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ACOs Unraveling the Implications of New ACO Regulatory Scheme

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Introduction

- The Regulations are *proposed*, not final
- Comments due June 6, 2011
- Comments on FTC/DOJ antitrust and IRS tax-exempt status pieces due May 31, 2011
- Commentary discusses various options being considered by CMS
- Encourage submission of comments

What is an ACO?

- Entity accountable for quality and cost of services to assigned patients
- Only Medicare fee-for-service patients

CMS Aims

- Patient Quality
- Patient Population Health Care Improvement
- Cost Reduction

First Look Observations

- Rules are very complex
- ACOs must satisfy many organizational and operational requirements-- akin to a health plan's requirements
- Will require a substantial expenditure of time, resources, and money
- Uncertain benefits

Eligibility

- Who can qualify to be an ACO?
 - Legal entity, under state law (probably easiest to use a new, special purpose entity)
 - Comprised of “eligible group” of ACO participants
 - ACO participants can be any Medicare providers or suppliers
 - Must have “ACO professionals” (i.e., primary care practitioners) who serve at least 5,000 Medicare fee-for-service beneficiaries

Note: (The proposed regulations use the terms “ACO participants” and “ACO provider/suppliers” but do not clearly distinguish them.)

Eligibility

- ACO Participants
 - ACO professionals (i.e., primary care practitioners) must be exclusive to one ACO, and commit to 3 years
 - All other ACO participants cannot be required to be exclusive, and must commit to 3 years
- ACO Agreement with CMS
 - ACO applies to participate, and if approved by CMS, ACO signs 3-year agreement
 - CMS must approve any “marketing materials or activities” (broadly defined) used by ACO
 - ACO must notify Medicare beneficiaries that their ACO providers/suppliers are participating in an ACO

Governance

- ACO must establish and maintain a governing body, which must include:
 - ACO participants (or their representatives)
 - One or Medicare beneficiary (who does not have a conflict of interest with the ACO)
 - At least 75% of governing body must be controlled by ACO participants
 - The governing body of ACO must be independent and separate from the governing bodies of the ACO participants (unless the ACO is comprised of a single member, in which case its governing body can be ACO's governing body)
- ACO must have an executive, officer, manager, or general partner
- ACO must have a “full-time senior-level medical director”

Management

- ACO participants and ACO providers/suppliers must have meaningful commitment to ACO (e.g., invest time, effort or money)
- ACO must have physician-directed quality assurance and process improvement
- ACO participants must agree to comply with evidence-based clinical guidelines
- ACO must have information technology infrastructure (including EHR)
- ACO must adopt a compliance plan
- ACO must have a written plan for achieving and distributing shared savings, and improving quality of care

Beneficiary Assignment

- Beneficiaries assigned to ACO are determined retrospectively at the end of each performance year
- Beneficiary is assigned to ACO if the plurality of the primary care services during the year are received from the ACO's primary care physicians
- Measured by allowed charges
- Primary care physicians are internal medicine, general practice, family practice, and geriatrics
- Primary care services include HCPCS 99201-15, 99304-349, 99341-50, annual and welcome visits

Beneficiary Assignment

- Assignment is only for purposes of determining whose care the ACO is accountable and for determining shared savings
- Does not restrict assigned beneficiary's freedom of choice
- ACO participants must post signs in each of their facilities and provide written notification for beneficiaries about their participation in the ACO program

Quality

- ACO must meet quality and continuous improvement goals defined by CMS to qualify for shared savings
- CMS designated quality measures
- ACO must submit data on the quality measures

Quality

- Five quality measure domains:
 - Patient/care giver experience
 - Care coordination
 - Patient safety
 - Preventive health
 - At-risk population/frail elderly health
- 65 performance standards within the domains

Quality

- CMS establishes quality performance standards for each measure, including a performance benchmark
- May be based on Medicare fee-for-services, MA, or ACO performance data
- For first performance year, standard based on complete and accurate reporting
- Subsequent years, based on measure scores
- Zero points if below minimum standard
- Sliding scale if above minimum but below standard
- Two “all or nothing” standards

Quality

- If ACO satisfies quality performance standards for each domain and meet all other applicable requirements, it is eligible for shared savings
- Each domain has equal weight
- Must score above minimum for all standards in a domain for the domain to be eligible for shared savings
- Obtain proportion of shared savings based on number of domains satisfied and score within the domain

Quality

- CMS may audit and validate the quality data
 - 3 phases. If greater than 10% discrepancy based on medical record review, no credit for the applicable quality target
- Failure to report data accurately, completely, and timely can lead to termination or other sanctions

