Accountable Care Organizations

Implications Under Physician Self-Referral, Anti-Kickback, Civil Monetary Penalty and Antitrust Laws

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Medicare Accountable Care Organizations: Section 3022 of Affordable Care Act

Basic Requirements for ACO Participation

- Formal legal structure to receive and distribute shared savings
- Minimum of 5,000 assigned beneficiaries
- Sufficient number of primary care professionals and sufficient information on professionals for beneficiary assignment and payments
- Participation in program for at least three years
- Leadership and management structure (including clinical and administrative systems)
- Processes to promote evidence-based medicine
Qualification for Shared Savings

- Participating ACO must meet specified quality performance standards for each 12-month period

- Eligibility to receive share of any savings
  - Actual per capita expenditures of assigned Medicare beneficiaries must be sufficient percentage below specified benchmark

- Benchmark
  - Based on most recent three years of per-beneficiary expenditures for Part A and B service for Medicare fee-for-service beneficiaries assigned to ACO
What ACO Legal Issues Covered Today: Issues Within Jurisdiction of FTC, CMS and HHS OIG

- What ACO legal issues not covered today
  - Federal income tax exemption issues for tax-exempt hospitals
  - State law issues
  - Contract law/Contract enforceability issues
Civil Monetary Penalty Law (CMPL)

- Prohibits a hospital from knowingly making payments to a physician to induce reduction or limitation of services to Medicare or Medicaid Beneficiaries
Anti-Kickback Statute (AKS)

- Prohibits payment, or offer of payment, to induce referral of items/services covered by Medicare/Medicaid
Physician Self-Referral Law/Stark

- Physician prohibited from referral of Medicare/Medicaid patients for designated health services to an entity with which physician has a financial relationship unless the relationship falls within an exception.
ACOs Implicate CMPL, AKS and Stark

- Physicians in ACO paid share of any cost savings and based on quality performance standards
ACO Problem With CMPL, AKS and Stark

- No statutory or regulatory safe harbor or exception specific to ACOs
- Existing safe harbors/exceptions
  - Limited usefulness
CMPL/AKS

- OIG advisory opinions on gainsharing
- OIG will not impose sanctions if sufficient safeguards to ensure quality of care
Favorable Features of Advisory Opinions

- Current members of hospital's medical staff
- Participation by a group of at least five physicians
- Payment by hospital to group of physicians on an aggregate basis
- Payment by physician group to each physician on *per capita* basis
- Objective measurements for changes in quality
- Annual resetting of cost savings baselines
- Independent reviewer/auditor to review program prior to commencement and annually
- Cost sharing capped at 50% of cost savings
- Duration of program
  - No more than three years
- Written notice to patient prior to procedure
2008 Proposed Stark Exception for Incentive Payment and Shared Savings Programs

- Transparency
- Quality controls
- Safeguards against payment for patient referrals
Quality or Cost Savings Measures

- Objective methodology
- Verifiable
- Supported by credible medical evidence
Independent Medical Review

- Prior to implementation and annually
Physician Participation and Payment

- Only physicians currently on medical staff
- Pools of at least five physicians
- Payment to each physician on *per capita* basis
- Cap at 50% of cost savings
- Duration of 1-3 years
Cost Savings

- Savings measured from baseline standards
- Annual rebasing of quality standards
Quality of Care

- Must show actual improvement from baseline standard
- No payment if quality of care diminished
Documentation

- All documents available to Secretary upon request
- Notice/Disclosure to patients
Other Requirements

- In writing
- Compensation formula set in advance
- Not based on volume/value of referrals
- Minimum term of one year
Panelists for CMP/AKS/Stark

