Antitrust Guidance for ACOs:

Understanding the Antitrust Enforcement Agencies' Final Policy Statement on Accountable Care Organizations

Wednesday, November 2, 2011 · 2:00-3:30 pm Eastern

This webinar is brought to you by the Antitrust Practice Group and the Accountable Care Organization Task Force (a joint endeavor of the Antitrust; Fraud and Abuse; Health Information and Technology; Healthcare Liability and Litigation; Hospitals and Health System; In-House Counsel; Labor and Employment; Life Sciences; Long Term Care, Senior Housing, In-Home Care, and Rehabilitation; Medical Staff, Credentialing, and Peer Review; Payors, Plans, and Managed Care; Physician Organizations; Regulation, Accreditation, and Payment; Tax and Finance; and Teaching Hospitals and Academic Medical Centers Practice Groups)

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Disclaimer

- Christine White's remarks reflect her own views and not necessarily those of the Commission or any Commissioner

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Overview

- Background
- Applicability of the Rule of Reason
- Safety zone
- Share calculations
- Outside the safety zone
- Voluntary review process
- Questions

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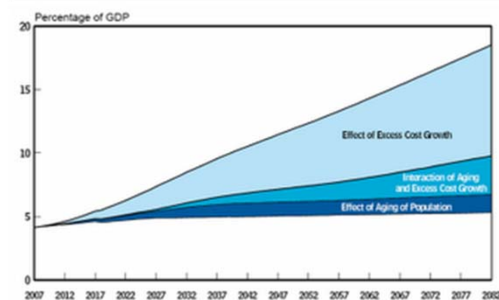
Background

- Why was the Policy Statement issued?
  - Medicare's Shared Savings Program
  - ACOs will operate in SSP and commercial market
  - Agency concern some ACOs will be anticompetitive



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Background

- Little case law on provider collaborations
  - *North Texas Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008)
- The FTC and DOJ have issued antitrust guidance in health care before:
  - Health Care Statements (1996)
  - Competitor Collaborations (2000)
  - Improving Health Care: A Dose of Competition
  - Merger Guidelines (2010)

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Background

- Proposed statement issued in March
  - Contained market power screens
  - ACOs > 50% shares were required to obtain FTC/DOJ review
- Comments received
  - AHLA member briefing (August 2011)
- Final Policy Statement issued October 20, 2011

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The Policy Statement

- Applies to:
  - All collaborations among otherwise independent providers that are eligible and intend, or have been approved, to participate in the SSP program
  - *Not* limited to collaborations formed after March 23, 2010
- Does not apply to:
  - Single integrated entities
  - Mergers and acquisitions

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Applicability of 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

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Applicability of 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

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Applicability of 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"

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Applicability of the Rule of Reason

- Sources of advice on clinical integration
  - 1996 “Statements of Antitrust Enforcement Policy in Health Care”
  - Letters, speeches
  - AHLA’s Clinical Integration Bibliography, available at: www.healthlawyers.org/Members/PracticeGroups/Antitrust/Pages/Bibliography.aspx

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Applicability of the Rule of Reason

- Financial integration well understood; clinical less so
- Policy Statement:
  - Greater certainty needed for ACOs
- Rule of reason treatment for ACOs that:
  - Comply with the CMS eligibility criteria for participation in SSP
  - Participate in SSP
  - Employ "the same governance and leadership structures and … clinical and administrative processes" in commercial business

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Applicability of the Rule of Reason

- So …
  - Qualifying ACO may jointly negotiate reimbursement terms with commercial payors without per se illegal price fixing
- *Are the standards going to change if the ACO withdraws from the SSP?*

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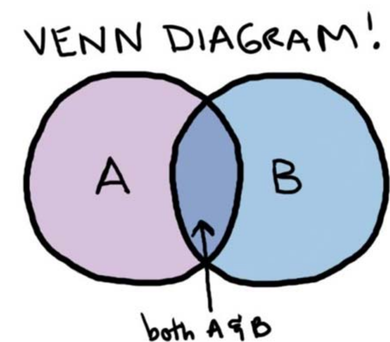
Safety zone

- 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



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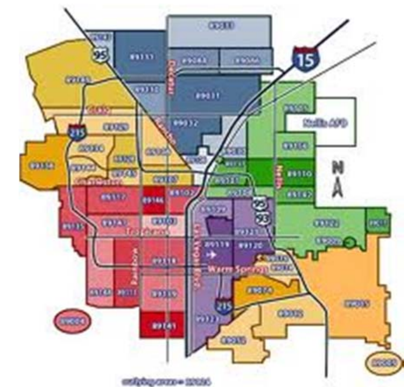
Safety zone

