Compliance Issues with Accountable Care Organizations

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Legal Issues Boot Camp
For Compliance Professionals

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ACO Basics

- Statutorily mandated in Health Care Reform Law

- Law directs HHS to establish a Medicare “shared savings program” by January 2012 that:
  
  “Promotes accountability for a patient population and coordinates items and services under [Medicare] parts A and B and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.”

  Under this program “groups of providers of services and suppliers … may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through accountable care organizations … and receive payments for shared savings”
ACO Basics

- Program participation—Eligible ACOs
  - “Groups of providers of services and suppliers which have established a mechanism for shared governance”
    - ACO professionals in group practice arrangements
    - Networks of individual practices of ACO professionals
    - Partnerships or joint venture arrangements between hospitals and ACO professionals
    - Hospitals employing ACO professionals
ACO Basics

- Participation requirements
  - Accountability for the quality, cost and care of Medicare beneficiaries assigned to ACO
  - 3-year minimum participation commitment
  - Formal legal structure that allows for the receipt and distribution of shared savings payments
  - Sufficient number of primary care professionals to treat minimum of 5,000 Medicare beneficiaries
  - A leadership and management structure that includes clinical and administrative systems
ACO Basics

- Participation requirements (cont.)
  - Processes for:
    - Promoting evidence-based medicine and patient engagement
    - Reporting on quality and cost measures
    - Coordinating care
      - Including “telehealth, remote patient monitoring and such other enabling technologies”
ACO Basics

- Participation requirements, cont.
  - *Demonstrated capacity to meet* “patient-centeredness criteria” *specified by HHS*
    - “… such as the use of patient and caregiver assessments or the use of individualized care plans”
  - *Preference will be given to ACOs*
    - “… who are participating in similar arrangements with other payers”
ACO Basics

- **Quality requirements**
  - *HHS determines quality metrics based on:*
    - “Clinical processes and outcomes”
    - “Patient and, where practicable, caregiver experience of care”
    - “Utilization (such as rates of hospital admissions for ambulatory care sensitive conditions)”
  - *HHS assigns Medicare beneficiaries*
    - “Based on utilization and primary care services”
ACO Basics

- Payment
  - An ACO shall be eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by HHS below the applicable benchmark.

- CMS has proposed both a shared savings model (one-sided model) and a shared savings/losses model (two-sided model). ACOs electing to initially enter the one-sided model automatically transition to a two-sided risk model during the final year of their initial agreement.
Legal Issues with ACOs

- All the “usual suspects”
  - Stark Law
  - Federal and state anti-kickback (AKS) statutes
  - Federal civil monetary penalty law (CMPL)
  - Antitrust
  - Corporate practice of medicine
  - Tax-exempt rules
  - State insurance regulation
  - Liability
  - Privacy
ACOs and the Stark Law

- The Stark Law
  - Prohibits a physician from referring Medicare and Medicaid patients for “designated health services” [DHS] when the physician has a financial arrangement (through ownership or compensation) with the entity and there is no exception for the arrangement

- Bright line statute
ACOs and the Stark Law

- **Employment Exception**
  - Compensation for personally performed, identifiable services
  - *Fair market value (FMV) compensation, cannot be based on volume or value of referrals*

- **Personal Services Agreements Exception**
  - One year, written agreement
  - *Requires FMV compensation, set in advance, cannot be based on volume or value of services*
ACOs and the Stark Law

- **Fair Market Value Exception**
  - Identifiable services, specified in agreement
  - Can be for less than one year but cannot be renewed within year for same services under different terms
  - FMV compensation, set in advance, cannot be based on volume or value of services

- **Risk Sharing Exception**
  - Arrangement between MCO or IPA with physician for services provided to enrollee of health plan
  - Arrangement doesn’t violate AKS
ACOs and the Stark Law

- Indirect compensation analysis
  - *Intervening entity between DHS entity and physician*
  - *Payment to physician cannot take into account volume or value of referrals to the DHS entity*

- Incentive payment & shared savings programs *(Proposed)*
  - *Published Nov. 19, 2008 (included in 2009 Medicare Physician Fee Schedule Update, 73 Fed. Reg. 69726)*
  - *Rule has not been finalized*
  - *Narrowly drafted; adopts many of the same criteria identified in the OIG Advisory Opinions*
ACOs and the Anti-Kickback Law

- The AKS
  - Precludes payment or receipt of remuneration, directly or indirectly, intended to induce the provision of covered services to government program patients