- Jeffrey Micklos, Esq. – Federation of American Hospitals
- Jonathan Diesenhaus, Esq. – American Hospital Association
- Tom Wilder, Esq. – Association of Health Insurance Plans
- Marcie Zakheim, Esq. – National Association of Community Health Centers
- Robert Saner, Esq. – Medical Group Management Association
- Ivy Baer, Esq. – Association of American Medical Colleges
- Chester Speed, Esq. – American Medical Group Association
- Jan Towers, Ph.D., CRNP, American Academy of Nurse Practitioners
- Nora Super - AARP
OIG/CMS Overview

- How Secretary should exercise waiver authority
- Safeguards needed under waiver
- Future: Beyond waiver authority, other exceptions/safe harbors
Dr. Berwick’s Triple A Objectives

- Better care for patients
- Better health for public generally
- Lower cost per capita
Will waiver positively affect ACOs and, if so, how?

If decide to exercise waiver authority, what needs to be included in waiver?
Assuming waiver authority is exercised, what else should HHS consider?
What types of providers and business arrangements should waiver cover?
What safeguards should be part of waiver?
Types of monitoring

Self monitoring

Government monitoring

What is the role of IT/EHR?
Legal Structure / Governance

- Should HHS dictate specifics regarding legal structure and governance?
Future: Beyond Waiver Authority

- What is working under current fraud and abuse laws and what can be used to build on?
Antitrust

- Prohibited Activities
  - Pricing fixing among competing providers
  - Division of geographic markets
  - Division of product markets
  - Mergers which may substantially lessen competition
  - Monopolization and attempted monopolization
Antitrust (cont’d)

- Illegal Group boycotts through wrongful or exclusionary means
- Sharing of confidential fee and other competitive information
Antitrust (cont’d)

- **Statutes**
  - Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1,2
  - Sections 7 of the Clayton Act, 15 U.S.C. § 18
  - State Antitrust Laws
Antitrust (cont’d)

- Guidance/Enforcement Policies
  - Statements of Antitrust Enforcement Policy in Health Care ("Statements")
  - Horizontal Merger Guidelines
Antitrust (cont’d)

- Enforcement Agencies
  - Department of Justice
  - Federal Trade Commission
  - State Attorneys General
Antitrust (cont’d)

- ACOs
  - Most ACOs will involve multiple independent providers
    - Hospitals
    - Physicians
    - AHPs
    - Medical Home
    - Surgicenters
    - Nursing Homes
Antitrust (cont’d)

- Under different arrangements
  - Employment
  - Independent Contracts
  - Multispecialty physician groups
  - Joint ventures
  - Co-management arrangements
Antitrust (cont’d)

- ACO Antitrust Issues
  - Price fixing among independent competitors in non-risk arrangements with private payors

Note:

- In Medicare/Medicaid arrangements where government unilaterally sets the price, there are no antitrust issues
- How are contracts being negotiated?
- Is ACO and its provider members at “financial risk” – capitation, bundled fees, global fees?
Antitrust (cont’d)

Has ACO achieved sufficient “clinical integration” to allow contract negotiations on behalf of all ACO members?

Will CMS/FTC/OIG view a certified ACO as a clinically integrated arrangement for antitrust purposes or “presumptively integrated”?

- Division of geographic and/or product markets
  - This conduct reduces competitors and consumer options and is likely to lessen competition and decrease quality
Antitrust (cont’d)

- Mergers, affiliations, acquisitions which may substantially lessen competition
  - The development of ACOs will likely trigger more consolidation activity among providers
  - Existing standards under Merger Guidelines and case law will clearly monitor resulting combinations within each strata of providers i.e., hospitals, physicians by specialty
  - FTC/DOJ will examine either before or after the fact if the ACO is exclusive and possesses market share beyond safety zone safe harbors (20% exclusive and 30% non-exclusive)
Antitrust (cont’d)

- Will CMS also be evaluating an ACO’s market power with FTC before certification is given?
- If smaller states are urging larger systems and groups to participate in ACOs, will this preempt federal intervention under state action doctrine if actively monitored by the state?

