarifies that individuals enrolled in a Medicare Advantage plan under part C, or in a PACE program or in a “Seniorcare” program under Section 1876 of the Act are not eligible for assignment to an ACO under the Shared Savings Program
Beneficiary Attribution

• The Final Rule retains the proposed definition of “primary care services”
• Proposed rule, CMS would have assigned beneficiaries to physicians designated as primary care providers
• Final Rule adopts a “step-wise” approach
  • Beneficiaries are first assigned to the ACO based on the primary care services provided by primary care physicians
  • Beneficiaries who are not receiving services from a primary care physician may be assigned to the ACO on the basis of primary care services provided by other physicians (i.e. non primary care providers)
Beneficiary Attribution

• Beneficiaries will be assigned to an ACO if they receive a plurality of their primary care services from it

• Plurality rule will be applied on the basis of accumulated allowed charges—not a service count

• The beneficiary must receive at least one primary care service from a physician
  • PA and ARNP services are taken into account in determining the total allowed charges for primary care services

• A beneficiary will be assigned to ACO if the allowed charges for primary care services are greater than the allowed charges for primary care services furnished by either another ACO or unaffiliated providers
Beneficiary Attribution

Proposed Rule: primary care physicians were required to be exclusive to an ACO in order for the attribution process to work

• Final Rule: process includes specialists who furnish primary care and the primary care services of PAs and NPs

• CMS adopted an “exclusivity” requirement based on the taxpayer identification number (TIN)s under which the services of specialists, PAs and NPs included in the assignment process must be exclusive to one ACO
Beneficiary Attribution

• Proposed rule provided for retrospective attribution of beneficiaries

• Final Rule assigns beneficiaries prospectively, with final retrospective reconciliation
  - CMS will provide a list of beneficiaries “likely to receive care” from the ACO
  - At the end of each year, CMS will “reconcile” the list

• Beneficiaries remain free to seek services wherever they wish

• ACOs may receive claims data from CMS about a particular beneficiary, but must first inform the beneficiary who may decline to have his/her claim data shared with the ACO
Quality Performance and Standards

- Annual reporting of quality performance measures designated by CMS
- There are now 33 measures instead of the proposed 65
  - Shared savings dependent on satisfying all measures
  - Standards will become higher & there will be more added over time
- Quality Performance Measures in four categories:
  - Patient/care giver experience
  - Care coordination/patient safety
  - Preventative health
  - At-risk population
- CMS designates the quality performance standard in each year
- Commencing 2014, ACOs must utilize a vendor to conduct and submit a patient experience of care survey
- Additional bonus payments paid for satisfying physician quality reporting system (PQRS) measures and for EHR adoption (no longer required, but are weighted higher)
Shared Savings (and Losses)

Two tracks:
- Track I – “one-sided” model – no losses (available only for the initial agreement period); shared savings up to 50% on a 1st dollar basis, but must meet a minimum savings rate of 3.9%-2% based on number of beneficiaries
- Track II – “two-sided” model – shared savings and losses; shared savings up to 60% on a 1st dollar basis, but must meet a minimum savings rate of 2%
  - Shared losses may not exceed 5% in the 1st performance year, 7.5% in the 2nd and 10% thereafter

• Calculating the benchmark:
  - Per capita Parts A & B FFS expenditures for beneficiaries that would have been assigned in any of the 3 most recent years prior to the agreement
  - Annual updates on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A & B
  - Benchmarks reset at the start of each agreement period
ACOs: Fraud and Abuse

• To be successful an ACO must
  • Establish an infrastructure that meets CMS requirements and permits its participating members to control costs and promote quality
  • Financially incent physicians and other ACO participants to provide quality care while using fewer resources
  • Encourage appropriate beneficiary behaviors

• The proscriptions of the fraud and abuse laws pose a significant barriers to achieve these goals

• As a general proposition the fraud & abuse laws are designed to separate or misalign the financial incentives of the various segments of the health care delivery system
  • Silos-------
ACOs: Fraud & Abuse

• Stark physician self-referral law, prohibits physicians from referring patients to entities with which they have a financial interest, for covered program services unless an exception applies.

