UPDATE ON HEALTH CARE FRAUD ENFORCEMENT

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June 2016

OVERVIEW

- **DOJ Developments**
- **Industry-Provider Focus**
- **HHS-OIG Activity**
- **False Claims Act Developments**

NEW DEVELOPMENTS FROM DOJ - POLICY DIRECTIONS -

- **Yates Memorandum**

  More Emphasis on Prosecuting Individuals

  On September 9, 2015 the Department of Justice issued a new policy entitled "Individual Accountability for Corporate Wrongdoing," (a/k/a the "Yates Memo").

  Revisions made to the U.S. Attorneys' Manual.

Emphasized a top priority of DOJ – Fighting Corporate Fraud.

Seeks accountability from those individuals responsible for the fraud in an organization.

- **Deterrence**
- **Promotes changes in corporate culture, and behavior inside the organization**
- **Brings to justice those individuals responsible for wrongdoing**
- **Enhances the trust of the public in the judicial system**

Special Challenges: Proving criminal intent

- **Diffuse authority within an organization, multiple layers of decision making, delegation of authority insulates higher corporate executives**

The Yates Memo strives to ensure that criminal and civil prosecutors take consistent best efforts to identify and prosecute individuals within an organization for illicit corporate conduct.

Six Steps Identified

1. **Cooperation credit to corporations will not be available unless, and until "all relevant facts" of misconduct by individuals are disclosed to the government.**
2. **Both criminal and civil investigations should establish an initial focus of the investigation on individuals and potential culpability.**

3. **There should be enhanced coordination between criminal and civil divisions in conducting corporate investigations.**
4. **Generally, DOJ will not release individuals from criminal or civil liability in the context of settlement with the corporate entity.**
5. **DOJ will not resolve a matter with a corporation absent a plan to resolve cases involving the liability of individuals.**

6. **Civil attorneys are directed to focus their investigations on both the corporate entity and individuals, and should seriously consider filing civil cases against individuals without consideration of ability to pay.**

Clarifications

There have been several clarifying statements made by DOJ officials regarding the level of effort that companies must expend to receive cooperation credit, in view of the broad criteria announced in the Yates Memo.

- **Some companies have wondered whether they would be eligible for cooperation credit even though they may have done investigations, made relevant facts known to the government, but were not able to identify culpable individuals.**

  DOJ has indicated that companies must take affirmative steps to learn about misconduct. Where companies provide to the government the relevant facts, and assist the government in obtaining

evidence, then the company would be eligible to obtain credit even though it did not identify individuals responsible for the wrongdoing. This suggests a "best efforts" standard.

- To obtain cooperation credit, companies will be presumed to have access to evidence of employee culpability, unless the company makes an affirmative showing that the company does not have access to, or is legally prohibited from producing it.

- No waiver of privileges, but the underlying facts are not privileged

DOJ recently announced an informal policy to require companies to confirm their disclosures as required under the Yates Memo.

<u>Examples</u>

- Pharmaceutical company Warner Chilcott:
  - October 2015, DOJ announced indictment of former president for alleged payment of kickbacks to physicians as inducements in marketing of drugs. Former president charged with one count of conspiracy to pay kickbacks.
  - Other former employees pled guilty or were indicted for illegal marketing of drugs.

- **A subsidiary of Warner Chilcott agreed to plead guilty to a felony charge of health care fraud.**
- **The company agreed to resolve civil liability under the False Claims Act, and state false claims acts, and agreed to pay $125 million to resolve civil and criminal liability.**

- **Bostwick Laboratories**
  - **January 8, 2016, the founder, owner and CEO David Bostwick resolved civil suit under the False Claims Act alleging that from 2006 through 2011 Bostwick directed his laboratory to bill the federal government for medical tests not necessary, and not ordered by physicians.**
  - **Additionally, Bostwick allegedly provided incentives to physicians to induce referrals of patients to the lab for testing.**

- **Under the FCA settlement, Bostwick agreed to pay over $2.6 million in addition to $1.125 million conditioned on certain contingencies occurring.**
- **Separately, Bostwick Laboratories settled FCA liability in two agreements for a total of $6.5 million, based on similar facts.**

- **DOJ Fast-Track Program under the Foreign Corrupt Practices Act**

  The government announced a one year fast-track program for self-reporting of violations under the FCPA.

- **New Focus on Criminal Prosecution of Individuals Arising From False Claims Act**

  DOJ to enhance coordination between the Criminal and Civil Divisions to identify worthy cases for criminal prosecution arising from False Claims Act *qui tam* lawsuits.