• Illegal group boycotts
  - Excluding access to ACO
  - Refusals to deal with payors
FTC Comments, Questions and Panel Responses
FTC Panelists

- Gloria Austin, Brown & Toland
- Terry Carroll, Fairview Health Services
- Dr. Lawrence Casalino, Weill Cornell Medical College
- Mary Jo Condon, St. Louis Area Business Health Coalition
- John Friend, Esq., TMC HealthCare
- Dr. Robert Galvin, Equity Healthcare
- Elizabeth Gilbertson, HEREIU Welfare Fund
- Douglas Hastings, Esq., Epstein, Becker Green

- Harold Miller, Center for Health Care Quality and Payment Reform
- Dr. Lee Sacks, Advocate Physician partners & Advocate Health Care
- Dr. Dana Safran, BC/BS Massachusetts
- Trudi Trysla, Fairview Health Services
- Joseph Turgeon, CIGNA
- Dr. Cecil B. Wilson, American Medical Association
- Dr. William C. Williams, Covenant Health Partners/Covenant Health Care
- Dr. Janet S. Wright, American College of Cardiology
Proposed Safe Harbor Under Consideration

- Newly formed joint venture or legal entity must comply with all statutory and regulatory requirements under Section 3022 of the Affordable Care Act

- Must participate in the Medicare shared savings program
The operational processes, procedures, policies, etc., for Medicare patients and private pay patients must be the same

- FTC to apply a rule of reason analysis
- Proposed safe harbor to be unveiled during the Fall
- FTC considering whether CMS certification of ACO, which requires adoption of clinical and administrative systems, evidence-based medicine, etc., will be treated as sufficiently clinically integrated for purpose of negotiating price on behalf of all ACO providers with private payors
Other Clinical Integration Factors

- Mechanisms to provide cost effective quality care
- Standards and protocols to govern treatment and utilization of services
- Information systems to measure and monitor individual physician and aggregate network performance
Other Clinical Integration Factors (cont’d)

- Procedures to modify physician behavior and assure adherence to network standards and protocols

- Web-based health information technology system that will help identify high-risk and high-cost patients and will facilitate the exchange of patients’ treatment and medical management information in order to more aggressively manage patients care than could achieve working independently
Other Clinical Integration Factors (cont’d)

- Develop clinical practice guidelines and monitor physicians adherence to them
- Develop software to review episodes of care, i.e., all of the medical care and services a patient receives from the onset of an illness or disease through final treatment to determine where performance improvement will have the greatest financial and quality benefits
Other Clinical Integration Factors (cont’d)

- Information used to review and, as appropriate, modify specific clinical guidelines or care protocols
- Identify instances of both overutilization and underutilization of services with physicians to address these issues
FTC Questions

- How many years of performance outcomes and metrics should FTC review in determining whether quality of care is improving?
- What, if anything, should FTC do if prices are increasing during this interim period?
- Given the existing safe harbors in the Statements related to market share, should there be a separate safe harbor specific to ACOs?
- How large must an ACO be in order to deliver care effectively?
FTC Questions (cont’d)

- Has there been much consolidation or announced consolidation since passage of the Accountable Care Act?
- Should any proposed safe harbor consider the geographic area in which providers compete differently than currently assessed?
- To what extent can exclusivity increase an ACO’s market power? Is exclusivity necessary in order to be successful?
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ACCOUNTABLE CARE ORGANIZATIONS:

IMPLICATIONS UNDER PHYSICIAN SELF-REFERRAL, ANTI-KICKBACK, CIVIL MONETARY PENALTY AND ANTITRUST LAWS

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I. Medicare Accountable Care Organizations: Shared Savings Program—Section 3022 of the Patient Protection and Affordable Care Act

A. Definition of Accountable Care Organization (ACO(s))

An organization of health care providers that agree to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it. “Assigned” means those beneficiaries for whom professionals in the ACO provide the bulk of primary care services. A beneficiary may continue to seek services from physicians and providers of their choice, whether or not the physician or provider is a part of an ACO.

