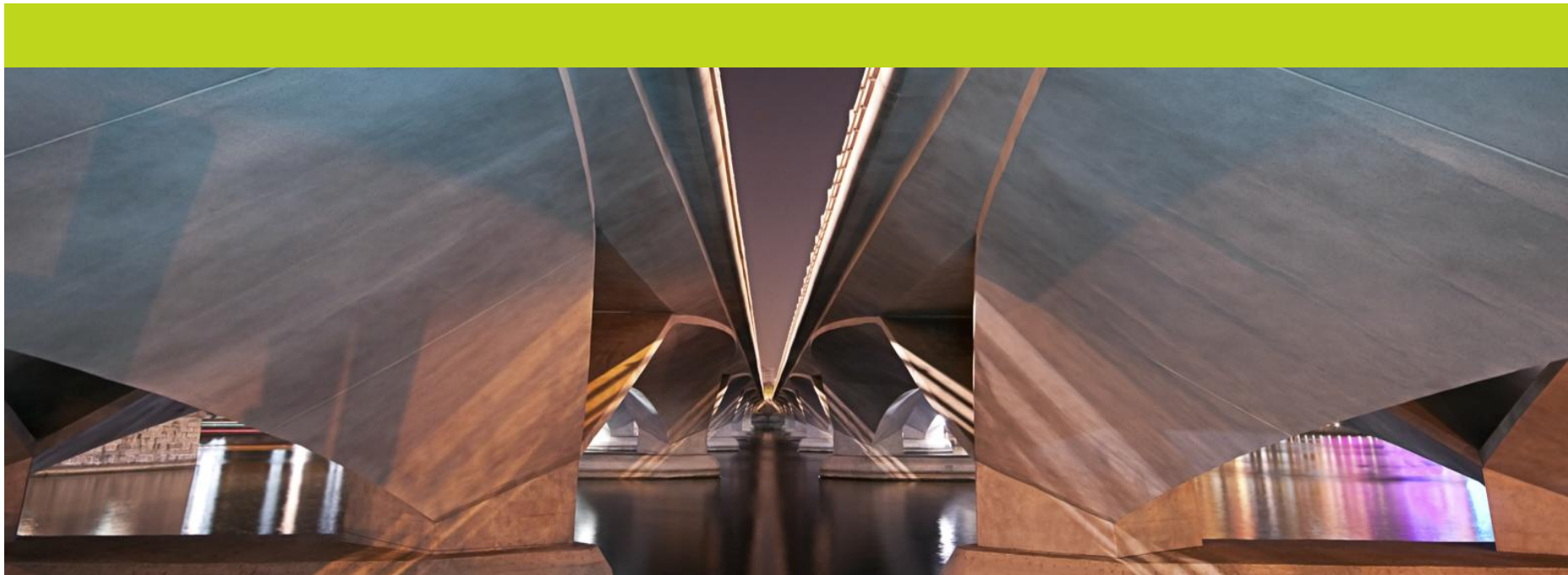


Accountable Care Organizations (ACOs) and the Medicare Shared Savings Program (MSSP): the Legal Issues

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Presentation overview

- Antitrust issues
- Fraud and abuse waivers
- Tax-exempt considerations
- Questions and answers

Antitrust Issues



Antitrust review and guidelines

- Administered by *both* the Federal Trade Commission (FTC) and the Department of Justice (DOJ)
- Applies to entities seeking to participate in MSSP formed after 3/23/2010
- Rule of reason treatment for
 - Centers for Medicare and Medicaid Services (CMS)-approved ACOs
 - If ACO uses in the commercial market the same
 - governance and leadership structure
 - clinical and administrative processes

Market power assessments

- Establishes streamlined analysis for evaluating competitive concerns
- Focus on the share of each ACO participant in its Primary Service Area (PSA)
 - PSA is the lowest number of contiguous zip codes from which each participant draws at least 75% of its patients
 - Consider for each different physician specialty, major diagnostic category (MDC), or outpatient category as defined by CMS
- Consider both
 - “Common” service lines
 - Also even if not overlapping, where a participant may be dominant (>50% share)
- Unprecedented shortcut to product and geographic market definition

Safety zone

- Where there is a common service, combined share must be 30% or less in *each* participant's PSA
- Every participating hospital or ACO must be non-exclusive regardless of PSA share
- Rural exception
 - May include one physician per county even if over 30% share, provided non-exclusive
 - May include rural hospitals even if over 30% share, provided if non-exclusive
- If ACO includes a participant with greater than 50% share (even if no common services):
 - participant must be non-exclusive
 - ACO cannot require commercial payers to contract exclusively with the ACO

Mandatory antitrust agency review

- If an ACO's share in *any* common service exceeds 50% -- cannot participate in MSSP unless
 - it obtains favorable DOJ/FTC letter; or
 - ACO meets rural exception
 - Note – one service >50% triggers mandatory review
- Agencies will conduct expedited 90-day review
 - Specific list of information sought
 - ACO can explain why higher shares should not be a concern
- Agency will indicate either
 - No present intent to challenge (perhaps conditioned on making certain changes); or
 - Would likely challenge