- **DOJ Hires Compliance Counsel**

  New compliance counsel to assist prosecutors in assessing effectiveness of corporate compliance programs.

  This is an important development because federal prosecutors consider the effectiveness of compliance programs in making charging decisions, and in sentencing recommendations.

This development makes clear the emphasis that DOJ is placing on effective corporate compliance programs when assessing whether to charge corporations for failing to detect or prevent criminal wrongdoing by employees.

The DOJ Criminal Division's Fraud Section indicated that it would be considering more closely compliance programs in the health care sector.

A DOJ representative indicated that the Department intends to hold companies to a "tough but realistic standard."

The new compliance counsel will take the initiative to meet with organizations that have the goal of establishing successful compliance programs.

Going forward, companies need to be prepared to address specific inquiries about the effectiveness and scope of their compliance programs.

Resources:

- A Resource Guide to the U.S. Foreign Corrupt Practices Act published by DOJ and the SEC provides helpful information on effective compliance programs, contained in a section entitled "Hallmarks of Effective Compliance Programs."
- For the health care sector specifically, the U.S. Dept. of Health and Human Services, Office of Inspector General, has issued a series of compliance program guidance.

- The OIG also publishes its Corporate Integrity Agreements.
- Chapter 8 of the United States Sentencing Guidelines (amended in April 2010)

- New DOJ Task Forces To Address Elder Fraud In Health Care

  Task Forces in 10 states will investigate and prosecute nursing homes for substandard quality of care. This is part of the Elder Justice Initiative spearheaded by DOJ.

The ten state states are:

California	**Maryland**
Georgia	**Ohio**
Kansas	**Pennsylvania**
Kentucky	**Tennessee**
Iowa	**Washington**

The Task Forces consist of representatives from the U.S. Attorney's Offices, state Medicaid Fraud Control Units, state and local prosecutors' offices, the U.S. Department of Health and Human Services, state adult protective services agencies, Long-Term Care Ombudsman Programs, and law enforcement.

INDUSTRY – PROVIDER FOCUS

- **Hospice Providers**

  On March 30, 2016, HHS-OIG issued a report on improper billing practices by hospices. Sample of claims were for 2012, indicating over $268 million in excessive claims for general inpatient care (GIP). This equated to nearly one-third of general inpatient care.

General inpatient care is the second most expensive level of Medicare hospice benefit.

- **Continuous Home Care**
- **General Inpatient Care**
- **Inpatient Respite Care**
- **Routine Home Care (most common)**

The report issued by HHS-OIG found that:

1. **For 20 percent of GIP stays, there was no medical necessity for that level of care**
2. **For 10 percent of GIP stays, the beneficiary initially needed that level of care, but the hospital continued to bill at that level after the beneficiary's symptoms were under control**

3. **There was double billing for drug claims. CMS paid for drugs under Medicare Part D, as well as under the GIP rate which covers drug costs for pain and symptom management. This double billing pertained to over half of drug claims**
4. **For 85 percent of GIP stays, there was a lack of compliance by hospices with all care planning requirements**

5. There were more inappropriate GIP stays in skilled nursing facilities compared with hospitals and hospice inpatient units
6. There were more inappropriate billings for GIP by for-profit hospices compared with nonprofit and publicly owned hospices
7. Among the states, Florida, Ohio and Arizona rated highest for inappropriate billing

HHS-OIG Recommendations Which Were Accepted By CMS:

- Increase contractor scrutiny of hospice GIP claims
- Provide for more physician involvement in GIP decisions
- Institute pre-payment reviews of longer GIP stays
- Provide for greater surveyor efforts

- Institute enforcement remedies
- Recoup improper payments
- Greater provider education

- Home Health Agencies

DOJ has made a substantial commitment of resources to pursuing criminal charges against individuals associated with illicit billings under federal health care programs for home health agency benefits.

The criminal charges have focused on billing for services not rendered, failure to have proper plans of care, falsification of documentation, and kickback schemes.

- **On November 12, 2015, Jury Returned Guilty Verdicts for co-owners of Global Healthcare, Inc. for defrauding the District of Columbia Medicaid program of over $80 million**

- **Pharmacies / Pharmacists and Medicare Part D**

On April 28, 2016, DOJ announced that criminal charges were filed against 25 Miami-area defendants in three separate cases, alleging fraud schemes against the Medicare Part D program, exposing the program to losses of approximately $26 million.

