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Antitrust Battles in Two Parts: Attacking Meritless Litigation and Powerful Providers and Powerful Plans

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Part I: Attacking the Meritless Lawsuit -- A Case Study

- *RP Health Care, Inc. v. Pfizer,* Case No. SCV 251081 (Cal. Sup'r Ct. Jan. 31, 2012) (complaint)
  - Pharmacies filed antitrust lawsuit against Pfizer, Ranbaxy, Daiichi, Caremark, Blue Shield of California, and Health Net in California state court.
  - They alleged that
    - Pfizer and Ranbaxy conspired to delay generic Lipitor from entering the U.S. market.
    - Health Net conspired with Pfizer to boycott generic Lipitor by not reimbursing patients or their PBMs for generic Lipitor and requiring pharmacists to buy the higher-priced branded Lipitor.
      - Boycott allegedly fueled by large kickbacks to exclude generic Lipitor from their drug formularies.

Complaint without merit

- Allegations against Health Net were baseless.
  - Plaintiffs made bare allegations in the complaint that provided no specifics about Health Net's supposed involvement in the alleged conspiracy.
  - More importantly, the allegations were simply wrong.
- Facts are
  - Generic Lipitor is on Health Net's formularies and has been since it became available.
  - Health Net reimburses for generic Lipitor.

Facing the long slog

- The usual route:
  - File a demurrer
  - Deal with complaint amendments
  - Engage in discovery
  - File a motion for summary judgment
- The problem with the "usual" route was that it would take too long and be very expensive.
- We had to find another way.

Alternative path

- We decided to convince the plaintiffs to dismiss Health Net from the case, even before we filed a demurrer.
  - Carrot: Do the right thing.
  - Stick: Face sanctions for filing a meritless lawsuit without adequate investigation. Cal. Civ. Proc. Code § 128.7; Fed. R. Civ. P. 11.
- We conducted an internal investigation and compiled evidence that directly refuted the plaintiffs' allegations.

Factual background

- The evidence consisted of:
  - Health Net's formularies, which showed that Health Net added generic Lipitor to its formularies as soon as it was available and that generic Lipitor is on a higher tier than branded Lipitor.
  - Claims data on Health Net's reimbursement of generic Lipitor to the plaintiff pharmacies.
    - Claims data showed that Health Net has covered generic Lipitor since December 2011 – immediately after generic Lipitor came on the market on November 30, 2011 – and that Health Net-covered prescriptions for branded Lipitor shifted rapidly to the generic version.

Positive results

- Plaintiffs voluntarily dismissed Health Net from the lawsuit without any consideration (April 9, 2012).
  - We had a face-to-face meeting with the plaintiffs' counsel where we went through the evidence that we had compiled.
  - Plaintiffs then undertook an investigation of their own. For example, they wanted to verify our data in comparison to their own data.

Part II: Powerful providers and powerful plans - - Tough issues in health care antitrust

- Recent antitrust cases and agency guidance address not only mergers, but also alleged anticompetitive conduct exercising market power by providers and payors.
  - Bundled or conditional discounting;
  - Exclusionary reciprocal dealing
  - Most favored nation clauses
  - Anti-tiering or anti-steering provisions
- The issues can be more complex than for price fixing and boycotts that have been the focus of traditional antitrust enforcement.

Merger wars

- DOJ and FTC continue active enforcement
- *United States v. Humana Inc*.
  - Complaint challenges alleged anticompetitive impact in Medicare Advantage county markets of Humana acquisition of Arcadian Health Management. Case No. 1:12-cv-00464 (D.D.C. March 27, 2012)
  - Proposed final judgment would requires divestiture in 7 regions, per consent agreement
- *FTC v. OSF Healthcare System*, No. 11-C-50344 (N.D. Ill. April 5, 2012) (preliminary injunction order against hospital merger in Rockford, Illinois) (parties then called off transaction)
- *FTC v. Promedica Health System*, No. 3:11 CV 47 (N.D. Ohio March 29, 2011) (preliminary injunction against hospital merger in Toledo, Ohio area); *In Re Promedica Health System*, FTC Dkt. 9346 (March 28, 2012) (opinion) (final order, subject to appeal)

Hospital pricing allegedly used as lever to exclude competition

- Courts and enforcers working to develop tools to distinguish aggressive price competition from exclusionary anticompetitive practices.
- *PeaceHealth* litigation in 9th Circuit a few years ago focused attention on bundled pricing by hospital linking sale of all its services to sale of tertiary services only it offered in local market area. *Cascade Health Solutions v. PeaceHealth, 515 F.3d 883 (9th Cir.* 2008).
- New DOJ enforcement action focuses on discounting conditioned on exclusion of competing hospital from managed care network.