• Anti-kickback statute is a broad prohibition on payments to induce referrals of items or services to be paid for by a federal health care benefit program.

• The federal Civil Money Penalties (CMP) statute (the “CMP”) has several elements:
  • Gainsharing CMP—prohibits hospitals from making payments directly or indirectly to physicians to induce the physician to reduce or limit services to Medicare or Medicaid beneficiaries.
  • Beneficiary Inducement CMP—prohibits offering anything of value to beneficiaries to influence the beneficiaries selection of a particular provider.

• State law prohibitions?
ACOs: Fraud & Abuse Waivers

- Section 3022(f) of the ACA grants the Secretary the authority to waive the requirements of the fraud & abuse laws “as may be required to carry out the Shared Savings Program provisions”
- On March 31, 2011, the CMS and OIG published a Joint Notice outlining proposed waivers
- October 20, 2011 an Interim Final Rule with Comment (“IFC”) was released establishing five separate waivers
ACOs: Fraud & Abuse Waivers

- IFC includes 5 waivers:
  - An “ACO pre-participation” waiver that applies to ACO-related start-up arrangements
  - An “ACO participation” waiver that applies during the period of when the entity is actively participating in the Shared Savings Program and for a limited time thereafter
  - A “patient incentive” waiver for in kind incentives offered by ACOs to beneficiaries to encourage preventive care and compliance with treatment regimens
  - A “shared savings distribution” waiver
  - A “compliance with Stark Law” waiver
ACOs: Fraud & Abuse Waivers

• The waivers apply only to the Shared Savings Program and participating ACOs
  • The ACA includes separate authority for Secretary to waive fraud and abuse laws for other demonstration projects and pilot programs
• The waivers only apply to the specific laws identified in the IFC (i.e. Stark, anti-kickback and CMPs) and not to any other provision of State or Federal law, including the Internal Revenue Code
• The waivers apply uniformly and are self implementing – no need to apply to CMS/OIG
Scope of Waivers

• Pre-participation Waiver and the ACO Participation Waiver both require that the covered arrangement be for “purposes of the Shared Savings Program”
• Phrase is broadly defined
• IFC notes that there are limits—“per referral payments” (i.e. $500 for each patient admitted) not reasonably related to purposes of SSP
• Governing Body must make a determination and maintain records of the basis for its determination
Scope of Waivers

- Arrangement must relate to Shared Savings Program but arrangements that involve care to both Medicare and non-Medicare patients are eligible for waiver.
- Arrangements adopted must meet specific transparency requirements.
- Waivers apply to arrangements with outside providers if related to the ACOs operations.
Pre Participation Waiver

- The Stark law, anti-kickback statute and Gainsharing CMP are waived with respect to start up arrangements that pre-date an ACO’s participation in the Shared Savings Program, provided:
  - The parties have a good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a particular year and to submit an application to participate in that year
  - The parties must take diligent steps to develop an ACO
  - ACO’s governing body must make a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program
  - Documentation of the arrangement, the governing body’s determination retained for at least 10 years
Pre Participation Waiver

• A description of the arrangement is publicly disclosed at a time and in a manner established in guidance to be issued by the Secretary

• **Note:** arrangements with drug and device manufacturers, distributors, DME and home health suppliers are **NOT** included in the pre participation waiver
ACO Participation Waiver

• The Stark law, anti-kickback statute and Gainsharing CMP are waived with respect to any arrangement of an ACO, its ACO participants and ACO providers/suppliers provided:

  • The ACO has entered into a participation agreement and remains in good standing under the Shared Savings Program

  • The ACO meets the governance, leadership and management requirements of an ACO

  • The ACO’s governing body has made a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program
ACO Participation Waiver

• Documentation of the arrangement, the governing body’s determination retained for at least 10 years

• A description of the arrangement is publicly disclosed at a time and in a manner established in guidance to be issued by the Secretary
Shared Savings Distribution Waiver

• The Stark law, anti-kickback statute and Gainsharing CMP are waived with respect to distributions of shared savings earned by an ACO, provided:

• The ACO has entered into a participation agreement and remains in good standing under the Shared Savings Program

• The shared savings are earned by the ACO pursuant to the Shared Savings Program

• The shared savings are earned by the ACO during the term of its participation agreement, even if the distribution or use of the shared savings occurs after expiration of the agreement
Shared Savings Distribution Waiver

- The shared savings are either distributed among ACO participants, ACO provided/suppliers or used for activities that are reasonably related to the purposes of the Shared Savings Program.