This initiative involved coordinated efforts between the Medicare Fraud Strike Force and the FBI.

The three cases are:

- ***United States v. Antonio Hevia, et al.*: This involved the participation of 18 defendants in a scheme to defraud the Medicare Part D program by the filing of false claims from eight separate Miami-Dade County area pharmacies**

  The indictments charge the defendants with various crimes, including conspiracy to commit health care fraud and wire fraud; substantive counts of health care fraud, and conspiracy to pay and receive kickbacks

The fraud scheme consisted of recruiters who arranged for individuals to be owners of pharmacies in Miami-Dade County. These pharmacies submitted false claims for prescription drugs that were not medically necessary and not provided to beneficiaries. Medicare beneficiaries were referred to the pharmacies by patient recruiters, and they received kickbacks for these patient referrals

- ***United States v. Kenia Gonzalez, et al.*: involves several defendants charging them with conspiracy to defraud the Medicare Part D program by receiving kickbacks to recruit Medicare beneficiaries as inducements to obtain prescriptions for drugs that were then billed by pharmacies for reimbursement**

- ***United States v. Ronald Diaz, et al.*: The indictment charges three individuals with conspiracy to commit health care fraud, health care fraud and money laundering. Through the use of various pharmacies, the defendants submitted false claims for drugs that were not medically necessary, and misrepresented that drugs had been prescribed by a physician and provided to Medicare beneficiaries**

- **Clinical Labs**

  On June 25, 2014, HHS-OIG issue a Special Fraud Alert on the subject of laboratory payments to referring physicians. This is an area of continuing interest by the enforcement authorities.

- **Physicians**

  There has been a series of criminal prosecutions against physicians for violation of the Anti-kickback Statute. This trend is likely to continue.

  As part of the growing enforcement trend to hold individuals accountable for wrongdoing, on June 9, 2015, HHS-OIG issued a new Fraud Alert, entitled "Physician Compensation Arrangements May Result in Significant Liability."

Potential exposure to liability, criminal, civil, or administratively imposed monetary penalties, will continue to be reflective of federal enforcement.

In the June 9 Fraud Alert, the agency made clear that it will focus on physician compensation arrangements.

The agency highlighted, as an example, medical directorships, and emphasized that it will examine whether those types of compensation arrangements reflect fair market value for bona fide services actually provided.

The focus of concern addressed in the Fraud Alert is violations of the Anti-Kickback Statute.

The "Takedown" on June 18, 2015, highlights physician exposure to liability. In the largest action to date by the Medicare Fraud Strike Force, federal and state officials announced a nationwide takedown of 243 individuals on charges related to approximately $712 million in alleged false Medicare billings. Of the total arrests, physicians accounted for 46 individuals apprehended. Some of the physicians were charged with violations of the Anti-Kickback Statute.

HHS-OIG has also established a new litigation team to address physician illicit conduct. This new litigation team will focus on:

- **The Civil Monetary Penalties Law**
- **The Stark Law**
- **The Anti-Kickback Statute**
- **Exclusion Authorities**

NEW DEVELOPMENTS FROM HHS-OIG

- **Exclusionary Authority**

  On April 18, 2016, HHS-OIG issued updated guidance on criteria that will be used to determine how to exercise the permissive exclusion authority that can be exercised by the Secretary of the Dept. of Health and Human Services. This is an update from initial guidance issued in 1997.

The April 18 issuance announced the use of a risk assessment "continuum." By issuing this guidance, HHS-OIG provides greater transparency in its decision-making.

As pertinent here, the permissive exclusion authority is codified at Section 1128(b)(7) of the Social Security Act. 42 U.S.C. § 1320a-7(b)(7).

The Secretary's permissive exclusion authority can be exercised for conduct that can also be addressed via the False Claims Act, namely:

- **False or fraudulent claims**
- **Anti-Kickback Statute**
- **Stark Law issues**

Over the years, HHS-OIG's permissive exclusion authority has been part of the process of negotiating settlements under the False Claims Act, in conjunction with the availability and imposition of a corporate integrity agreement (CIA).

The presumption of exclusion has remained as a guiding principle, but has been weighed against other factors, including the imposition of a CIA, that are available in the choice of measures available to HHS-OIG.

Through time, the mix of measures that have been used by HHS-OIG in the context of settlement for False Claims Act liability has included "unilateral monitoring" by HHS-OIG and by choosing not to require a CIA, but also "reserving" permissive exclusion authority by declining to explicitly provide a release in a settlement agreement.