B. Forms of ACO Organizations

1. Physicians and other professionals in group practices
2. Physicians and other professionals in networks of practices
3. Partnerships or joint venture arrangements between hospitals and physicians/professionals
4. Hospitals employing physicians/professionals
5. Other forms that the HHS Secretary may determine appropriate

C. Basic Requirements For ACO Participation

1. A formal legal structure to receive and distribute shared savings
2. A sufficient number of primary care professionals for the number of assigned beneficiaries which will be 5,000 at a minimum
3. Agreement to participate in the program for not less than a 3-year period
4. Sufficient information on participating health care professionals as the HHS Secretary determines necessary to support beneficiary assignment and for the determination of payments for shared savings
5. A leadership and management structure that includes clinical and administrative systems
6. Defined processes to promote evidence-based medicine; report necessary data to evaluate quality and costs measures; and coordinate care
7. Demonstrate satisfaction of patient-centeredness criteria, as determined by the HHS Secretary

D. ACO Qualification For Shared Savings

For each 12 month period, participating ACOs that meet specified quality performance standards will be eligible to receive a share (a percentage or any limits to be determined by the HHS Secretary) of any savings if the actual per capita expenditures of their assigned Medicare beneficiaries are a sufficient percentage below their specified benchmark amount.

The benchmark for each ACO will be based on the most recent available three years of per-beneficiary expenditures for Part A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. The benchmark for each ACO will be adjusted for beneficiary characteristics and other factors determined...
appropriate by the Secretary and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B.

E. Quality Performance Standards

The quality performance standards will be determined by the HHS Secretary and provided for in the program’s regulations but will include measures in such categories as clinical processes and outcomes of care, patient experience, and utilization (amounts and rates) of services.

II. Civil Monetary Penalty Law (“CMPL”)

Prohibited Activity: Hospitals knowingly making payments to a physician, directly or indirectly, to induce a reduction/limitation in services to Medicare or Medicaid fee-for-service beneficiaries.

Statute: Social Security Act Sec. 1128A(b)(1)-(2); 42 U.S.C. Sec. 1320a-7a(b)(1)-(2)

Regulations: 42 C.F.R. Part 1003

Enforcement Agency: HHS OIG

ACO Implications: Paying physicians for cost savings resulting from reducing or limiting services to Medicare and Medicaid beneficiaries implicates CMPL. There is no exception in the statute or regulation that protects such payments. (Note: OIG has determined that CMPL is not applicable to Medicare or Medicaid managed care plans and beneficiaries.)

However, in a series of advisory opinions beginning in 2001 addressing physician payments based on shared cost saving, OIG has taken the position that it will not impose sanctions where there are sufficient safeguards in place to ensure quality of care is not compromised. (OIG Advisory Opinions No. 01-1 (Jan. 18, 2001); 05-01 (Jan. 28, 2005); 05-02 (Feb. 10, 2005); 05-03 (Feb. 10, 2005); 05-04 (Feb. 10, 2005); 05-05 (Feb. 10, 2005); 05-06 (Feb. 10, 2005); 06-22 (Nov. 9, 2006); 07-21 (Dec. 28, 2007); 07-22 (Dec. 28, 2007); 08-09 (Aug. 7, 2008); 08-15 (Oct. 14, 2008); 08-21 (Nov. 25, 2008)). In Advisory Opinion No. 08-16 (Oct. 14, 2008), OIG issued a favorable ruling on a pay for performance program.

III. Anti-Kickback Statute (“AKS”)

Prohibited Activity: Knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, to induce referrals of items or services covered by Medicare, Medicaid, or any other federally funded program.

Statute: Social Security Act Sec. 1128B(b); 42 U.S.C. Sec. 1320a-7b(b)

Regulations: 42 C.F.R. Sec. 1001.952 et seq.