Quality

- ACO “eligible professionals” can qualify for Physician Quality Reporting System incentive of 0.5% by reporting quality measures
- At least 50% of ACO’s primary care physicians must be meaningful EHR users

Payment of Shared Savings

- Process will require sharing in savings and losses
- Shared savings/losses calculated annually
- Shared savings/losses subject to minimum savings or losses as triggers
- Some shared savings also subject to thresholds (deductibles)
- Shared savings/losses subject to caps
- Shared savings payments subject to 25% withhold
- Must meet requirements ensuring repayment of shared losses

Two Models Available

- ACO may choose “one-sided model”, which involves sharing of losses only in the third year of the initial agreement, and thereafter
- ACO may alternatively choose “two-sided” model by which the ACO assumes immediate risk for losses
- Once the one-sided model assumes risk for losses, it is treated largely the same as the two-sided model
- The two-sided model provides greater upside to the ACO, along with the greater risk

Benchmark

- Based on per capita expenditures for beneficiaries who would have been assigned for 3 most recent years
- Fixed benchmark adjusted:
 - For trends/growth from prior years to the third year of the benchmark, based on national growth rate
 - For health status of beneficiary population, proposed to be based on CMS-HCC model from Medicare Advantage program
 - Weighting the benchmark years at 10%, 20% and 60% for benchmark years 1 to 3
 - Truncates per capita expenditures at 99th percentile
 - Will not account for certain expenditure increases (i.e. Physician Quality Reporting, Electronic prescribing and HITECH incentives for eligible professionals)

Shared Savings

- Based on comparison of estimated average per capita Medicare expenditures (Parts A and B), adjusted for beneficiary characteristics, to the applicable benchmark
- Truncates expenditures at 99th percentile, to minimize impact of catastrophically large claims
- Savings must exceed minimum savings rate (MSR), which decreases as the number of assigned beneficiaries increases (3.9%--5000 benis, 2.0%--60,000 benis or 2-sided model)
- Under one-sided model, savings shared only for savings over 2% threshold

Shared Savings (continued)

- Final sharing rate varies based on whether risk of loss applies, and quality performance
- Shared savings rate may be increased by up to 2.5% if the ACO includes a rural health clinic (RHC) or federally qualified health center (FQHC)
- Maximum is 52.5% in one-sided model, 65% in 2-sided model
- Shared savings are subject to cap of 7.5% of benchmark for one-sided model and 10% for two-side model

Shared Losses

- Applies to one-sided model in third year and after
- Applies immediately to two-sided Model
- Also has minimum loss rate (2%)
- No threshold; once minimum loss rate hit, ACO shares in first dollar of losses
- Shared loss rate is inverse of shared savings rate (1 minus shared savings rate).
- Subject to annually increasing loss cap: 5%, 7.5% and 10% of benchmark

Shared Savings/Losses Overview

Design Element	One-Sided Model (performance years 1 & 2)	Two-Sided Model
Maximum Sharing Rate	52.5 percent	65 percent
Quality Scoring	Sharing rate up to 50 percent based on quality performance	Sharing rate up to 60 percent based on quality performance
FQHC/RHC Participation Services	Up to 2.5 percentage points	Up to 5 percentage points
Minimum Savings Rate	Varies by population	Flat 2 percent regardless of size
Minimum Loss Rate	None	Flat 2 percent regardless of size
Maximum Sharing Cap	Payment capped at 7.5 percent of ACO's benchmark	Payments capped at 10 percent of ACO's benchmark
Shared Savings	Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2 percent threshold; up to 52.5 percent of net savings up to cap.	Savings shared once MSR is exceeded; up to 65 percent of gross savings up to cap

Shared Savings/Losses Overview (continued)

Design Element	One-Sided Model (performance years 1 & 2)	Two-Sided Model
Shared Losses	None	<p>First dollar shared losses once the minimum loss rate is exceeded.</p> <p>Cap on the amount of losses to be shared phased in over three years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3.</p> <p>Losses in excess of the annual cap would not be shared. Final loss sharing rate will be inverse of final savings sharing rate</p>

Ensuring Repayment of Shared Losses

- CMS can look to 25% of prior shared savings withheld
- Propose requiring self-executing method for repaying losses, equal to at least 1% of per capita expenditures for assigned beneficiaries for most recent available year
 - Reinsurance, bonds or line of credit
 - Escrowed funds or similar available repayment methods
- This applies to one-sided plan as well even though it will not take on risk until 3rd year
- CMS can carry forward unpaid losses and offset against future shared savings payments

