Compliance as a Quality of Care Metric

Transition toward Quality of Care-driven Delivery/Payment System

Fee-for-Service System
### New Models of Care

- Group of providers that is jointly responsible for the quality and cost of healthcare services for a population of patients
- Combination of one or more hospitals, physician groups (primary care and specialty), and other providers
- Financial incentives to meet quality benchmarks or cost-savings
- Shared governance structure
- Formal legal structure that allows organization to receive and distribute payments for shared savings to participating providers
- Leadership and management structure that includes clinical and administrative systems
New Models of Care

- Model of Care that includes:
  - personal physicians
  - whole person orientation
  - coordinated and integrated care
  - safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements
  - expanded access to care; and
  - payment that recognizes added value from additional components of patient-centered care

Medicare Shared Savings Program

- The Medicare Shared Savings Program (MSSP) was created to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce unnecessary costs.
- Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating or participating in an Accountable Care Organization (ACO).
- The Shared Savings Program is designed to improve beneficiary outcomes and increase value of care by:
  - Promoting accountability for the care of Medicare FFS beneficiaries
  - Requiring coordinated care for all services provided under Medicare FFS
  - Encouraging investment in infrastructure and redesigned care processes
- The Shared Savings Program will reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care and putting patients first.

Medicare Shared Savings Program

- ACO: Groups of providers, organized as a separate legal entity, who work together to manage and coordinate care for Medicare FFS beneficiaries (called an Accountable Care Organization).
- Entities eligible to form ACOs:
  - ACO Professionals (MD, PA, NP, CNS) in group practices
  - Networks of individual practices of ACO Professionals
  - ACO Professional/Hospital Joint Ventures
  - Hospitals employing ACO Professionals
  - Certain CAH
  - FQHCs and RHCs
- Primary Care Provider Participation
  - Cannot participate in more than one Medicare ACO
  - Each ACO participant TIN must be exclusive to one ACO
- Medicare Beneficiaries
  - Must serve at least 5,000 beneficiaries
ACO: Shared Savings Model

Payor

- ACO
  - Shared Savings
    - FFS
    - Human Services Agency
    - Behavioral Health
    - Primary Care
    - Rehab and LTC
    - Distribution of Shared Savings
    - Specialty and Hospital Care

ACO: Full Risk Capitation Model

Payor

- ACO
  - Cap
    - Human Services Agencies
    - Behavioral Health
    - Primary Care
    - Rehab and LTC
    - FFS
    - Profit Distribution
    - Specialty and Hospital Care

Compliance Risks under New Payment Models
Antitrust Laws

- **Purpose:** To promote competition and protect consumers
- **Maxim:** Antitrust laws protect competition, not competitors
- **1972:** “Antitrust laws...are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms.” United States v. Topco Assoc.
- **1975:** Supreme Court decides that antitrust laws apply to “learned professions”. Goldfarb v. Virginia State Bar.
- **1982:** Supreme Court applies antitrust laws to physicians. Arizona v. Maricopa County Medical Society.

The Sherman Act

- **Section 1** – Forbids contracts, combinations and conspiracies in restraint of trade
  - “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal.”
  - Supreme Court – Section 1 only prohibits “unreasonable” restraints
  - No exemption for non-profits
  - Requires agreement (collusion) – does not apply to unilateral action by a single firm
  - Generally state laws mirror Sherman Act

Per Se Violations

- Conduct deemed so pernicious and plainly anticompetitive that it is condemned “without elaborate inquiry” as to the precise harm caused or business excuse for its use
  - Actual harm to competition or participants’ intent irrelevant
- Per se violations: Price fixing, market allocation, boycotts, certain “tie-in” arrangements
- Enforcement
  - Criminal: DOJ
  - Civil penalties: DOJ, FTC, and private parties
Price Fixing

- Price as the “central nervous system” of a competitive economy
- Executives go to jail for price fixing, large corporate fines
- Agreements between or among competitors on prices or price-related terms
- Agreement can be “a wink and a nod”

Market Allocation

- Agreement between or among competitors to divide customers or territories
- Like price fixing, a *per se* violation if it is a “naked” restraint
- Examples:
  - “If you stay out of dental, I’ll stay out of behavioral health”
  - “I won’t open a health center on the east side if you don’t open one on the west side”

Rule of Reason

- Applies to all conduct not covered by the *per se* rule
- Requires weighing of anticompetitive and pro-competitive effects of the conduct
  - Factors include market definition, market share, barriers to entry, efficiency considerations
  - Bottom line is net impact on competition
- Permits “ancillary restraints” reasonably related to procompetitive ventures
  - Example: price agreements related to legitimate joint ventures
Provider Networks

- Major antitrust issue is collusion (price fixing, boycott) in collective negotiations with payors
- Concern is that provider networks will use market power to increase rates, driving up costs for payors, and ultimately, for consumers
- Mixed messages
  
  “If you fix prices— that is, if independent doctors jointly negotiate the fees they charge— we will make you stop. But if you join together to improve patient care and lower costs, not only will we leave you alone, we’ll applaud you.”
  