- With respect to the Gainsharing CMP waiver, the shared savings distributions made directly or indirectly from a hospital to a physician may not be knowingly made to reduce or limit medically necessary care to patients under the direct care of the physician.

  - The IFC clarifies that payments to encourage best practices or compliance with clinical protocols are not prohibited by this provision.
Compliance With Stark Law Waiver

• The Gainsharing CMP and the anti-kickback statute are waived with respect to any financial relationship among the ACO, its participants, and its ACO providers/suppliers that implicates the Stark law, provided:

• The ACO has entered into a participation agreement and remains in good standing under the Shared Savings Program

• The financial relationship is reasonably related to the purposes of the Shared Savings Program

• The financial relationship fits within an exception to the Stark law
ACO Waiver: Stark

- Historically CMS and OIG have maintained that the Stark law, anti-kickback statute and CMP law were all separate.

- Compliance with one did not affect whether the arrangement complied with another— the Stark ACO Waiver is a significant departure from this historical position.

- Existing Stark exceptions--- employment, FMV arrangements, EHR donations, risk sharing . . .
Beneficiary Inducement Waiver

• The Beneficiary Inducement CMP and the anti-kickback statute are waived with respect to items or services provided by an ACO to beneficiaries for free or below fair market value provided:

• The ACO has entered into a participation agreement and remains in good standing under the Shared Savings Program

• There is a reasonable connection between the items or services and the medical care of the beneficiary

• The items or services are in kind (no cash or cash equivalent payments)

• The items and services are (a) preventive care; or (b) advance one or more of the following goals: (i) adherence to a treatment regime; (ii) adherence to a drug regime; (iii) adherence to a follow-up plan of care; (iv) management of a chronic disease or condition

• Note: not limited to beneficiaries assigned to the ACO
Comments?

• The IFC published in the Federal Register on Nov 2, 2011
• Sixty day comment period
• CMS/OIG solicited comments on
  • Whether to clarify definition of “reasonably related to purposes of Shared Savings Program”
  • Should participation waiver include conditions requiring FMV or commercial reasonableness of terms or prohibiting exclusivity?
  • Should waivers be modified to exclude outside party arrangements?
  • Whether waiver protection for distribution of shared savings should be extended to commercially sponsored programs?
Bottom Line on ACO Waivers

• Stunning

• Far more flexibility than anticipated

• Real opportunities for creative arrangements
  • But remember State law restrictions, IRS requirements and antitrust laws still must be addressed
Tax Exempt Organizations as ACOs

- Internal Revenue Service issued a new Fact Sheet on ACOs
  - "Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations"
- Fact Sheet confirms IRS’ prior statements on ACOs in Notice released in March 2011
- IRS stated that it will review ACO arrangements on a case-by-case basis, based on all the facts and circumstances
IRS Fact Sheet

• HOWEVER, because of CMS regulation and oversight of the Shared Saving Program, IRS generally "expects" that it will not consider a tax-exempt hospital's participation in an ACO to result in inurement or private benefit if certain factors are met
IRS: Type of Entity

- CMS has no specific requirement for the type of legal entity for an ACO other than that it must be separate from its participants, except for a clinically integrated organization.
- The type of entity selected will ultimately determine the tax consequences.
  - Separate corporation—separate taxable entity
  - Partnership or LLC—activities attributed to partners
IRS: Inurement and Private Benefit

• The exempt organization's participation must not result in inurement or being operated for the benefit of private parties participating in the ACO
• Facts & circumstances analysis
• No statement regarding presumptions related to Share Savings Program
IRS: Charitable Purpose

