INTEGRITY PROVISIONS UNDER PPACA:

PRACTICAL COMPLIANCE IMPLICATIONS TO MANUFACTURERS

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PRESENTATION OVERVIEW

I. Key PPACA Changes

II. Top 10 Practical Compliance Considerations

POLLING QUESTION

From a corporate compliance perspective, the most challenging aspect of Health Reform implementation is the following:

1. Keeping current on Health Reform developments – legal and operational
2. Identifying and implementing the impact of Health Reform on corporate compliance programs
3. Obtaining senior management recognition regarding the impact of Health Reform on corporate compliance
4. Collaborating with new business areas due to Health Reform developments
5. Other(s)
6. All of the above

MANUFACTURER IMPACT

- Health Reform impact on corporate compliance infrastructure
  - Focus on business and operations
  - Assess current resources
  - Determine priorities
  - Involve others - Board, senior management, line management

I. KEY PPACA CHANGES

ENFORCEMENT CLIMATE

- More funding for government enforcement agencies
  - $1.9 billion in 2011 budget for HHS fraud fighting activities
- Enhanced government infrastructure
- Health Care Fraud Prevention and Enforcement Action Team (HEAT) Medicare Fraud Strike Force
  - Stronger role for OIG to seek information from providers, suppliers and others who directly or indirectly provide, order, manufacture, distribute, arrange for, prescribe, supply or receive medical or other items or services payable by any FHCP, regardless of how the item is paid for, or to whom such payment is made in order to "protect the integrity of the Medicare and Medicaid programs"
- Greater penalties

ENFORCEMENT CLIMATE (CONT'D)

- Opportunities and challenges created by Health Reform impose on manufacturers new legal and regulatory requirements at Federal and state levels
  - Transparency, Government Program Pricing, Part D program, payment reform, coverage, etc.
- More than new laws "on the books" or amendments to current laws
  - How will the Health Reform integrity provisions be applied and interpreted?
  - When will they be enforced?

KEY PROVISIONS FOR MANUFACTURERS

1. Federal Health Care Program Anti-Kickback Statute (AKS)
2. Civil False Claims Act (FCA)
3. Civil Monetary Penalties (CMP)
4. Permissive Exclusion and Medicaid Exclusion Expansion
5. Other Key Health Reform Areas

1. ANTI-KICKBACK STATUTE

- Health Reform amended the AKS in two significant ways
  - First, it codified the so-called "bootstrap theory," under which an alleged violation of the AKS also triggered a violation of the Civil False Claims Act regardless of who submits the claim
    - "Implied certification," "tainted claim" or "bootstrap theory" that has been used in several court cases and settlements, including those involving pharmaceutical manufacturers
    - As a result of Health Reform, Congress ended any doubt by providing that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purpose of [the FCA]…"
      - Other elements of the FCA must be satisfied

1. ANTI-KICKBACK STATUTE (CONT'D)

- Health Reform amended the AKS in two significant ways
  - Second, Health Reform amends the intent requirement of the AKS
    - AKS is a felony statute that generally requires a "knowing or willful" intent to offer, pay, solicit, or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under a FHCP
    - Health reform now defines "knowing and willful" as -- "with respect to violations of [the AKS] a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of this section"
      - In the past, "knowing and willful" now has been interpreted differently by the courts
      - Adoption of the "one purpose test"
      - Bottom line – did the person know that conduct was unlawful?

1. ANTI-KICKBACK STATUTE (CONT'D)

- Health Reform also amends several sections of the criminal code, including the federal crime of health care fraud
  - The federal crime of health care fraud prohibits a person from "knowingly and willfully" executing or attempting to execute a scheme or artifice to defraud any health care benefit program in connection with the delivery of, or payment for, health care benefits, items, or services
    - Health Reform now provides that a violation of the federal crime of health care fraud constitutes a false claim in violation of the FCA
    - Health Reform also amends the intent standard to clarify that proof of actual knowledge or specific intent to violate the statute is not required
    - Definition of "federal crime of health care fraud" also amended to include violations of AKS, FDCA and ERISA

2. CIVIL FALSE CLAIMS ACT

- The Fraud Enforcement and Recovery Act (FERA)
  - Adopted May 20, 2009 primarily to combat mortgage, securities and financial institution fraud includes significant modifications to the FCA
  - Retroactive to claims pending on or after June 7, 2008
    - Eliminates “substantial need” requirement and court approval for documents obtained during an investigation to be shared with other Government agencies
    - Permits the Government to share information obtained during an investigation with qui tam relators
    - If the Government decides to intervene, allows the Government’s amended complaint to “relate back” to the date when the qui tam complaint was filed
    - Makes the retention of an overpayment that did not result from the submission of any false record or statement a violation – “reverse false claim”

2. CIVIL FALSE CLAIMS ACT (CONT'D)

- Health Reform makes significant changes to the "public disclosure" bar of the FCA including
  - Prior to Health Reform, a qui tam action was barred such that a court lacked the power to hear an FCA case if the information on which the action was based had been disclosed publicly unless the relator was the "original source" of the information
  - Health Reform authorizes a person to qualify as an "original source" if the person "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions…."