United States v. United Regional Health System

- United States and Texas AG accuse United Regional Health System of monopolizing markets for general acute-care inpatient hospital services and outpatient surgical services sold to commercial health insurers in the Wichita Falls area. Complaint, Case No.: 7:11-cv-00030 (N.D. Tex. 2/25/2011).
- Final judgment imposes constraints on hospital (9/29/2011).

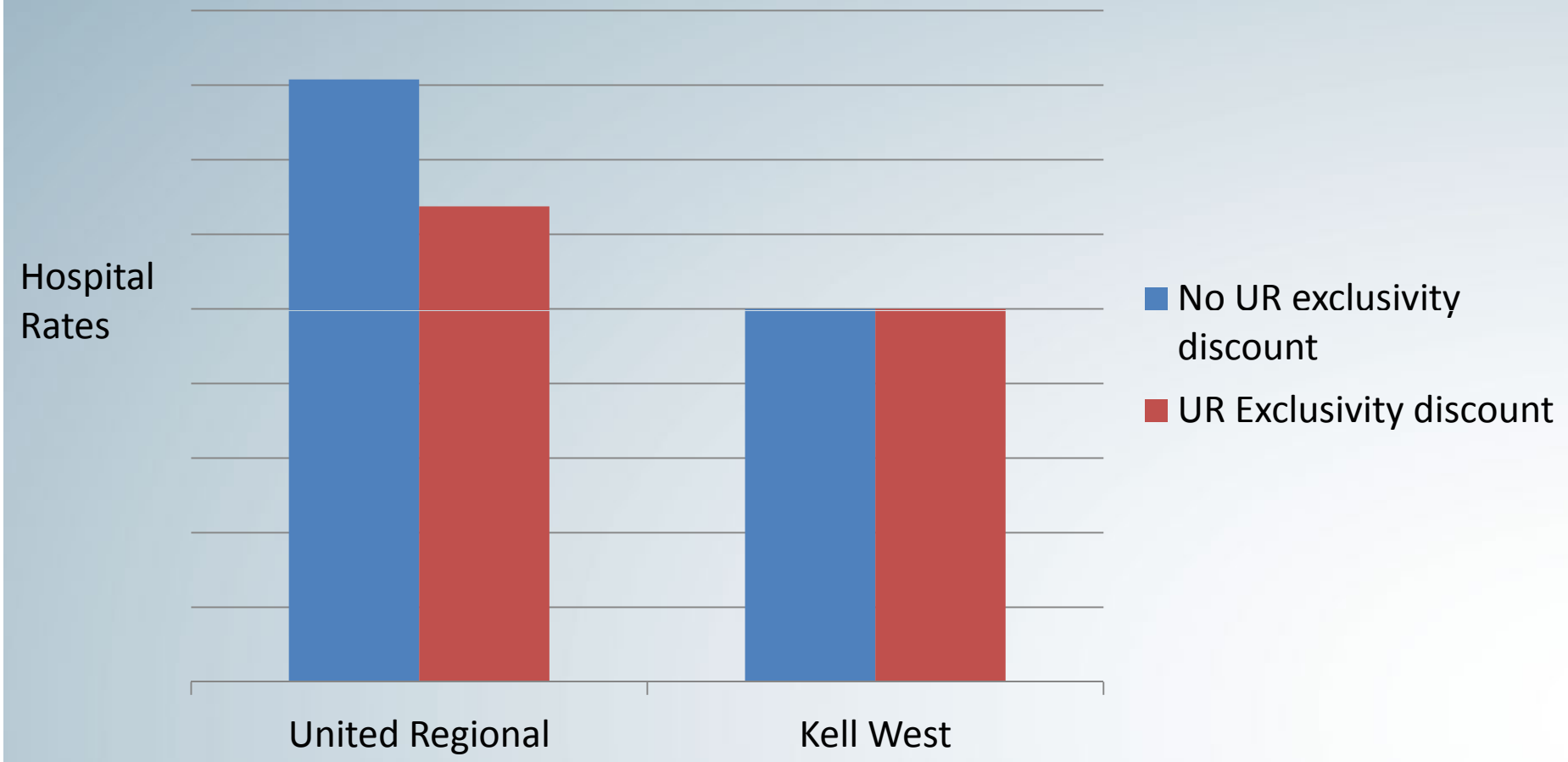
Allegations of monopoly power

- United Regional formed in 1997 by merger of two hospitals; no other acute-care hospitals in metropolitan area at the time.
- Merger had antitrust exemption via Texas Legislature.
- 369-bed hospital with trauma, cardiac, and neonatal care services that make it a “must have” hospital for insurers.
- Provides 90 percent of inpatient hospital services and 65 percent of outpatient surgical services in Wichita Falls area.
- Competitors are Kell West Regional Hospital , a 41-bed acute care hospital that opened shortly after the merger, and an ambulatory surgery center.
- DOJ claims United Regional is one of the most expensive hospitals in Texas, with rates 70 percent higher than Kell West’s.