  - FTC Chairman Jon Leibowitz (June 14, 2010)

Antitrust “Safety Zone”

FTC/DOJ Statements of Antitrust Enforcement in Health Care

- Statement 8 - Creates “safety zone” for provider networks that allows a network to negotiate and contract with third parties as a single entity on behalf of its participants and to engage in other activities typically considered anti-competitive, if the participants are sufficiently integrated.

  - Financial Integration: substantial financial risk sharing by network participants in providing all the services that are jointly priced through the network
  
  - Capitation, percentage of premium, or significant financial incentives

- Market Share Limitations
  
  - If the collaboration is not exclusive, it must be comprised of no more than 30% of the primary care or specialty physicians in the relevant market.
  
  - If the collaboration is exclusive, it must be comprised of no more than 20% of the primary care or specialty physicians for the relevant market.

Clinical Integration

- Conduct outside safety zone may still be permissible under the antitrust laws.

- “Rule of Reason” test applies to determine whether providers’ integration through the network is likely to produce significant efficiencies that benefit consumers and
  
  the price agreements by the network physicians are reasonably necessary to
  
  realize those efficiencies.

- Clinical Integration: Active and ongoing programs to evaluate and modify clinical practice patterns of all network providers
  
  - High degree of interdependence and cooperation among all network providers to control costs and ensure quality care
  
  - Share patient clinical information
  
  - Develop and implement practice protocols
  
  - Monitor performance to improve outcomes and control costs
  
  - Sanction for non-compliance

- FTC issues Advisory Opinions to guide organizations on clinical integration
Medicare Shared Savings Program

Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the MSSP (76 Fed. Reg. 67026)

- Applicable to collaborations among providers that seek to participate, or have been approved to participate, in the MSSP as well as any other ACO initiatives by CMS so long as those ACOs are substantially clinically or financially integrated.
- Creates a safety zone for ACOs that satisfy the criteria established by CMS for participation in the MSSP.
- Market Share Limitation: ACOs combined common service share in each participant’s Primary Service Area (PSA) must be 30% or less to qualify for the antitrust safety zone.
  - Hospitals and ambulatory surgery centers must participate on a non-exclusive basis.
  - Physicians can be exclusive to a particular ACO unless they fall within the Rural Exception or Dominant Participant Limitation.

Medicare Shared Savings Program

- ACOs with high PSA shares may nevertheless be procompetitive and lawful.
- "An ACO that does not impede the functioning of a competitive market will not raise competitive concerns."
- ACOs with high PSA shares should avoid:
  - Tying sales of the ACO’s services to the purchase by commercial payers of other services including services from providers outside of the ACO or providers affiliated with an ACO participant.
  - Contracting with ACO hospitals, ambulatory surgery centers, physician specialists other than primary care physicians, or other providers on an exclusive basis.
  - Restricting a commercial payer’s ability to provide cost, quality, efficiency, and performance information to aid health plan enrollees if such information is similar to the cost, quality, efficiency and performance measures used in the MSSP.
  - Sharing competitively sensitive data that an ACO’s provider participants could use to set prices or other terms for services they provide outside of the ACO.

Medicare Shared Savings Program

- Laws to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, and other harms
  - Stark (physician self-referral law)
  - Anti-kickback statute
  - Civil Monetary Penalties Law
- Stakeholders expressed concern that these laws impede development of innovative-care models envisioned by the Shared Savings Program (compensation to incentivize more efficient and effective care)
- CMS and OIG: Final Waivers Rule for Fraud and Abuse Laws - effective November 2, 2012
  - May narrow waivers for applicants entering the program after June 2013
* NOTE: Waivers are exclusive to the Shared Savings Program
Physician Self-Referral Prohibition (Stark Law)