The new guidance for the exercise of permissive exclusion ushers in a new approach, by using a risk assessment "continuum." This approach includes all of the options available to HHS-OIG in determining whether to exclude entities and individuals.

The options, from high-to-low risk, are:

- Exclusion
- Heightened Scrutiny: HHS-OIG monitoring; referrals to CMS or contractors
- CIA
- "Reserving" the exclusion authority, with no further action
- Waiving the exclusion authority in instances of self-disclosure

The HHS-OIG guidance addresses specific reasons for choosing the four options In any given case. It also explains four categories when making a risk assessment.

Arriving at a risk assessment is a focused view of future risk in noncompliant behavior. The assessment though considers past conduct to derive future noncompliance and harm to federal health care programs.

- **CMS Releases Proposed Protocol for Voluntary Self-Referral Disclosures**

  On May 6, 2016, CMS issued a proposal to revise its Voluntary Self-Referral Disclosure Protocol (SRDP).

  Providers will use this to disclose actual or potential violations of the federal physician self-referral prohibition, also known as the Stark Law.

CMS initially established the current SRDP in September 23, 2010 as mandated by the Patient Protection and Affordable Care Act.

Principle purposes of the proposed changes to the SRDP are to reduce the time to resolve disclosures, and to streamline the process with less burden on the disclosing party on the amount of information that is required.

The proposed revisions seek to accomplish several things.

1. **Extend the lookback period to six years to report prohibited referral arrangements (previous lookback period was four years)**
2. **When making a disclosure, the report must address the "pervasiveness of the noncompliance relative to the disclosing party's similar financial relationships [ ] or similar services furnished"**
3. **There also must be a financial analysis of the potential overpayment based on six-year lookback period**

- **Demonstration Program for Prior Authorization of Home Health Services**

  On February 5, 2016, CMS announced that it would establish a demonstration program to test prior authorization requirements for home health services provided to beneficiaries under Medicare fee-for-service.

  OMB needs to approve the program, and a public comment period ended on April 5, 2016.

The project will launch in phases, to cover designated states. The first phase will encompass Florida, Texas and Illinois. The second phase will be in Michigan and Massachusetts.

The prior authorization program has several purposes.

1. **To screen the provision of home health services prior to payment of claims**
2. **To assist in developing enforcement policy to reduce fraud and improper payments**

3. **To identify home health agencies for future potential enforcement**

The Federal Register notice also indicated that CMS would engage in a pilot program for the gathering of information to be used to establish a baseline estimate of probable fraud in payments for home health services. The goal is to establish an estimate of the percentage of total payments that are associated with probable fraud and the percentage of all claims that are associated with probable fraud. It is anticipated that this information would provide valuable guidance in establishing policies and further tools to combat fraud.

FALSE CLAIMS ACT DEVELOPMENTS

- **Sixty-Day Repayment Rule**

  It is anticipated that further litigation will be brought under the reverse false claims provision of the FCA for failure to repay overpayments with sixty days from the time that such overpayments are identified. The sixty-day provision was added to the Social Security Act by the Patient Protection and Affordable Care Act, and is codified at 42 U.S.C. § 1320a-7k(d).

- ***Kane ex rel. United states v. Healthfirst, Inc.,* 120 F.Supp.3d 370 (S.D. N.Y. Aug. 3, 2015)**

- **Congressional Interest In Amendments To the False Claims Act**

  On April 28, 2016, hearings were held on Capitol Hill on proposals to amend the FCA. The hearings were sponsored by the House Judiciary Committee's Subcommittee on the Constitution and Civil Justice.

The hearing considered two primary proposals to amend the statute.

- **Require corporate whistleblowers to report suspected frauds internally prior to the filing of a FCA lawsuit**
- **Limit or eliminate monetary liability of those companies that have adopted a corporate compliance program that meets a "gold standard"**

These proposals arise from recommendations made by the U.S. Chamber of Commerce in a 2013 report. There, the FCA was viewed as providing ill-advised incentives to file meritless lawsuits giving rise to "irrationally excessive penalties for technical violations."

Senator Chuck Grassley testified at the hearing. He stated that the *qui tam* provisions of the FCA were essential to protect taxpayer dollars against fraud. Senator Grassley opined that imposing internal reporting of fraud prior to filing a lawsuit would erect significant obstacles in protecting whistleblowers from retaliation.

At the hearing, the Subcommittee explored the option of reducing the significant monetary liability that the FCA imposes where a company has put in place a "gold standard" compliance program.

