The Affordable Care Act for Compliance Professionals

March 14, 2014
HCCA Regional Annual Conference – Washington, DC

Lester J. Perling, Esq., CHC
Partner, Broad and Cassel
Fort Lauderdale, Florida

The Patient Protection and Affordable Care Act

- Public Law 111-148
- Purpose: To provide access to comprehensive, affordable healthcare for all
- Enacted on March 23, 2010
- Regulations describe the structure of Accountable Care Organizations
  - Entity formation, governance, distribution of shared savings
  - State licensure if necessary

Features of the Affordable Care Act

- Removal of annual/lifetime limits
- Removal of preexisting conditions
- First dollar coverage for preventive care
- Young adult coverage
- Employers must offer certain coverage
- Subsidies for qualifying individuals
- Insurance company rebates (if do not spend enough on services/quality improvements)
- Accountable Care Organizations (ACOs)
Health Care Reform and Fraud & Abuse Enforcement

- Fraud Enforcement Recovery Act (FERA) passed in 2009 amended the False Claims Act
- Broadened the definition of "claims" so that False Claims Act liability will attach to a claim for federal funds if money is spent on the government's behalf or to advance a government program or interest
- Materiality requirement for False Claims Act liability: "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"
- Patient Protection and Affordable Care Act (PPACA or ACA) passed in 2010 and also amended the False Claims Act
  - A violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act

Health Care Reform and Fraud & Abuse Enforcement (cont’d)

- Liability for overpayments and failure to return a known overpayment within 60 days from identification
- Return of known overpayment an affirmative and express obligation
- Statutory obligation: Social Security Act § 1128L(d)
- CMS proposed rule-making to this effect on Feb. 16, 2012
- Jan. 10, 2014: HHS Proposed rule for 60-day requirement expanded to Medicare Advantage plans and drug benefit programs under Medicare Parts C and D, but does not apply to downstream provider/supplier payments
- Suggests the 60-day rule applies to providers and suppliers only when receiving overpayments under Medicare Parts A, B or Medicaid
- Still no final rule

Health Care Reform and Fraud & Abuse Enforcement (cont’d)

- FCA public disclosure ban no longer jurisdictional and does not require dismissal of a case if the government opposes dismissal
  - State proceedings and private litigation do not qualify as public disclosure, but federal proceedings and news media reports do qualify for public disclosure
  - Original source no longer requires "direct and independent knowledge", but only independent knowledge of previously publicly disclosed information that materially adds to publicly disclosed information
Exchanges

- Qualified health plans (QHPs) are available through health insurance marketplaces, also known as exchanges
- Individuals receive a refundable tax credit when purchasing a plan (42 U.S.C. § 18071(C)(3)(A)).
- Strict Conflict of Interest Rules
- In a letter from Secretary Sebelius of HHS, she stated that QHPs are not considered "federal health care programs"
- This means the Anti-Kickback Statute does NOT apply
- Drug manufacturers may therefore offer co-payment coupon programs
- Nonetheless, this interpretation may be challenged in court

Required Compliance Plan

- ACA § 6401 requires that providers of health care items or services, skilled nursing facilities (SNFs) and nursing facilities (NFs) have a compliance program as a condition of enrollment in Medicare, Medicaid or CHIP
  - "The Secretary shall determine the timeline for establishment of the core elements [of a compliance program] and the date of implementation"
  - The Secretary has yet to publish a timeline or date of implementation for health care providers/suppliers

Required Compliance Plan (cont’d.)

- ACA § 6102 overlaps with § 6401 by requiring compliance programs specifically for NFs and SNFs
- ACA made compliance plans mandatory for SNFs as of March 23, 2013, but OIG failed to establish the core elements by its deadline (2 years after ACA’s enactment)
- In the meantime, nursing homes should look to established OIG compliance guidance
- ACOs must have compliance plans to deal with fraud and abuse laws
Required Compliance Plan (cont’d.)