Monitoring ACOs

- General (analyze data, site visits, complaints, audits)
- Avoidance of “at-risk” beneficiaries
 - submit corrective action plan (CAP)
 - no shared savings when under CAP
 - termination if continue to avoid “at risk” beneficiaries
- Compliance with quality performance standards
 - warning if ACO fails to meet “minimum attainment level” for one or more domain
 - re-evaluated the following year (termination or other action if problem continues)
 - termination for failure to report data without “reasonable explanation”
- Other (ACO eligibility, notices to beneficiaries, marketing)

Termination

Pre-Termination Action

- At CMS' sole discretion, CMS may:
 - issue warning notice
 - request corrective action plan (CAP)
 - place ACO on “special monitoring plan”

Termination, Suspension, Repayment

- Grounds for termination (e.g., failure to satisfy requirements, breach of law, etc.)
- Reapplication (only after end of original 3-year term)
- Forfeit mandatory 25% withhold of share savings
- Notices to ACO participants, beneficiaries, etc.

Reconsideration Review Process

- There is no reconsideration, appeal or review for:
 - specification of quality and performance standards
 - assessment of quality of care furnished by ACO
 - assignment of beneficiaries
 - calculation of shared savings due to ACO
 - percent of shared savings available and limits on same
 - termination of ACO for failure to meet quality standards
 - determination to challenge ACO by antitrust agency

Reconsideration Review Process (continued)

Reconsideration Review Process

- All other initial determinations are subject to “reconsideration review”
 - ACO must request review within 15 days
 - there is a somewhat informal process by “reconsideration official”
 - burden of proof is on ACO
 - decision by reconsideration official can be appealed to CMS
 - CMS’s decision after review of the reconsideration official’s recommendation is “final and binding”

Audits and Record Retention

- CMS requires ACOs to agree to give CMS broad right to audit the ACO, its participants and contractors
- ACOs and their participants and contracted entities must
 - maintain books and records for 10 years
 - this can be extended another 6 years
 - ❖ on 30 days notice, if
 - ❖ termination, dispute, allegations of fraud, or similar fault by ACO or its participants or contracted entities
- ACO has ultimate responsibility for these requirements

Antitrust

Existing antitrust enforcement policies permit joint price negotiation if there is—

- financial integration (such as risk-sharing through capitation)
 - ACOs are fee-for-service, and do not involve financial integration of this kind
- clinical integration sufficient to ensure significant efficiencies

The enforcement agencies have approved several clinically integrated joint ventures, but have not established bright-line criteria for clinical integration

Antitrust

- Proposed regulations are accompanied by a proposed Statement of Antitrust Enforcement Policy Regarding ACOs to be issued by the FTC and the DOJ
- Applies to collaborations among independent providers formed after March 23, 2010 that seek to participate as ACOs in Medicare Shared Savings Program

Antitrust

- Agencies will apply “rule of reason” analysis to ACOs operating in the commercial market that meet CMS eligibility criteria to qualify for the Medicare Shared Savings Program
- Rule of reason analysis balances potential anti-competitive effects against potential pro-competitive efficiencies
- FTC and DOJ have established antitrust “safety zones” for arrangements that will not be challenged, absent extraordinary circumstances

Antitrust

- Proposed policy would create a new “safety zone” for ACOs where independent ACO participants providing the same service have a combined share of 30% or less of each common service in each participant’s Primary Service Area (PSA)
- PSA is the lowest number of contiguous zip codes from which the participant draws at least 75% of its patients for the service
- Hospitals and ASCs must be non-exclusive to the ACO, irrespective of market share

Antitrust

Rural exception:

- ACOs within the safety zone may include—
 - one physician per specialty from each rural county (as defined by Census Bureau)
 - Any Rural Hospital (i.e., a Sole Community Hospital or a Critical Access Hospital)on a non-exclusive basis, even if as a result the ACO's share of a common service exceeds 30% of a participant's PSA for that service

Antitrust

Dominant Provider Limitation:

- A dominant provider is one that has more than a 50% share in its PSA of any service, and is the sole ACO provider of that service in its PSA
- Dominant providers must be non-exclusive to the ACO
- An ACO with a dominant provider cannot restrict a commercial payer from contracting with other ACOs or provider networks

Antitrust

- Safety zone remains in effect for the duration of the ACO's agreement with CMS, unless there is a significant change in provider composition
- ACO that initially qualifies does not lose protection if it exceeds the 30% limitation because it attracts more patients

Antitrust

- ACOs that do not qualify for the rural exception and exceed a 50% share for any common service that two or more ACO participants provide in the same PSA must obtain antitrust review
- Agencies will consider data reflecting limited market power or pro-competitive justification

Antitrust

- Agencies will provide review within 90 days, and will advise ACO either—
 - They have no present intent to challenge the ACO (this may be conditioned on ACO's taking steps to address concerns), or
 - They are likely to challenge the ACO if it proceeds
- CMS will require a “no present intent” letter as a condition of eligibility