- Employment safe harbor
  - Bona fide employment relationship with employer

- Personal service arrangements safe harbor
  - FMV compensation, set in advance, not based on volume or value of services
  - Agreement for part-time arrangements must set forth exactly the schedule of such intervals, their precise length, and the exact charge for such intervals
ACOs and the Anti-Kickback Law

- OIG advisory opinions (AO) on gainsharing
  - Series of AOs starting in 2001 involving cardiologists, cardiovascular surgeons, orthopedic surgeons, neurosurgeons and anesthesiologists
- OIG identified criteria that minimized risk of violating AKS
  - Participation limited to physicians on hospital’s medical staff
  - Potential savings capped based on prior year’s admissions
  - Only one-year program
  - Overall payment amount capped
  - Payments distributed to physicians per capita
  - Contracts set forth significant specificity as to how payments could be earned
ACOs and the CMPL

- SSA § 1128A(b)(1)-(2)
  - Prohibits payments that are intended to induce a physician to reduce or limit services to Medicare or Medicaid patients

- OIG’s July 1999 Bulletin—Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries
  - “[a]bsent legislative relief, section 1128A(b)(1) of the Act prohibits any gainsharing arrangements that involve payments by or on behalf of a hospital to physicians with clinical care responsibilities, directly or indirectly, to induce a reduction or limitation of services to Medicare or Medicaid patients.”
ACOs and the CMPL

- The CMPL
  - Primary focus of OIG AOs on gainsharing programs
  - Narrowly interpreted by OIG to permit only very carefully crafted programs reviewed by independent medical expert

- Criteria identified by OIG that support a permissible program [AO 09-06 (June 09)] –
  - Specific cost-saving actions and resulting savings were clearly and separately identified
  - Credible medical support that implementation of the recommendations did not adversely affect patient care
ACOs and the CMPL

- Criteria identified by OIG, cont.
  - Calculated payment amounts based on all procedures performed, regardless of patients’ insurance coverage, subject to cap on payment for federal healthcare program procedures
  - Protected against inappropriate service reductions by utilizing objective historical / clinical measures to establish baseline thresholds
  - Ensured that individual physicians had available same selection of devices and supplies after implementation as before
  - Written disclosures by physicians of their involvement in the arrangement to patients whose care might have been affected
  - Financial incentives were reasonably limited in duration and amount
  - Each physician group distributed profits to members on a per capita basis
Fraud & Abuse Waivers

- On March 31, 2011, OIG and CMS jointly issued a notice (with comment period) to establish an ACO waiver of the Stark Law, anti-kickback statute, and the “gainsharing” CMPL (i.e., hospital payments to reduce or limit services)
- Notice does not propose regulatory language
- CMS and OIG are seeking comments on expanding the waivers
- *Threshold qualification* -- waivers are only for ACOs with CMS agreement to participate in MSSP and that are in compliance with the agreement and all ACO regulations
Fraud & Abuse Waivers

- HHS would waive application of both the Stark Law and AKS to *distributions of shared savings received by an ACO from CMS* to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants during the year in which the shared savings were earned by the ACO; or... for activities necessary for and directly related to the ACO’s participation in and operations under MSSP.
Fraud & Abuse Waivers

- A second waiver from application of AKS would be permitted for a financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the MSSP that implicates the Stark Law and fully complies with a Stark exception.

- This waiver is intended to protect conduct from AKS if it complies fully with the Stark Law.
Fraud & Abuse Waivers

- A waiver from the “gainsharing” CMPL would be permitted for MSSP distributions made from a hospital to a physician, provided that
  - payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and
  - [the] hospital and physician are ACO participants or ACO providers/suppliers, or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.”
Fraud & Abuse Waivers

- A second waiver from the “gainsharing” CMPL would be available for any financial relationship among the ACO, its participants and its providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the MSSP that implicates the Stark Law and fully complies with a Stark exception.
Fraud & Abuse Waivers

- CMS and OIG solicited comments on developing waivers for financial relationships, other than distribution of MSSP:
  - arrangements related to establishing the ACO (e.g., start-up expenses)
  - arrangements between or among ACO participants related to ongoing operations and achieving ACO goals
  - arrangements between the ACO and its participants and outside individuals or entities
  - distribution of shared savings received from private payors
  - separate waivers when ACO participants bear risk under the MSSP two-sided risk model