Information requested for mandatory review

- Application to CMS and all supporting documents
- Documents related to
 - ability of ACO Participants to compete with the ACO either individually or through other ACOs or entities
 - Any financial or other incentives to encourage ACO participants to contract with CMS or commercial payers through the ACO
- Documents discussing
 - the ACO's business strategies to compete in Medicare and commercial markets
 - the ACO's likely impact on prices, cost or quality for Medicare or commercial payers
- Documents showing formation of any ACO or ACO Participant after 3/23/2010

Information requested, *cont'd*

- Information sufficient to show:
 - ACO's PSA share calculations for each common service for Medicare, and for commercial customers where significantly different (e.g. for pediatric or obstetric services)
 - Restrictions that prevent ACO participants from obtaining information regarding prices that other ACO participants charge commercial plans that do not contract through the ACO
 - Identity, including point of contact, of five largest commercial health plans for the ACO's services
 - Identity of other existing or planned ACOs in any PSA in which the ACO will provide services

Options for ACOs that fall between safety zone and mandatory review

- Two options:
 - Seek voluntary agency review
 - Rely on advice of counsel
- Five types of conduct to avoid in order to lower antitrust concerns
 1. Preventing efforts by payers to steer patients
 2. Tying – e.g. requiring payer to contract for all hospitals in a network
 3. Contracting with non-primary care physicians on an exclusive basis
 4. Restricting payers from making cost, quality, efficiency and other information available
 5. Participants sharing competitively sensitive information on services provided outside the ACO

ACO review by FTC or DOJ: a summary

	Market Share	Considerations	Exceptions
Safety Zone (no required review by FTC/DOJ)	For <u>every</u> common service, must have ≤30% combined share in <u>each</u> participant's PSA	<ul style="list-style-type: none"> •Participants with >50% share must be non-exclusive (no exclusive relationship with the ACO or commercial payers) •Every hospital or ASC must be non-exclusive (regardless of share) 	<p><u>Rural Participant</u>: may include 1 physician per rural county even if >30% (but must be non-exclusive)</p> <p><u>Rural Hospital</u>: may include rural hospitals even if >30% (but must be non-exclusive)</p>
Optional Review (can request expedited 90-day review)	Outside the safety zone but no mandatory review required (can seek voluntary agency review)	Avoiding the following can reduce risk of antitrust investigation: <ul style="list-style-type: none"> -Preventing efforts by payers to steer patients -Tying sales of ACO services to commercial plans to purchase of other provider services -Contracting with non-PCPs on exclusive basis -Restricting payers from making cost, quality, efficiency & other info available -Sharing competitively sensitive information 	
Mandatory Review (90-day expedited)	If for <u>any</u> common service, >50% combined share in <u>any</u> ACO participant's PSA	<ul style="list-style-type: none"> -ACO given opportunity to explain why higher shares are not problematic -Agencies seek specific information (including documents related to compensation, business strategies/plans) -Concerns reduced if ACO avoids 5 types of conduct outlined in optional review 	ACOs that qualify for rural exception

Observations

- More clarity on how to get to Rule of Reason
 - Automatic for CMS-approved ACOs
 - Much more fulsome examples of what a CI program looks like
- Focus will switch to market power concerns
- Antitrust guidelines
 - *Few* ACOs will meet safety zone requirements
 - *Many* will trigger mandatory review
 - Will require substantial effort to meet agency information request
 - Not clear if agencies will be able to evaluate in a timely basis
- Will antitrust outcome depend on which agency reviews?
- To get agency clearance, most ACOs will:
 - Need to be non-exclusive
 - Avoid five types of conduct identified by the agencies, and perhaps agree to other conduct remedies
- Unprecedented “regulatory” approach by *enforcement* agencies

Fraud and Abuse Waivers



Fraud and abuse waivers

- Joint CMS and Office of Inspector General (OIG)–HHS “Notice” with comment period published in Federal Register April 7, 2011
 - Outlines two narrow “waivers” of fraud and abuse laws
 - Distribution of MSSP payments from CMS
 - Referral sources within ACO generally protected
 - Referral sources outside of ACO only protected for “activities necessary for and directly related to” participation in the MSSP
 - Any other financial relationship for “activities necessary for and directly related to” participation in the MSSP
 - Only Stark-compliant financial arrangements protected
 - Acknowledges agencies remain in a fact-finding mode
 - Lists 7 additional types of arrangements that agencies recognize may also need to be protected by waivers
 - Solicits additional comment and information on each

Fraud and abuse waivers (*cont'd*)

- Statutory authority for waivers:

“The Secretary may waive such requirements of [anti-kickback (AKS), Stark and civil monetary penalty (CMP)] as may be necessary to carry out the provisions of this section.”