- 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



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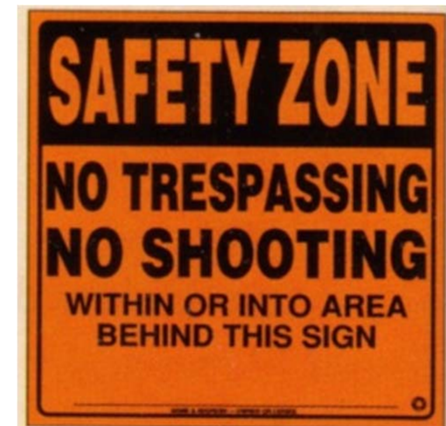
Safety zone

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



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Safety zone

- Hospitals and ASCs
  - Must be non-exclusive to fall within the safety zone
  - Regardless of number of hospitals/ASCs in area
- So, if a hospital participates on an exclusive basis:
  - The ACO doesn't fall within the safety zone
  - Not necessarily unlawful

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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

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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*
- *What if that group independently decides r participate in other ACOs?*

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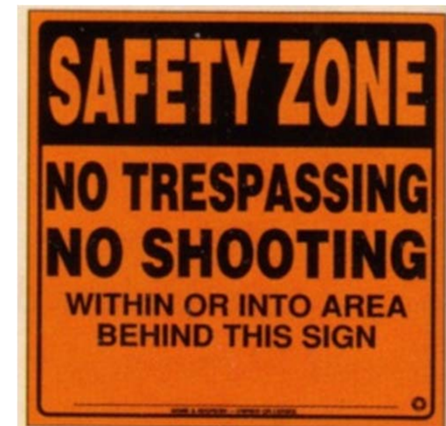
Safety zone

- *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
- *What if the ACO's number of patients increases?*
  - Doesn't matter



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Share calculations: Data

- Medicare Specialty Codes (physician)
  - 55 physician specialties
- Major Diagnostic Categories (inpatient)
  - 25 MDCs
- Ambulatory Patient Classifications (outpatient)

Share calculations

Mix of Small and Large Providers		Hospital A	Hospital B	Ancillary K	Ancillary L	Physician X	Physician Y	Total
		A - large, full-service		K - small, limited service		X - large, multi-specialty		
		B - mid-sized, limited service		L - small, limited service		Y - smaller, limited specialty		
	Inpatient Services (MDC)	MDCs 1 - 25	MDCs 1 - 12					
	Outpatient Services (OPS)	OPS 1 - 16	OPS 1 - 9	OPS 1 - 4	OPS 1			
	Physician Specialties (MSC)					MSCs 1 - 55	MSCs 1 - 10	
	Likely Number of PSAs and Share Calculations	**21**	**21**	**1**	**1**	**10**	**10**	**64**
All Large Providers		**Hospital A**	**Hospital B**	**Ancillary K**	**Ancillary L**	**Physician X**	**Physician Y**	**Total**
		A - large, full-service		K - large, multi-specialty		X- large, multi-specialty		
		B - large, full-service		L - large, multi-specialty		Y - large, multi-specialty		
	Inpatient Services (MDC)	MDCs 1 - 25	MDCs 1 - 25					
	Outpatient Services (OPS)	OPS 1 - 16	OPS 1 - 16	OPS 1 - 16	OPS 1 - 16			
	Physician Specialties (MSC)					MSCs 1 - 55	MSCs 1 - 55	
	Maximum Number of PSAs and Share Calculations	**41**	**41**	**16**	**16**	**55**	**55**	**224**

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Share calculations: MDCs

- MDC – Major Diagnostic Category
  - Groupings of major diseases or disorders
  - Each MDC typically includes dozens of DRGs
  - Individual services with MDCs are generally not substitutes, usually thought of as “cluster markets” in antitrust analysis
- Using MDC as a “common service”
  - Large enough to group dissimilar services
  - Small enough for subset of services to matter

Share calculations: Use of MDCs

- Some DRGs are low intensity, others tertiary
- Hospitals in ACO might not offer all DRGs
- Could have overlap at MDC level, possibly with high shares, but no overlap in DRGs that are driving the high shares

	MDC 5: Diseases & Disorders of Circulatory System	**High-Intensity DRGs (wgt.=5.3):** Cardiac valve, bypass, defib implant, other major surgery	**Lower-Intensity DRGs (wgt.=1.6):** Medical and minor surgical cardiac services
ACO Hospital A	2,759	1,758	1,001
ACO Hospital B	209	0	209
Other Hospital C	2,811	850	1,961
Other Hospital D	953	0	953
ACO A+B Share	**44.1%**	**67.4%**	**29.3%**

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Share calculations: PSA

- The PSA for each participant is defined as the lowest number of postal zip codes from which the ACO participant draws at least 75 percent of its patients for that service
  - Each common service as defined in Policy Statement
  - Recall discussion of MDC

