Fraud & Abuse Developments in Healthcare Reform

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Agenda

- More activities will be considered fraud
- The government has new tools to prevent fraud
- It will be easier for the government to detect fraud
- It will be easier for the government to investigate and enforce the new fraud proscriptions
- It will be harder (and more costly) for health care companies to escape the enforcement spotlight
- ***Back to our roots: an ounce of prevention is worth a pound of cure***

Pre-Reform Environment Reflected Bipartisan Effort to "Get Tough" On Health Care Fraud

- Prior to enactment, Administration had previously (May 2009) established first Cabinet-level working group to "fight fraud" – Health Care Fraud Prevention and Enforcement Action Team, or HEAT.

- Congress had passed Fraud Enforcement and Recovery Act further strengthening the False Claims Act.

Pre-Reform Environment Reflected Bipartisan Effort to "Get Tough" On Health Care Fraud

- **Persistent Entreaties by DOJ, HHS-OIG, and Relators' Bar to Congress to "Close Legal Loopholes"**
  - Reviewed unfavorable case law and legal interpretations and sought legislative fixes.
  - Developed "dream" combination of new and better detection and investigatory tools.
  - Focused on keeping transgressors out of federal programs in first place and punishing them harshly when they were caught.

- **Result of New Legislation**
  - The government has been freshly armed with clearer, tougher health care fraud laws and greater power to ferret out and prosecute fraud.
  - Fraud investigations and prosecutions will increase; risks have grown.
  - Compliance and prevention measures more essential than ever.
  - This is serious.

Antikickback Statute Changes

- The Antikickback Statute
  - Kickback violations are now explicitly linked to false claims; argument as to whether claim "certification" covers AKS conformance is now moot.
  - "Specific intent" to violate the AKS need not be proven; eliminates Ninth Circuit *Hanlester* minority view that "intent" to specifically violate the AKS must be proven; general intent to perform an illegal act is sufficient.
  - AKS will be relevant – both directly and via False Claims Act applicability – to state-run "exchanges" designed to increase competition.
  - Changes to the CMP definition of "remuneration" exclude beneficiary inducement provisions that promote access to care and pose a low risk of harm to patients and the federal health care program (applies to providers, practitioners, suppliers, and plans).

False Claims Act Changes (see previous presentation)

- "Overpayments" that are not returned timely when "obligation" exists constitute reverse false claims.
- Public disclosure bar to *qui tam* suit no longer "jurisdictional" if government opposes dismissal.
- Public disclosure bar now limited only to proceedings, reports, audits, etc., in which federal government participates.
- To overcome public disclosure bar relator previously had to qualify as an original source with direct and independent knowledge of the allegations. NOW relator qualifies if either a) relator provides the information to the government prior to the public disclosure, or b) the information is independent of and materially adds to the public disclosure.

Health Care Fraud Statutes

- Definition of health care offense under 18 U.S.C. § 24(a) expanded to include violations of AKS and certain FDA and ERISA provisions. This makes the proceeds of these violations subject to:
  - criminal forfeiture
  - obstruction prosecution
  - money laundering prosecution
  - use of administrative subpoenas
- Enhanced penalties under U.S. Sentencing Guidelines for offenses in excess of $1 million in losses; clarification that for sentencing purposes "losses" means the "aggregate amount of billings," not proceeds.
- "Specific intent" requirement eliminated from health care fraud statute.

New and Revised Intermediate Sanctions and Civil Monetary Penalties

- **New intermediate sanctions against MA and Part D plans for:**
  - Marketing plans misrepresenting or falsifying information (up to amount claimed based on the falsification or misrepresentation).
  - Enrolling individuals without their consent.
  - Transferring persons from one plan to another to earn commissions.
  - Failing to comply with marketing restrictions related to approval of marketing materials and prohibited activities.
  - Employing individuals or entities who engage in conduct for which intermediate sanctions may be applied.
- **Other new CMPs for:**
  - Slow or false responses to HHS-OIG inquiries, including providing timely access for audits, investigations, etc.
  - False statements on enrollment applications.
  - Knowingly making a false record or statement material to a false or fraudulent claim.
  - Knowingly failing to report an overpayment.
  - Ordering or prescribing while under program exclusion.
- **CMP penalties for false claims increased to $50,000 per claim**.

Other Important/Interesting Fraud and Abuse Changes

- Stark Self-Disclosure Protocol to be established
  - To be run by CMS.
  - Authorizes CMS to reduce penalties in certain cases.
- New transparency requirements for disclosure of relationships between:
  - physicians and hospitals
  - manufacturers, GPOs, and physicians
  - physicians and “in-office ancillary services”
  - manufacturers and distributors of prescription drugs, PBMs, etc.
- New administrative penalties for beneficiaries knowingly participating in a health care fraud offense.

Prevention, Detection, and Enforcement

- Expanded use and funding of claims and payment data analysis
  - Integrated Data Repository
    - Providers
    - MA and Part D
  - ZPICs, MICs (must report ROIs: powerful incentives)
  - MACs and all others
    - Self-analysis required as an element of an effective compliance program: the auditing and monitoring prong (Sentencing Guidelines, etc.)

Prevention, Detection, and Enforcement

- Eligibility requirements, *e.g.*, surety bonds, certifications, registration, disclosures
  - Providers
  - Plans
  - Billing agents and clearinghouses
- Recovery Audit Contractors
- Uniform Fraud and Abuse Referral Format (National State Insurance Commissioners)
- Earlier suspension of provider payments

Prevention, Detection, and Enforcement

- Federal Awardee Performance and Integrity Information System (FAPIS):
  - New contractor and grantee registration requirements designed to capture past and current misconduct of the entity and its principals
    - Information can be used to suspend/debar the contractor and/or declare it ineligible for award
    - Will ultimately include state and local government information as well as federal
- FAR Mandatory Disclosures – to the IG and the Contracting Officer
    - Failure to disclose is cause for suspension/debarment quite apart from the underlying (mis)conduct

Prevention, Detection, and Enforcement

- Government audits of entity's internal systems to detect and investigate misconduct
  - Internal reporting systems
  - Types of reports
  - No reports: a good thing or a really bad thing?
  - Method for responding to reports
    - Timely?
    - Thorough?
    - Who makes the call? Compliance Officer, Legal, IA, Other?
    - Documentation

Prevention, Detection, and Enforcement

- Expanded subpoena power for information and records (and access to some types of institutions)
  - HHS-OIG
  - DOJ

Ounce of Prevention

- Selling Compliance
  - Stress the commercial value of compliance
  - Stress individual consequences
  - This is not a “box checking” exercise
  - There is no such thing as “boilerplate”
  - Sufficient operational resources reduce mistakes and improve compliance
    - If we are scrambling, are we approaching “reckless disregard”
  - The government will measure “corporate culture” – have you?
  - Pay now or pay later

Ounce of Prevention

- Be prepared to demonstrate that the governing body has received compliance training
- Be prepared to turn over the compliance reports that were furnished to the governing body
- Part of your detection toolkit: exit interview forms, employee self-evaluations (I need more resources!!)
  - Be prepared to answer these questions:
    - how much did the company spend on compliance
    - how much did the company spend on marketing and business development