- IRS confirmed that a tax-exempt hospital can further charitable purposes by participating in an ACO whose sole activity is participating in the Shared Savings Program.
- A tax-exempt hospital generally does not need to have control over an ACO treated as a tax partnership that is solely participating in the Shared Savings Program to ensure that it furthers charitable purposes.
- Certain activities of the ACO that are outside of Shared Savings Program may also further charitable purposes.
- However, not all ACO activities will further charitable purposes:
  - Promotion of health??
IRS: Tax Exempt Status

- If an ACO conducts non Shared Savings Program activities, in some circumstances such activities may or may not jeopardize the exempt status of the hospital
- IRS will apply facts and circumstances analysis
- ACO conducts an activity lacking a charitable purpose, it does not necessarily mean that the exempt status of the hospital participant will be jeopardized
IRS: Tax Exempt Status

- If the ACO's activities are not attributed to the tax-exempt hospital participant (such as when the ACO is a corporation or a blocker corporation is used), the IRS indicated that exempt status cannot be in jeopardy.
- When the ACO's activities are attributed to the tax-exempt hospital (such as when the ACO is a tax partnership), exempt status will not be jeopardized if the ACO's non-charitable activities represent no more than an insubstantial part of the tax-exempt hospital's total activities.
IRS: Unrelated Business Income

- IRS expects that a tax-exempt hospital's shared saving payments will not be subject to unrelated business income tax since such payments would be derived from activities substantially related to charitable purposes.
- Non-Shared Savings Program Activities will not automatically generate unrelated business taxable income—such activities may further a charitable purpose.
IRS: Separate tax exempt status

- Certain ACO entities (such as nonprofit corporations or nonprofit LLCs that have elected to be taxed as corporations) may qualify separately for Section 501(c)(3) status.
- The ACO would need to ensure that its Non-Shared Savings Program Activities further a charitable purpose.
**IRS: Clarification**

- Fact sheet clarified that the 5 factors set forth in the IRS’ earlier guidance need not all be satisfied to avoid jeopardizing a hospital’s exempt status

- The five factors include:
  - terms of the tax-exempt hospital's participation in the ACO are set forth in advance in a written agreement negotiated at arm's length—
    - IRS clarified that agreements need not include all of the details
  - CMS must have accepted the ACO into the Shared Savings program, and not terminated the ACO
    - IRS clarified that if the ACO is later terminated from the Shared Savings Program, such action would not automatically jeopardize the 501(c)(3) status
IRS: Clarification

- the tax-exempt hospital's share of economic benefits derived from the ACO is proportional to the benefits or contributions the hospital provides to the ACO
  - IRS clarified that ownership interests in the ACO do not need to be directly proportional to capital contributions and distributions of shared savings payments do not necessarily need to be made in proportion to ownership interests
  - IRS will consider the totality of circumstances
IRS: Clarification

• The tax-exempt hospital's share of the ACO's losses does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled

• All contracts and transactions entered into by the tax-exempt hospital with the ACO are at fair market value
  • IRS did not provide any further clarification on these last two factors
  • May not be required because of general statement that all 5 factors not necessary but . . .
Antitrust Policy Statement

• Proposed statement issued in March
  • ACOs > 50% shares were required to obtain FTC/DOJ review
• Comments received
• Final policy statement issued October 20, 2011
Antitrust Policy Statement

• When the statement applies
• The Rule of Reason
• Safety zone
• Outside the safety zone
• Voluntary review process
When the Statement Applies

• Applies to:
  • All collaborations among otherwise independent providers that are eligible and intend, or have been approved, to participate in the SSP program

• Does not apply to:
  • Single integrated entities
  • Mergers and acquisitions
The Rule of Reason

• What’s the issue?
• Section 1 of the Sherman Act
  • Prohibits agreements that reduce competition
  • Per se rule
    • No harm to competition need be shown
  • Rule of Reason
    • Must establish harm to competition
• So: Rule of Reason treatment is important
The Rule of Reason

• Agreements among competing providers
  • Per se treatment for “naked” restraints
  • Rule of Reason treatment if “integrated” and setting price is reasonably necessary to achieve benefits