Social Security Act (SSA) sec. 1899(f)

- Similar authority conferred for demonstration and pilot projects of new CMS Center for Innovation

- Policy problem:

- Agencies skeptical of ACO participant motives have over-read narrowness of statute
- Ignore permissiveness of statute and focus instead on perceived need for proof that waivers are “necessary” and “directly related” to achieving ACO functions

Fraud and abuse waivers (*cont'd*)

- Agencies claim to be constrained by concerns for uncontrolled risk of fraud and abuse under guise of ACO formation and operation
- List Includes:
 - Overutilization in fee-for-service reimbursements
 - Stinting or steering
 - “Cherry picking”
 - “Lemon dropping”
 - Swapping
 - Gaming outcomes and data

Fraud and abuse waivers (*cont'd*)

- Stark law (one proposed waiver / scope limited)
 - Essentially would protect the distribution of shared savings to ACO participants from any Stark law liability
 - Would protect distribution of shared savings to non-participants only if it was for activities necessary and directly related to the ACO's participation in the MSSP
 - Any other waivers would be limited to the shared savings program funds and will not cover financial relationships created through sharing of other funds
- Federal Anti-Kickback Statute (two proposed waivers / scope limited)
 - First waiver would protect the distribution of MSSP savings to ACO participants *and* to non-participants for activities necessary and directly related to the ACO's participation in the MSSP
 - Second waiver would provide that any financial arrangement necessary to the operation of the ACO in the MSSP that implicates the Stark law but fits squarely within a Stark law exception would be deemed compliant with the AKS

Fraud and abuse waivers (*cont'd*)

- Gainsharing CMP (2 proposed waivers)
 - Applies to situations where the shared savings distribution are made from a hospital to a physician; and
 - (a) the payments are not knowingly made to induce a physician to reduce or limit *medically necessary* items or services; *and*
 - (b) the hospital and physician are ACO Participants or ACO providers/suppliers or were during the year in which the shared savings were earned by the ACO
 - Any financial relationship between or among the ACO participants necessary for and directly related to the ACO's participation in the MSSP that implicates the Stark law and fully complies with a Stark law regulatory exception

Observations

- Only ACOs that have executed (and are in compliance with) an agreement with CMS to participate in the MSSP are eligible for the waivers
 - Appears inconsistent with recognition that MSSP is to be an incubator for broader reinvention of structures to deliver health care for all
- Failure to credit overlapping structures within the ACO program that CMS designed to guard against the same risks
 - Even within ACO construct—transparency, governance, disclosure
- Failure to address CMP prohibiting beneficiary inducements
 - Incentives to use of ACO participant providers/suppliers
 - Rewards for compliance with ACO treatment protocols
- Certainty of ACO program design could resolve many open issues
 - Retrospective assignment versus prospective assignment

Tax-Exempt Considerations

IRS Notice 2011-20 (Issued March 31, 2011)



Tax-exempt considerations

- Notice 2011-20 addressed two issues of concern for tax-exempt organizations:
 - Whether participation in an ACO will compromise 501(c)(3) status
 - Whether MSSP payments would result in unrelated business income tax (UBIT)

Maintaining 501(c)(3) status

- A tax-exempt organization will maintain 501(c)(3) status if it operates for a charitable purpose and avoids private inurement and private benefit
 - Charitable purpose includes lessening burdens of government and promoting health
- Although Internal Revenue Service (IRS) will evaluate each ACO on a case-by-case basis, a tax-exempt organization generally will maintain 501(c)(3) status if ACO participants observe the following rules:
 - Terms of tax-exempt member's participation are set forth in advance in a written agreement negotiated at arm's length
 - The ACO is participating in the MSSP with CMS oversight
 - Tax-exempt organization's share of economic benefits is proportional to its ACO contribution
 - If organization receives ownership interest in an ACO, the ownership interest is proportional to its capital contribution to the ACO
 - Returns of capital, allocations, and distributions are made in proportion to ownership interests
 - Tax-exempt organization's share of ACO's losses does not exceed the share of ACO economic benefits to which it is entitled
 - Contracts/transactions between an ACO and a tax-exempt organization are at fair market value

Avoiding UBIT

- UBIT is defined by Internal Revenue Code (IRC) § 512 as:
 - Gross income derived by a tax-exempt organization from an unrelated trade or business, regularly carried on, and not substantially related to the accomplishment of the organization's charitable purpose
- A tax-exempt organization will not generate UBIT from MSSP payments received through an ACO if:
 - An ACO meets all the eligibility requirements established by CMS for participation in the MSSP, and
 - The tax-exempt organization avoids private inurement and private benefit
- If the above criteria are met, any MSSP payments received by a tax-exempt organization from an ACO would be deemed to be derived from activities that are substantially related to the performance of the organization's charitable purpose
 - An ACO reduces the government's burden in providing Medicare benefits and thus advances the charitable purpose of lessening burdens of government

Outstanding issues

- What additional guidance, if any, is necessary to facilitate participation by a tax-exempt organization in the MSSP through ACOs
- Whether and under what circumstances a tax-exempt organization's participation in non-MSSP activities through an ACO will be consistent with the organization's tax-exempt status or will not result in UBIT
- Whether the IRS will consider granting tax-exempt status to ACOs

Questions?



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