3. CIVIL MONETARY PENALTIES

- New CMPs include
  1. Knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in a FHCP application, agreement, bid or contract
  2. Failing to grant timely access, upon reasonable request, to OIG-HHS for audits, investigations, evaluations or other statutory functions
  3. As a manufacturer, failing to provide applicable beneficiaries discounts for applicable drugs of the manufacturer per its CMS Part D coverage gap discount program agreement
  4. For a manufacturer with a Pharmaceutical Pricing Agreement that knowingly and intentionally charges a covered entity under the 340B programs a price for purchase of a drug that exceeds the allowed contract price

3. CIVIL MONETARY PENALTIES (CONT'D)

- Health Reform authorizes DHHS Secretary to promulgate regulations specifying new categories of payments that do not constitute "remuneration" for purposes of CMP law
  - Secretary must determine that the excluded remuneration promotes access to care and poses a low risk of harm to patients and FHCPs
- Health Reform also now excepts from CMPs
  - Certain coupons, rebates or "other rewards" from a "retailer," if available to the general public, without regard to health insurance status
  - Certain items or services that are offered or transferred for free or less than fair market value by a person if (1) the items or services are not offered as part of any advertisement or solicitation; (2) there is a reasonable connection between the items or services and the medical care of the individual; and (4) the items or services are provided after determining in good faith that the individual is in financial need

** **Certain CMP changes in Health Reform may not apply directly to manufacturers to the extent that a Manufacturer is not a "provider" or "supplier" as defined by the OIG for purposes of the Social Security Act** **

4. PERMISSIVE EXCLUSION AND MEDICAID EXCLUSION EXPANSION

- Health Reform expands CMS' permissive exclusion authority
  - Making false statements or misrepresentations of material facts
  - Obstruction of a Government investigation or audit
- Health Reform also expands Medicaid Exclusion Requirements
  - States are required to exclude any individual or entity if such individual or entity owns, controls, or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that)
    - Failed to repay overpayments
    - Is suspended, excluded or terminated from participation in any Medicaid program
    - Is affiliated with an individual or entity that has been suspended, excluded or terminated from the Medicaid program

**** Congress has been working on the repeal of this section ****

***** Note other legislative developments *****

4. PERMISSIVE EXCLUSION AND MEDICAID EXCLUSION EXPANSION (CONT'D)

- Key Considerations
  - Potentially prevents limiting civil and criminal liability to a corporate box as it extends to "affiliates" of excluded entities
  - Creates concerns regarding access, among others

5. OTHER KEY HEALTH REFORM AREAS

- Health Reform changes Medicaid prescription drug rebate calculations including redefining AMP, expanding 340B program
- Health Reform provisions related to transparency, drug sample reporting and PBM rebates
- Health Reform includes numerous new payment paradigms that reward quality and efficiency such as value based purchasing, ACOs, CE

5. OTHER KEY HEALTH REFORM AREAS (CONT'D)

- Health Reform provides manufacturers potential opportunity for increased market share through coverage mandates
  - Commercial plans
  - Exchanges
  - FHCPs
- Health Reform also provides manufacturers opportunity to participate in payment reform
  - ACOs (Cost and outcome accountability)
  - Center for Medicare and Medicaid Innovation (CMMI) within CMS (1/1/11)
    - DHHS charged to "test innovative payment and service delivery models to reduce program expenditures … while preserving or enhancing the quality of care …
    - Budget neutrality not a condition to approval of a model (20 types of models)

5. OTHER KEY HEALTH REFORM AREAS (CONT'D)

- "Patient-Centered Outcomes Research Institute" (PCORI)
  - Private, non-profit independent entity
  - 19 member Board appointed by comptroller general
  - To "assist patients, clinicians, purchasers, and policy-makers in making informed health care decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can be effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations …"
  - Compare effectiveness of 2 or more alternative therapies in patient subpopulations
  - Not being used for mandating coverage, reimbursement or policies

II. TOP 10 COMPLIANCE CONSIDERATIONS

TOP 10 COMPLIANCE CONSIDERATIONS

KEY CHANGES

- Federal Health Care Program Anti-Kickback Statute (AKS)
- Civil False Claims Act (FCA)
- Civil Monetary Penalties (CMP)
- Medicaid Exclusion and Permissive Exclusion Expansion
- Other Key Health Reform Areas including, by way of example, changes in payment reform, coverage

COMPLIANCE INFRASTRUCTURE

- ❑ Compliance Officer and Committee
- ❑ Written Policies and Procedures
- ❑ Training and Education
- ❑ Open Lines of Communications
- ❑ Monitoring and Auditing
- ❑ Disciplinary Guidelines
- ❑ Detect Problems and Corrective Actions Systems
- ❑ CIA, DPA, other integrity commitments

TOP 10 COMPLIANCE CONSIDERATIONS

1. Compliance policy and procedures review for updates – examples to consider:
   - Financial relationships with referral sources (or potential referral sources) from an AKS perspective?
   - Interactions with customers, formulary committees
   - Reimbursement support
   - IIR
   - Product promotion and labeling
   - Promotional review processes
   - Government Program Pricing
   - Contracting with third party vendors
   - “Knock at the Door” Exit interview protocols for departing employees
   - Record retention and maintenance
   - Use of company property and information
   - Check-out procedures

TOP 10 COMPLIANCE CONSIDERATIONS

2. "Open door" communications
   - Relator may now "enforce" the AKS due to the FCA change -- prior to Health Reform, a financial arrangement with a referral source that did not satisfy an AKS statutory exception or a "safe harbor," would be analyzed on its "facts and circumstances" including, if applicable, the cumulative relationships between the parties
3. Retraining
   - Updated policies and procedures
   - How to write an e-mail
4. Auditing and monitoring (including third parties)
5. Exclusion list review
6. Corporate structures
   - Consider impact on change in ownership/transactions
7. Code of Conduct review
   - False statements

TOP 10 COMPLIANCE CONSIDERATIONS

8. Review and update investigation protocols
9. BoD involvement
10. Compliance committee structure – operations and business

POLLING QUESTION

Health Reform presents significant opportunities for the Corporate Compliance Department?

- True
- False

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