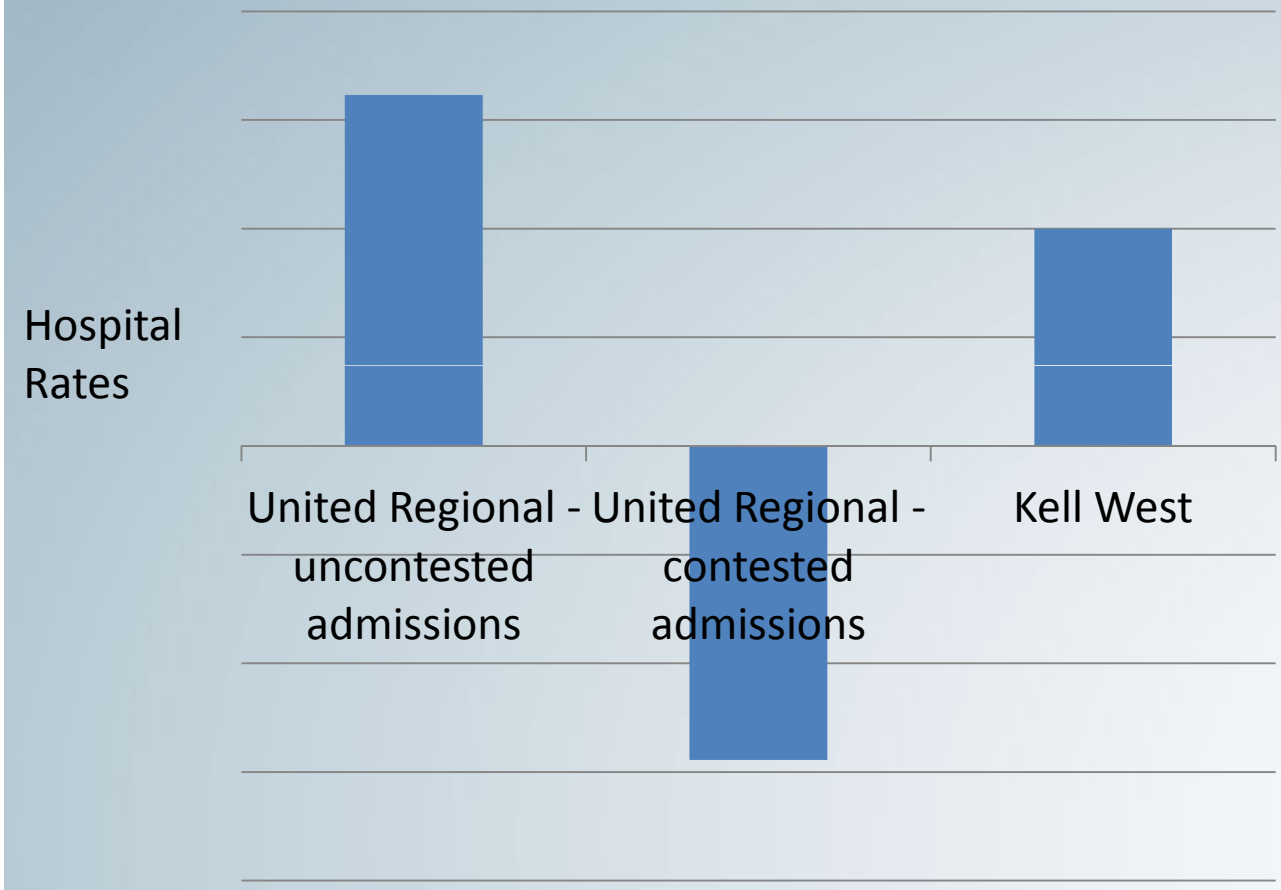
United Regional – challenged conduct

- "Discounts" (up to 25%) off billed charges, but if insurer contracts with a competing facility, discount falls to 5%.
- Provisions adopted within three months of Kell West opening.
- Attributing value of the discount difference across all United Regional patients to the rates for patients that might otherwise have gone to Kell West, the net rates for these "contested" patients would not even cover United Regional's marginal cost
  - Equally efficient competitor could not conceivably compete for payor business
  - Alternative framing is that the 5% discount is not a bona fide alternative. United River was effectively requiring exclusivity as a condition of doing business, knowing payors could not accept the alternate proposal.
- Apart from BCBS Texas, "not one insurer opted for the non-exclusive rate for more than twelve years." BCBS Tennessee premiums in Wichita Falls are higher than other payors.

Unallocated discount illustration



Allocated discount illustration



Ratios used are for illustrative purposes only.

United Regional -- remedy

- May not condition any insurer's contract or rates on it not contracting with a competitor.
- May not refuse to contract, terminate a contract, or discriminate in contracting terms because an insurer contracts with a competing provider.
- May not contract on conditional volume discount basis, except for certain permitted "incremental" volume discounts
- May not bar insurers from encouraging use of other providers
- May offer "incremental volume discount" where ratio of rates applicable after threshold volume is achieved, divided by billed charges, exceeds the hospital's cost to charge ratio in its Medicare cost report.
- Note: Allegations dependent on monopoly power; remedy includes "fencing in" language premised on defendant having crossed the line