• Integrated
  • Financially
  • Clinically
The Rule of Reason

- What’s financial integration?
  - E.g. – capitation; fee schedule with a substantial risk withhold
- What’s clinical integration?
  - “the implementation by a network of an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and the creation of a high degree of interdependence and cooperation among the physicians to control costs and ensure quality”
The Rule of Reason

• So:
  • Qualifying ACO may jointly negotiate reimbursement terms with commercial payors without price fixing
Safety zone

• Agencies will not challenge ACOs within safety zone “absent extraordinary circumstances”

• Safety zone
  • Two or more independent ACO participants providing a common service
  • Have a combined share of 30% or less in each participant’s PSA
Safety zone

- Common services
  - Physician: primary specialty (MSC)
  - Inpatient facilities: MDCs
  - Outpatient facilities: category as defined by CMS
- PSA
  - Lowest number of zip codes making up 75%
  - Borrowed from Stark
Safety zone

• What does “safety zone” mean?
  • No agency challenge, absent extraordinary circumstances
  • Does not foreclose private litigants
  • No presumption of illegality outside 30%
Safety zone

• Hospitals and ASCs
  • Must be non-exclusive to fall within the safety zone
  • Regardless of number of hospitals/ASCs in area
• Can an ACO qualify for participation in the SSP if a hospital participates on an exclusive basis?
  • Yes – it just doesn’t fall within the safety zone
Safety zone

• Rural exception: physicians
  • Physicians: ACO in a rural area can include one physician (or group) per specialty in each "rural area" even if that takes the ACO over 30%
  • So long as: physician is not exclusive to the ACO

• Rural exception: hospitals
  • ACO can include a "Rural Hospital" and still qualify even if the resulting share exceeds 30%
  • The hospital cannot be exclusive to the ACO
Safety zone

• Dominant Provider Limitation
  • If a provider with a share > 50% is included, the ACO still qualifies if the provider is:
    • Non-exclusive
    • The only provider of the service

• If an ACO includes a single group of OBs who have a 60% share, can the ACO fall within the safety zone?
  • Yes – but only if it is non-exclusive to the ACO
Safety zone

• How long does protection last?
• For the duration of the ACO’s agreement with CMS
  • Provided: the ACO continues to meet the safety zone requirements
  • Patient growth doesn’t matter
Outside the safety zone

• **Not** necessarily illegal
• Conduct to avoid
  • Discouraging steering
  • Tying
  • Exclusive contracting with ACO participants
  • Restricting payor’s ability to share cost, quality, efficiency, and performance information with enrollees
• All ACOs should avoid improper sharing of competitively sensitive information
Voluntary review process

• “Newly formed” ACO may seek antitrust review
  • As of March 23, 2010, had not signed or negotiated contracts with a commercial payor, and had not participated in the Shared Savings Program
• Inform FTC and DOJ using a form on website
  • www.ftc.gov/os/2011/10/111020acocoversheet.pdf
• One agency takes review and tells ACO
• ACO submits required information
Voluntary review process

Information submitted:

• Application and supporting documents to CMS
• ACO’s strategies or plans to compete in Medicare and commercial markets including the impact on quality/price
• Documents discussing competition among ACO participants and in markets to be served by the ACO
• Information sufficient to show the common services offered by ACO, share calculations by PSA
  • “or other data that show the current competitive significance of the ACO or ACO participants.”
Voluntary review process

- Within 90 days of receiving “all” required information, the reviewing agency informs the ACO it:
  - “Does not likely raise competitive concerns”
  - “Potentially raises competitive concerns”
  - “Likely raises competitive concerns”
- Agency may condition finding of no competitive concerns on agreement by ACO to take prescribed steps to remedy concerns
Voluntary review process

• How much information should be supplied with a request for an advisory letter?
• Will agency tell ACO in advance if a negative opinion is forthcoming?
• How much investigation will agencies do to prepare their letters?
Voluntary review process

- Can others see the application and response?
- Can the agencies ask for more information?
- Will the responses be consistent between agencies?
Observations

• PSA is not an antitrust market
• No Medicare data for obstetrics, pediatrics
• Hospital outpatient department and ambulatory surgery center reimbursed at different rates
• Shares of providers with unusually high Medicare populations not representative of shares of commercial (and possibly opposite)
Questions?

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