Enforcement Agency: DOJ (criminal) and HHS OIG (exclusion authority)

ACO Implications: Paying physicians for cost savings, even if based on quality performance standards, implicates the AKS because it raises the issue whether “a purpose” of the payment (even if there are legitimate and proper purposes for the payment) may be to induce referrals of items or services covered by federally funded programs. There is no statutory or regulatory safe harbor specific to shared savings or incentive payment programs. There are a few existing safe harbors, such as the employment and personal services safe harbors, that may be available to protect such incentive payments. But, there can be difficulties with such existing safe harbors, such as where the physicians are paid based on a percentage of cost savings and the applicable safe harbor requires that the compensation be set in
advance. NOTE: Failure to qualify for an AKS safe harbor does not mean that the AKS has been violated; it simply means that the immunity afforded by the safe harbor is not available. As noted above, OIG has indicated, in various advisory opinions on cost saving arrangements, that it will not impose sanctions where sufficient safeguards exist.

IV. Physician Self-Referral Law/Stark

Prohibited Activity: Physician referral of Medicare/Medicaid patients for designated health services to an entity with which the physician has a financial relationship, unless the relationship falls within an exception.

Statute: Social Security Act Sec. 1877; 42 U.S.C. Sec. 1395nn

Regulations: 42 C.F.R. Sec. 411.350 et seq.

Enforcement Agency: CMS

ACO Implications: Paying physicians for cost savings typically will involve a financial relationship between the physicians and a hospital and referrals of Medicare/Medicaid patients by such physicians to the hospital for designated health services. In such cases, to be compliant, the arrangement must qualify for one of the Stark exceptions. However, there is no exception that is specific to physician payments based on cost savings and quality standards, except for exceptions that are limited to Medicare/Medicaid managed care physician incentive plans. There are more general Stark exceptions, such as the employment and personal services exceptions, that may be available, depending on the details of a particular arrangement.

NOTE: CMS, not OIG, enforces the Stark law and thus the OIG advisory opinions cited above have no application to Stark law compliance.


In 2008, CMS proposed a Stark exception for incentive payment and shared savings programs. The requirements under this proposed exception focus on aspects which CMS considers critical to a properly structured, non-abusive incentive payment or shared savings program: transparency, quality controls and safeguards against payments for referrals.

A. Documented program: Remuneration must be part of a documented program to achieve:

1. the improvement of quality of patient care through changes in physician clinical or administrative practices; or
2. actual cost savings without diminution of quality of patient care.

B. Quality or cost savings measures: The program identifies patient care quality measures or cost savings measures, or both, that:

1. use an objective methodology, are verifiable, are supported by credible medical evidence, and are individually tracked;
2. are reasonably related to hospital’s or a comparable hospitals’ practices and patient population;
3. with respect to patient care quality measures, are listed in CMS’s manual;
4. are monitored throughout the term of the arrangement to protect against inappropriate reductions or limitations in patient care services.

C. Performance measures: The program establishes:
1. baselines of performance; and
2. target levels of performance developed by comparing the hospital’s historical data with data for comparable hospitals; and
3. thresholds above/below which no payment will accrue to physicians.

D. Minimum number of participants: At least 5 physicians must participate in each performance measure. Physicians participating in the program must be on the medical staff of the hospital at the commencement of the program.

E. Independent medical review: The program requires independent medical review of the program’s impact on the quality of patient care and corrective action if the review indicates a diminution in the quality of hospital patient care services.

F. Physician choice: Under the program:
1. Physicians must have access to the same selection of items, supplies, or devices;
2. The hospital may not make payments to physicians for use of an item, supply, or device in which the physician or physician organization has an ownership interest; and
3. The hospital may not limit the availability of new technology.

G. Patient notice: The hospital provides effective prior written notice to affected patients.

H. Written arrangement: The arrangement is set out in writing.

I. Legitimate business interest: The performance measures provided for under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates Federal or State law and, in the aggregate, are reasonable and necessary for the legitimate business purposes of the arrangement.