Possible risk for payors

- United Regional suit brought only against hospital as Sherman Act §2 monopolization claim.
- Private plaintiff in similar suit could conceivably bring suit on Sherman Act §1 conspiracy/agreement theory, and bring payors into the case.
  - Note that DOJ MFN suit in Michigan claims that plan's agreements with hospitals violated §1, which implies hospitals were co-conspirators with plan dominant party insisting on restrictive language.
- Some parallels to cases where new entrant hospital or surgi-center claims that payor(s) conspired with dominant hospital or each other to exclude new entrant provider. See *Heartland Surgical Specialty Hospital LLC v. Midwest Division Inc.,* 527 F.2d 1257 (D.Kan. 2007).

West Penn Allegheny v. UPMC and Highmark

WEST PENN ALLEGHENY HEALTH SYSTEM

vs.

UPMC LIFE CHANGING MEDICINE

HIGHMARK.

Powerful hospital + powerful plan

- West Penn Allegheny Health System sued Highmark, dominant insurer in Pittsburgh area, and University of Pittsburgh Medical Center, the leading health system, for conspiracy --
  - UPMC to use its power to protect Highmark by refusing to contract with other insurers and gutting its own competing health plan;
  - Highmark by paying artificially depressed rates to Allegheny, removing its own "low cost" health plan from the market, charging high rates to cover high costs at UPMC and take other anti-Allegheny acts.
- Court of appeals reversed dismissal. *West Penn Allegheny Health System v. UPMC*, No. 09-4468 (3d Cir. 2010).
  - Even if premiums were lower on short run, scheme could still result in "suboptimal output, reduced quality, allocative ineffiencies, and . . . higher prices for consumers in the long run."

Now: West Penn Allegheny becoming corporate affiliate of Highmark

vs.