- Compliance plan must have the following minimum requirements:
  - Designated compliance official who reports to the ACOs governing body
  - Ability to identify and address compliance issues
  - Method for reporting suspected fraud or abuse related to the ACO
  - Compliance training program for employees and contractors/suppliers
  - Mandate reporting of suspected violations of fraud and abuse laws

Shared Savings Program

- Section 3022
- Goals of the Program:
  - Better health for populations
  - Better care for individuals
  - Lower growth in expenditures
  - Allows qualified provider groups to earn a "share" of the savings from reducing the cost of providing care to a specific population of Medicare fee-for-service beneficiaries
- Participants in the Share Savings Program must form an Accountable Care Organization (ACO)
  - Required certification of compliance 76 Fed. Reg. 67823; 42 C.F.R. 425.208(c)

Shared Savings Programs and Fraud & Abuse

- Existing fraud and abuse laws prohibit shared savings distributions among health care entities and individuals
- Law grants the Secretary of Health and Human Services authority to waive certain provisions to facilitate ACO formation and functioning
- Waivers only apply to federal laws
  - What does this mean for state fraud and abuse laws?
CMS and OIG Waivers

- Section 3022(f) grants the Secretary authority to waive fraud and abuse laws to facilitate ACO formation and shared savings
- The 5 waivers are meant to provide flexibility in care coordination and collaboration
  - ACO Pre-Participation Waiver
  - ACO Participation Waiver
  - Shared Savings Distribution Waiver
  - Compliance with Physician Self-Referral Law Waiver
  - Patient Incentive Waiver

Implicated Fraud & Abuse Laws

- Gainsharing Civil Money Penalty
  - 42 U.S.C. 1320a-7a(b)
- Beneficiary Inducement Civil Money Penalty
  - 42 U.S.C. 1320a-7a(a)(5)
- Stark Law
  - 42 U.S.C. 1395nn
- Anti-Kickback Statute
  - 42 U.S.C. 1320a-7b(b)(1) and (2)
- Prohibition against charging/collecting more than Medicare allowable
  - 42 U.S.C. 1320a-7a(a)(2)

Gainsharing CMP

- Gainsharing arrangement: hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts
- Civil Money Penalty Law prohibits payments to reduce or limit care
  - Hospital may not knowingly make a payment, directly or indirectly to a physician in order to incentivize the physician to reduce or limit services provided to a Medicare or Medicaid beneficiary
Beneficiary Inducement CMP

- Beneficiary inducement occurs when a person attempts to influence a Medicare or Medicaid beneficiary's choice of provider
- Civil Money Penalty Law prohibits inducements to beneficiaries
- A person may not offer or provide any remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services.

Stark Law

- Prohibits a physician from referring Medicare or Medicaid patients for designated health services to an entity with which the physician, or an immediate family member, has a financial relationship unless an exception applies
- An entity that receives a prohibited referral may not bill the Medicare or Medicaid programs for the related items or services

Anti-Kickback Statute

- Prohibits knowingly or willfully offering, paying, soliciting or receiving anything of value to induce or reward referral or general federal health care program business
- Voluntary safe harbors exist
- Criminal penalties in addition to civil and administrative
Prohibition against charging/collecting more than the Medicare allowable

- Medicare beneficiaries may assign payment directly to the provider.
- If the provider accepts assignment, Medicare will directly pay the fee schedule amount and the beneficiary will be responsible for paying any coinsurance or remaining deductible.
- The provider is prohibited from charging more than the Medicare allowable amount, which is the combination of the fee schedule payment and coinsurance/deductible.

Prohibition against charging/collecting more than the Medicare allowable (cont’d.)

- 42 U.S.C. § 1395jjj(d) instructs that payments shall continue to be made according to the original Medicare fee-for-service program under parts A and B, but participating ACOs are eligible to receive additional shared savings under certain conditions.
- 42 U.S.C. § 1395jjj(d) allows the Secretary to waive the requirements of the CMP (42 U.S.C. § 1320a-7a(a)(2)) to allow providers to recoup the traditional fee-for-service payment in addition to shared savings (potentially resulting in more than Medicare allowable).