- Stark: 42 U.S.C. § 1395nn
  - Prohibits a physician with a financial relationship with an entity from making a referral to that entity for "designated health services" paid for by a Federal health care program unless the relationship or service qualifies for a defined exception
  - Designated Health Service (DHS) include hospital services, lab services, radiology, durable medical equipment, outpatient drugs
  - No intent requirement; strict liability unless exception applies
- Potential ACO risks:
  - Compensation arrangements between a hospital and a physician group, such as sharing cost savings, would violate Stark (did not fit within original safe harbor exceptions)

Physician Self-Referral Prohibition (Stark Law)

- Shared Savings Distribution Waiver
  - Shared savings distribution must either be used for activities "reasonably related" to the purposes of the Shared Savings Program or distributed to or among the ACO's participants:
  - "Reasonably related"
    - Promoting accountability for the quality, cost and overall care for the Medicare population
    - Managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO
    - Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries
  - ACO has entered into a participation agreement and remains in good standing
  - If the shared savings distributions are made directly or indirectly by a hospital to a physician, the payments may not be made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the physician's direct care
  - However, does protect incentives to provide alternative and appropriate care

Federal Anti-Kickback Statute

- Prohibits persons and entities from knowingly or willingly
  - Soliciting or receiving remuneration directly or indirectly, in cash or in kind
  - To induce patient referrals or the purchase or lease of equipment, goods or services
  - Payable in whole or in part by a Federal health care program.
- Health Reform Law eliminates specific intent requirement
  - "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section."
- Financial arrangements (including capital investments and distributions) between referring providers are likely to implicate the Anti-Kickback Statute
### Federal Anti-Kickback Statute

- Violations of the statute can result in
  - Criminal liability
    - Felony conviction - $25K fine, imprisonment up to 5 years, or both
  - Civil penalties
    - Up to $50K fine and damages of 3x amount of remuneration
  - False Claims liability
    - Health Reform Law amended Anti-Kickback statute to codify FCA liability for claims resulting from violations of AKS
    - Administrative proceedings
      - Suspension or exclusion from participating in Federal health care programs

### Safe Harbors – arrangements deemed by Congress / HHS to present a low risk of fraud and abuse

- Examples:
  - Discounted arrangements
  - Employment arrangements
  - Personal services and management contracts
  - Waiver of co-insurance and deductible amounts
  - Sale of practice and investment interests
  - Group purchasing organizations
  - Other safe harbors specifically for HPSAs
  - Discounts to managed care organizations

- Series of favorable OIG Advisory Opinions on “gainsharing” in which a hospital rewards physicians for efforts to reduce costs

### Shared Savings Distribution Waiver

- Compliance with the Stark Law Waiver

  - Financial relationships between ACO participants are waived if various criteria are satisfied, including but not limited to the following:
    - ACO has entered into a participation agreement and remains in good standing
    - Complies with one of the Stark Law’s existing exceptions
    - Arrangement is “reasonably related” to the purposes of the Medicare Shared Savings Program

  - See slide 26
  - Both the arrangement and its authorization by the governing body are documented
Federal Anti-Kickback Statute

- Program Participation Waiver
  - Broad ability to exchange items, services, or facilities at a non fair market value basis
  - Similarities to shared savings distribution waiver
    - Remuneration (and overall arrangement) must be "reasonably related" to the program purposes
    - ACO must have entered into a participation agreement and remain in good standing
    - ACO must disclose the parties’ names on the ACO’s website

- Patient Incentives Waiver
  - Items or services provided by an ACO (or its participants) to Medicare beneficiaries for free or below fair-market value if various criteria are satisfied, including but not limited to the following:
    - ACO has entered into a participation agreement and remains in good standing
    - Arrangement is "reasonably related" to the purposes of the Medicare Shared Savings Program
  - See slide 26
  - Items and services are in-kind
  - Are preventive care items or services
  - Advance one or more of the following clinical goals:
    - Adherence to a treatment regime, drug regime, a follow-up care plan, or management of a chronic disease or condition
    - Examples: blood pressure monitors for hypertensive patients
  - Does NOT protect gifts to Medicare beneficiaries to induce them to remain in an ACO

Civil Monetary Penalties

- Gainsharing
  - Prohibits hospital payments to a physician to induce the physician to reduce or limit care to Medicare/Medicaid beneficiaries
    - Shared Savings Distribution Waiver
    - Compliance with Stark Law Waiver
    - Program Participation Waiver

- Beneficiary Inducements
  - Prohibits inducements to Medicare/Medicaid beneficiaries likely to influence the beneficiary’s choice or a provider
    - Patient Incentives Waiver
Questions?

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