Reversal of roles

- Highmark now acquiring West Penn, investing $475 million.
- UPMC initially announced it would refuse to contract with Highmark if it acquired West Penn and entered into new contracts with other payors.
- DOJ announced it would not challenge affiliation of Highmark and West Penn, finding it would actually "increase incentives of market participants to compete vigorously". http://www.justice.gov/opa/pr/2012/April/12-at-439.html

DOJ closing statement includes striking comment on long-term contracts

"Long-term contracts between dominant hospitals and insurers can dull their incentives to compete, leading to higher pries and fewer services. If a dominant hospital is guaranteed a predictable revenue stream for many years from a dominant insurer, then the hospital may less likely to promote the growth of new insurers by offering them competitive rates. Similarly, if a dominant health insurer is guaranteed rates from a dominant hospital for an extended period, then the insurer may be less likely to promote competition in the hospital market by investing in more affordable hospitals. Contracts with shorter terms can provide significant benefits, while at the same time encouraging dominant hospitals to promote competition among hospitals. The foreseeable expiration of the contracts increases the need for both the dominant hospital and the insurer to have alternatives to their dominant counterparts."

Empirically based?

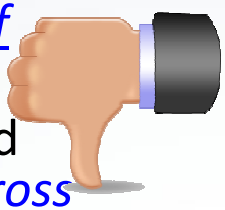
- Is DOJ statement based on evidence?
- Couldn't short term contract between dominant insurer and dominant hospital also discourage plan and hospital from rocking the boat by giving attactive terms to smaller players?

"Most favored nation" clauses

- Provider promises insurer to give it best price given to any other insurer or an even better price.
- Government concern -- May drive up prices to smaller competitors when imposed by dominant insurer
- Justifications
  - Helps assure that insurer is paying no more than market price;
  - May help insurer's customers reduce shopping time by assuring that insurer's provider discounts are competitive.
- DOJ has sued BCBS Michigan, and other opened other MFN investigations, but not clear if any other DOJ challenges will be brought.
  - Highlights fact-specific issues regarding MFN impact.

"Most favored nation" clauses

- DOJ and Michigan AG sued BCBS Michigan for anticompetitive use of MFN terms. United States v. Blue Cross Blue Shield of Michigan, Civ. Act. 2:10-cv-15155-DPH-MKM (E.D.Mich. Feb. 18, 2010)
  - BCBSMI allegedly has 60% or higher market share
  - In many cases, allegedly required up to 40% differential between BCBSMI rates and rates to other payers
  - Traded higher prices for MFN "protection from competition"
  - BCBSMI reports "medical cost advantage, delivered primarily through its facility discounts, is its largest source of competitive advantage"
  - Per DOJ, differences in reimbursement methods can cause uncertainty for hospital comparing payor rates, so hospitals may contract with other plans at higher prices to avoid being penalized if audited for MFN compliance.
- District court denied motion to dismiss. *U.S. v. Blue Cross Blue Shield of Michigan*, No. 10-14155 (E.D. Mich. Aug. 12, 2011).
- City of Pontiac's follow on suit dismissed for failure to adequately plead sufficient facts under antitrust rule of reason. *City of Pontiac v. Blue Cross Blue Shielf of Michigan*, No. 11-10276 (E.D. Mich. March 30, 2012).
- Aetna has now filed its own antitrust suit. *Aetna, Inc. v. Blue Cross Blue Shield of Michigan*, No. 2:11-cv-15346 (E.D. Mich. Dec. 6, 2011).



Accountable Care Organizations ("ACOs")

- Health reform law provides for provider-sponsored ACOs in Shared Savings Program ("SSP") under fee for service Medicare program.
- CMS originally proposed antitrust pre-screening mechanism to deny participation to ACOs hitting antitrust risk threshold that do not get favorable advance review from FTC or DOJ.
- FTC and DOJ proposed new policy guidance.
- CMS final rule abandons mandatory prior antitrust review. 76 *Fed. Reg.* 67,806 (Nov. 2, 2011).
- Antitrust agencies issue revised final guidance, including new "safety zone" -- *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,* 76 *Fed. Reg.* 67,026 (Oct. 28 , 2011).
- CMS will give antitrust agencies aggregate claims data on allowed charges and fee-for-service payments for ACOs accepted into the SSP and copies of SSP applications of ACOs formed after March 23, 2010.