Antitrust

- ACOs outside the safety zone and below the 50% mandatory review threshold are not viewed as necessarily anticompetitive, but may be subject to investigation and enforcement action
- Proposed policy would provide guidance on conduct that, if avoided, would significantly reduce the risk of scrutiny
- The ACO may also seek expedited antitrust review

Antitrust

Conduct to avoid:

- Preventing or discouraging payers from directing or incentivizing patients to choose other providers
- Tying sales to the payer's purchase of services from non-ACO participants (and vice versa)
- Exclusive provider contracting (except for PCPs)
- Restricting availability to payers of cost, quality, efficiency and performance data
- Sharing competitively sensitive price or other data that could be used to set prices or terms of service outside the ACO

Proposed Fraud and Abuse Law Waivers for ACOs

- Joint OIG/CMS notice proposes waivers of 3 fraud and abuse laws as applied to ACOs:
 - Stark (42 U.S.C. 1395nn(a))
 - AKS (42 U.S.C. 1320a-7b(b)(1) and (2))
 - CMP (42 U.S.C. 1320a-7a(b)(1) and (2))

Proposed Fraud and Abuse Law Waivers for ACOs

- Waivers to be issued concurrently with CMS publication of final ACO regs
- Waiver authority specific to Medicare ACOs – does not apply to other integrated models or ACOs
- CMS/OIG may consider waivers, exceptions, safe harbors for other types of ACOs and integrated models, financial arrangements at a later date

Proposed Stark Waiver

- Waive application of Stark to distributions of shared savings received by an ACO from CMS under MSSP:
 - Within the ACO: To/among qualified ACO participants, ACO providers/suppliers
 - Outside the ACO: Only for activities “necessary for and directly related to” ACO’s participation in and operations under MSSP
- Waiver applies only to distribution of shared savings
 - All other financial relationships must meet an existing exception
 - Waiver applies even if distribution occurs after expiration of ACOs agreement with CMS

Proposed AKS Waiver

- Waive application of AKS in 2 scenarios
- Scenario 1: same criteria as proposed Stark waiver
- Scenario 2: any financial relationship within the ACO “necessary for and directly related to” ACO’s participation in, operations under MSSP that implicates Stark and fully complies with an exception
 - Goes beyond Stark ACO exception to protect financial relationships other than distributions of shared savings, if they meet Stark exception
 - However, it does not protect non-physician financial relationships

Proposed CMP Waiver

- Waive application of CMP in 2 scenarios
- Scenario 1: Distribution of shared savings received by ACO from CMS under MSSP, where distributions made from hospital to physician, and:
 - Payments not made knowingly to induce physician to reduce/limit medically necessary items or services; and
 - Hospital and physician are ACO participants / providers / suppliers, or were during year in which ACO earned the shared savings
- Scenario 1 waiver applies to distribution of shared savings, even if distribution occurs after expiration of ACO's agreement with CMS
- Scenario 2: Same criteria as proposed AKS waiver, Scenario 2: Distributions within ACO, implicates Stark and meets an exception (i.e., payments that are not distributions of shared savings are alright if meet a Stark exception)

Additional Proposed Waivers

- What is not covered?
 - ACO start-up costs
 - Continuing ACO operating expenses
 - Reimbursement for losses
 - Any financial arrangements that do not involve distribution of shared savings (e.g., shared risk, pooling of resources, incentive payments, etc.)
 - Private payor shared savings distributions
 - Required referrals within ACO
 - Beneficiary inducements

Tax-Exempt Issues

- **Tax-Exempt Issues – IRS Notice 2011-20**

- ACO participation by tax-exempt entities will not result in private inurement or impermissible private benefit where the following are met:
 - ❖ Terms are set forth in a written agreement negotiated at arm's length
 - ❖ CMS has accepted and not terminated ACO
 - ❖ Tax-exempt economic benefits and losses are based on its contribution
 - ❖ All contracts among participants are FMV
- IRS indicated should not result in UBIT, because ACO is related to the charitable purpose of lessening burden on government
- Potential issues related to ACO participation with private payers and other programs, which would be analyzed on a case by case basis. If such programs are desired, it would be even more important to ensure non-profit control
- IRS also seeking comments – due on before May 31, 2011

State Law Issues

- No express federal pre-emption of state law.
- Corporate Practice
- HMO regulations and related issues
- State anti-kickback laws
- State self-referral laws
- State antitrust

If you have additional questions and would like more information, Hooper, Lundy & Bookman, P.C. invites you to contact members of our ACO Task Force directly:

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