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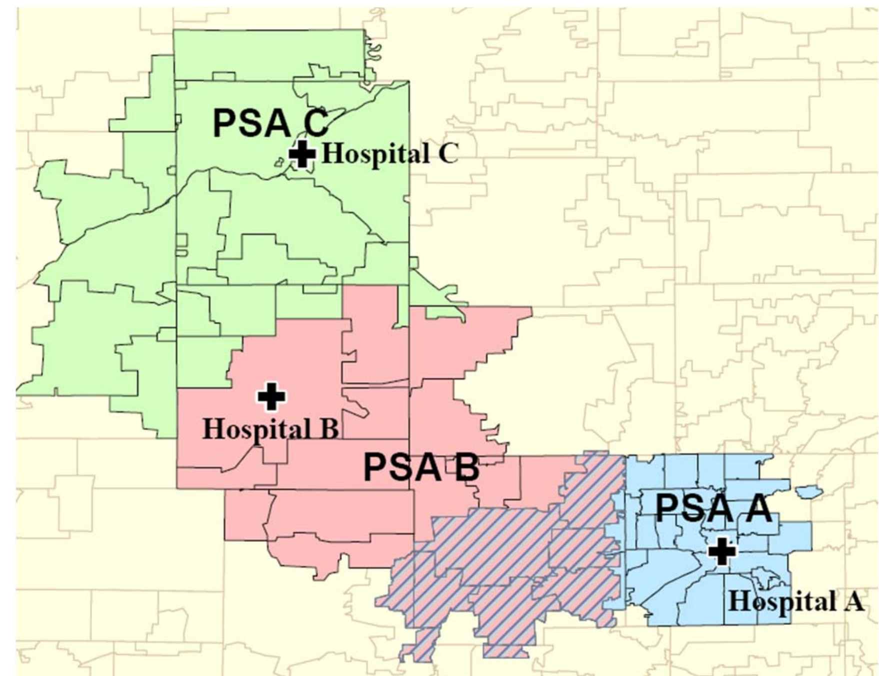
Share calculations: PSA shares

- Hypothetical PSAs of three hospitals for a single MDC
- PSAs might overlap, or be adjacent or even not touch each other
- Placement does not matter, but rather whether participants serve patients who reside in other PSA
  - A/B ACO obviously needs share calculation
  - B/C ACO may need share calculation also



Share calculations: PSA shares

- "[C]alculate the ACO's PSA share in the PSA of each participant that provides that service if at least two participants provide that service from that PSA."
- Shares for two-hospital (A/B) and three-hospital (A/B/C) ACOs
- Include entities affiliated with ACO participant even if the entities are not themselves participants (A/B(C))
  - May switch from inside safety zone to outside even though ACO participants did not change

		Hospital Discharges in MDC					ACO Shares		
	Zip Code	Hosp A	Hosp B	Hosp C	Other Hosp	Zip Total	A/B ACO	A/B/C ACO	A/B(C) ACO
Hosp A's PSA	99999	10	2	10	80	102			
	99998	20	4	10	80	114			
	99997	30	6	10	80	126			
	99996	40	8	10	80	138			
	99995	50	10	10	80	150			
		76.9%					**28.6%**	**36.5%**	**36.5%**
Hosp B's PSA	99994	2	10	0	100	112			
	99993	4	20	0	100	124			
	99992	6	30	0	100	136			
	99991	8	40	0	100	148			
	99990	10	50	0	100	160			
			75.0%				**26.5%**	**26.5%**	**26.5%**
Hosp C's PSA	99989	1	2	10	50	63			
	99988	2	3	20	50	75			
	99987	3	4	30	50	87			
	99986	4	5	40	50	99			
	99985	5	6	50	50	111			
				75.0%			--	**42.5%**	--
	99984	0	0	0	20	20			
	Total	195	200	200	1,170	1,765			

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Outside the safety zone

- Not necessarily illegal
- Conduct to avoid
  - Discouraging steering
  - Tying
  - Exclusive contracting with ACO participants
    - No exception for primary care physicians
  - Restricting payor’s ability to share cost, quality, efficiency, and performance information with enrollees
- All ACOs should avoid improper sharing of competitively sensitive information

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Outside the safety zone

- Final statement does not mandate review for any ACO
  - Proposed statement required review for ACOs if shares > 50%
  - Not in the final
- *What is the significance of a share greater than 50%?*

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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

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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”

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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

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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?*

Questions

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Questions

- Voluntary review process
  - *Can others see the application and response?*
  - *Can the agencies ask for more information?*
  - *Will the responses be consistent between agencies?*
- *Is a PSA the same as an antitrust relevant market?*
- *How will the agencies use PSAs in merger analysis?*

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Questions

- Data issues
  - *No Medicare data for obstetrics, pediatrics*
  - *Hospital outpatient departments and ambulatory surgery centers are reimbursed at different rates*
  - *Shares of providers with unusually high Medicare populations are not representative of shares of commercial payors (and possibly opposite)*
  - *Supplemental physician data – physicians located within PSA*