New FTC-DOJ enforcement policy on ACOs

- FTC-DOJ guidance applies to all Medicare ACOs, including those that wish to contract with commercial payers, regardless of date of formation.
- New "safety zone" for ACOs meeting specific standards.
- Safety zone applicability tied to provider membership relative to provider participation thresholds in defined "Primary Service Areas" ("PSAs").

Antitrust Issues – Clinical Integration

- Prior antitrust guidance indicated that providers could avoid application of "*per se*" rule against price-fixing for joint negotiations with payers if they are (1) financially integrated via risk sharing or (2) clinically integrated and price negotiation by the provider network is reasonably necessary for venture to work.
  - Under 1996 policy statement, clinical integration is shown by implementing an ongoing program to evaluate and modify practice patterns by provider participants and creating a high degree of interdependence and cooperation among providers to control costs and ensure quality.
- New Enforcement Policy confirms that satisfaction of CMS's requirements to be an ACO under the SSP would be sufficient to defeat *per se* pricing treatment of joint price negotiations by the ACO with commercial payers:
  - [I]f a CMS-approved ACO provides the same or essentially the same services in the commercial market, . . . [t]he [CMS] integration criteria are sufficiently rigorous that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO's primary purpose of improving health care services. . . . [T]he Agencies 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.

New "Safety Zone"

- The Agencies will not challenge Medicare ACOs that fall within a new "safety zone," absent extraordinary circumstances.
- To qualify, every independent ACO participant (e.g., *each* physician group, individual practitioner, or hospital) that provides the same service ("common service") must have a combined share of 30% or less of each common service in each participant's Primary Service Area, wherever two or more ACO participants provide that service to patients from that PSA.
  - PSA is the "lowest number of postal zip codes from which the [ACO participant] draws at least 75 percent of its patients" for the particular service being measured
  - PSA to be score separately for each independent provider in ACO

New "Safety Zone"

- Hospitals and ambulatory surgery centers must be "non-exclusive" to the ACO to be in the safety zone, regardless of PSA share.
  - To be non-exclusive, the provider must be allowed to contract individually or affiliate with other ACOs or commercial payers.
  - Exclusivity will be assessed based on practical realities, rather than simply by nominal phrasing of organizational documents or contracts.
- "Dominant provider limitation" if an individual provider in the ACO has a share in a PSA greater than 50% of any service that no other ACO participant provides to patients in the PSA.
  - Where the limitation applies, the provider must be non-exclusive to the ACO in order to qualify for the safety zone.
- Rural exception permits inclusion of one physician or group in any specialty regardless of share.

Determining PSA share levels

- To perform the PSA calculations, an ACO must: (1) identify each service provided by two or more independent ACO participants; (2) collect patient zip code data from those participants; (3) collect coding or billing data from those participants (which may or may not be in the same computer file as the zip code data); and (4) match the zip codes to the Medicare Specialty Codes ("MSCs") (in the case of physicians), outpatient treatment categories (in the case of outpatient facilities), or Major Diagnostic Categories ("MDCs") (in the case of hospitals).

- Then the ACO must match Medicare fee-for-service allowed charges (physicians), Medicare fee-for-service payments (outpatient facilities), or inpatient discharges (hospitals) to the zip codes and specialty codes or categories.

Suspect behavior?

- Agencies flag four types of conduct that may be OK, but where present could raise potential competition concerns:
  - Use of ‘‘anti-steering,’’ ‘‘anti-tiering,’’ ‘‘guaranteed inclusion,’’ ‘‘most-favored-nation,’’ or similar clauses to discourage payers from directing or incentivizing patients to choose certain providers
  - Tying, expressly or via pricing policies, ACO’s services to payer’s purchase of other services from providers outside the ACO venture (and vice versa)
  - Contracting on an exclusive basis with providers
  - Restricting a payer’s ability to make cost, quality, efficiency, and performance information available to enrollees, if it is similar to information used in Medicare Shared Savings Program
- When might any of these restrictions itself be an antitrust violation if employed by a powerful provider organization?

Review process

- Agencies will provide process for expedited voluntary requests for review.
- For ACOs that do not qualify for safety zone, agencies will consider a range of information suggesting that PSA shares may not reflect actual market power.
- They will also consider pro-competitive justifications.