J. Term: The term of the arrangement is no less than 1 year and no more than 3 years.

K. Account for previous payments: Payments must take into account previous payments made for performance measures already achieved to ensure that the participating physicians do not receive payment related to patient care quality improvements or cost savings that were achieved during a prior period of the arrangement.
IMPLICATIONS UNDER PHYSICIAN SELF-REFERRAL, ANTI-KICKBACK, CIVIL MONETARY PENALTY AND ANTITRUST LAWS

No payment may be made for the achievement of cost savings that results in a diminution in hospital patient care quality with respect to that performance measure.

L. Duration and amount: Payments are limited in duration and amount.

M. Remuneration to be paid over the term of the arrangement is:
   1. set in advance;
   2. not based on reduction in the length of stay for a patient or in the aggregate for the hospital;
   3. distributed to physicians on a per capita basis with respect to each performance measure; and
   4. paid directly to participating physicians or qualified physician organizations.

N. No volume benefit: The remuneration paid to physicians may not include any amount that takes into account the provision of a greater volume of Federal health care patient procedures or services.

O. Documentation: The hospital maintains documentation of the program and makes it available to the HHS Secretary upon request.

P. Compliance with fraud and abuse laws: The arrangement does not violate the Anti-Kickback Statute or any Federal or State law or regulation governing billing or claims submission.

VI. Antitrust

Prohibited Activities:

- Price fixing among competing providers
- Division of geographic markets
- Division of product markets
- Mergers which may substantially lessen competition
- Monopolization and attempted monopolization
- Illegal Group boycotts through wrongful or exclusionary means
- Sharing of confidential fee and other competitive information


Enforcement Agencies: Department of Justice, Federal Trade Commission, State Attorneys General
ACO Implications: Although ACOs can take many forms, comprehensive ACOs are likely to involve the participation of multiple independent providers, such as hospitals, physicians, AHPs, home health agencies, medical homes and nursing homes, under different employment, independent contractor, joint venture and other arrangements which contract with Medicare/Medicaid and private payors to provide cradle to the grave health care services to an assigned and contracted patient population. Whenever independent competitors gather to discuss and actually render patient care, there is always the risk that prices will be fixed, geographic and product markets will be divided and/or illegal group boycott and exclusionary strategies will be developed thus resulting in artificially higher prices, higher costs and no countervailing pro-competitive or community benefits.

Another area of antitrust risk is whether each subset of providers, through exclusive or even non-exclusive participation in an ACO, has obtained sufficient market power so as to be in a position to impose a not insubstantial increase in prices. The safe harbor under the Statements is 20% market share in the relevant product and geographic market for exclusive arrangements and 30% for non-exclusive. The previous Merger Guidelines that used a 35% market share figure as raising concerns has now been abandoned so as to allow for a more flexible and dynamic evaluation of market power.

The question is whether the existing laws, guidelines and enforcement statements are sufficiently flexible and instructive enough so as to not unreasonably obstruct the development of successful ACOs.

Public Payors: Where Medicare/Medicaid unilaterally sets the price, e.g., bundled payment, capitated or global rates, etc., there are no antitrust issues.

Private Payors: Medicare/Medicaid payments only cover a percentage of a provider’s total reimbursement. Therefore, ACOs are likely to attempt to contract with private insurance companies. A Medicare certified ACO must be able to demonstrate that, among other things, it has a formal legal structure to treat a minimum of 5,000 assigned beneficiaries, defined processes to promote evidence-based medicine, the ability to evaluate quality and cost measures, and coordinate care with sufficient infrastructure to manage some form of risk based payment methodology. ACOs must be at “financial risk” in all payor arrangement, e.g., capitation, and/or be sufficiently “clinically integrated” and not have excessive market power in order to negate rates on behalf of all independent providers in the ACO. A question will be whether the certified ACO therefore will be deemed to be sufficiently “clinically integrated” under antitrust standards when contracting with the private sector in non-risk arrangements.