Scope and Application of Waivers

- The 5 waivers only apply to the Shared Savings Program and participating ACOs.
- Secretary has authority to individually provide waivers of fraud and abuse laws to other projects or programs.
- The waivers apply uniformly to all ACOs, participants and providers/suppliers.
- There is no need to apply for individualized waivers, they apply automatically to participants of the Program.
- CMS and OIG jointly established the waivers, showcasing a coordinated effort to waive the laws and facilitate success among ACOs.
Scope and Application of Waivers (cont'd.)

- Waivers contemplate the ACO governing body to be the intermediary responsible for ensuring all protected arrangements further the ACO purpose
- Transparency: arrangements subject to waiver must be publicly disclosed
  - This is meant to deter fraudulent conduct
  - Incentives ACOs not to abuse what arrangements they claim under waiver

(1) ACO Pre-Participation Waiver

- One time waiver applies to start up arrangement that pre-dates an ACO participation agreement
- Good faith intent to develop an ACO that will participate in the Shared Savings Program
- Governing body must approve that the arrangement is reasonably related to CMS program purposes
- Prepare documentation of waived relationships at the time of each transaction and retain for 10 years (CMS may request documents at any point)
- Laws waived:
  - Stark Law
  - Anti-Kickback Statute
  - Gainsharing CMP

(2) ACO Participation Waiver

- Waiver begins when CMS ACO agreement is entered into and remains while in good standing
- ACO must meet governance, leadership and management requirements
- Protects all parties to the arrangement
- Laws Waived:
  - Stark Law
  - Anti-Kickback Statute
  - Gainsharing CMP
(3) Shared Savings Distribution Waiver

- ACO enters into a participation agreement, remains in good standing, earns shared savings and distributes those savings
- Shared savings distributed to ACO participants, providers or suppliers or used for activities reasonably related to the purposes of the Shared Savings Program
- Does not apply to hospital distributions to physician knowingly made to reduce/limit medically necessary services, but does protect incentives for alternative evidence-based care that is medically necessary
- Laws waived:
  - Stark Law
  - Anti-Kickback Statute
  - Gainsharing CMP

(4) Stark Law Waiver

- Financial relationship among ACO participants, providers and supplier if in good standing in the ACO program, the relationship is reasonably related to ACO program and the relationship complies with a Stark Law exception
- Laws Waived:
  - Anti-Kickback Statute
  - Gainsharing CMP

(5) Patient Incentives Waiver

- Waiver applies to free/reduced items or services to beneficiaries
- Must be a reasonable connection between the item/service (in kind only, no cash or cash equivalent payments) and medical care to the beneficiary
- Items/services must be preventive care or advance a clinical goal (like adherence to a treatment or drug regime or management of a chronic condition)
- Laws waived:
  - Anti-Kickback Statute
  - Beneficiary Inducement CMP
What isn’t covered under the waivers?

- Provider relationships that are not genuinely related to the purpose of the ACO
- Commercial ACO arrangements
- Waivers do not apply to any similar integrated-care delivery model, only the Shared Savings Program
- State laws or regulations, nor the Internal Revenue Code

ACO New Enforcement Areas

- Electronic Health Records (EHR) Adoption
  - Incentives paid for "meaningful use". Government contracts out "meaningful use" audits
- Use of care coordinators
  - Will care coordinators be seen as "beneficiary inducements" to make a provider appear more attractive to a potential patient?
  - Are those sources potential sources of Stark or Anti-Kickback violations?
  - Will they been seen as steering patients?

ACOs: Where are we now?

- CMS announced on December 23, 2013 that 123 new ACOs were participating in the Medicare Shared Savings Program
  - Total number of Medicare ACOs: 366
  - Total number of public and private ACOs: 606
- Success of those ACOs center on compliance professionals
  - Ensure effective MSSP compliance plan requirements
  - Monitor agreements between ACO and its participants, providers and suppliers
  - Determine conflicts of interest within the ACO governing body
  - Carefully monitor the prohibition against ACO beneficiary inducements
Questions?

lperling@broadandcassel.com