The proposal focused on the damages multiplier and administrative exclusion authorities.

For companies that adopt a compliance program meeting criteria viewed as a "gold standard," monetary liability would not include these aspects of relief that can be imposed under the FCA.

- **False Claims Act Penalties To Increase**

  As a result of a budget deal the Administration reached with Congress, all federal agencies are directed to issue regulations by July 1, 2016 that would increase civil penalties under the FCA for cases that fall within their jurisdiction.

The first agency to do this, via an interim final rule, was the Railroad Retirement Board. The RRB indicated in the rulemaking that for false claims or statement made on or after August 1, 2016, the range of civil penalties in FCA cases under the RRB's jurisdiction will increase from the current minimum of $5,500 and the maximum of $11,000, to a newly set range established by formula.

The new range for FCA cases within the RRB's jurisdiction will be a new minimum of $10,781 and a new maximum of $21,563, applied per false claim.

The formula used by the RRB is set by statute, and applies to all other agencies where the FCA falls within their jurisdiction. There is no discretion provided in setting the new range for penalties.

It is expected that other agencies will be announcing increases in the range of FCA penalties over the next few months.

These increases in the FCA penalty range will encourage further arguments that the penalties under the FCA are punitive in nature, and violate the Constitutional prohibition under the Eight Amendment against excessive fines.

Noteworthy Cases -

- ***Universal Health Services, Inc. v. United States and Commonwealth of Massachusetts ex rel. Escobar***

  On December 4, 2015, the U.S. Supreme Court granted writ of certiorari to the First Circuit. Oral argument occurred on April 19, 2016. A decision by the Supreme Court is expected in June.

  Issue: The validity of the implied certification theory of liability under the FCA.

Background:

The matter arises under the Massachusetts Medicaid program, known as MassHealth. The focus was specifically on the regulations implementing the program for the provision of mental health services. The federal government and the Commonwealth of Massachusetts declined to intervene in the *qui tam* action. Before the Supreme Court, the Petitioner has argued for a rejection of the implied certification theory, based on a common sense interpretation

of the word "false or fraudulent" under the FCA, and also predicated on notions of common law fraud.

Alternatively, the Petitioner has argued that, assuming the Court is inclined to uphold the validity of the implied certification theory generally, as a matter of law, the theory only should have applicability for FCA liability where the underlying statute, regulation or contract expressly states that compliance therewith is a condition of payment.

- ***United States ex rel. Michaels v. Agape Senior Community, Inc.*** **Nos. 15-2145(L) and 15-2147**

  The Fourth Circuit granted an interlocutory appeal from a decision by the U.S. District Court for South Carolina.

  - ***United States ex rel. Michaels v. Agape Senior Community, Inc.*****, No. 0:12—3466 (D. S.C.)**

  Issue: Whether statistical sampling can be used to prove liability and damages under the FCA.

- ***U.S. v. Life Care Centers*****, 114 F.Supp.3d 549 (E.D. Tenn. Sept. 29, 2014)**
- ***U.S. ex rel. Ruckh v. Genoa Healthcare, LLC*****, 2015 U.S. Dist. LEXIS 55384 (M.D. Fla. April 28, 2015)**

- ***United States v. AseraCare, Inc.*****, 2016 U.S. Dist. LEXIS 42986 (N.D. AL)**

  On March 31, 2016, the U.S. District Court for the Northern District of Alabama granted summary judgment to AseraCare, dismissing a FCA case against the hospice provider, holding that differences of medical opinion are insufficient to establish falsity of claims.

- ***United States ex rel. Bunk v. Birkart Globistics GmbH & Co.***

  The Fourth Circuit will decide the test to use for successor liability under the FCA.

  Issue: Whether successor liability may be imposed on a successor, in the context of an acquisition, for damages and penalties imposed on its predecessor under the FCA.

  - **Split among the lower courts on the test to apply to determine successor liability.**

- **Dueling tests – "Traditional Rule" (common law) or "Substantial Continuity Rule"**

Oral argument was held before the Fourth Circuit on May 11, 2016.

- ***PharMerica Corporation v. United States ex rel. Gadbois***

  On April 22, 2016, a Petition for Writ of Certiorari was filed seeking review by the U.S. Supreme Court of a First Circuit decision on the first-to-file bar under the FCA.

  - ***United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1 (1st Cir. Dec. 16, 2015)**

  Issue: To resolve a split among the courts of appeals on the interpretation of the first-to-file bar under 31 U.S.C. § 3730(b)(5).