

# HEALTHCARE PRACTICE

10 NEW REASONS TO TUNE UP  
YOUR COMPLIANCE PROGRAM

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## HEALTHCARE PRACTICE

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## TURNING UP THE HEAT

### IT IS TIME TO UPDATE YOUR COMPLIANCE PLAN TO MEET THE NEW CHALLENGES OF HEALTH CARE REFORM

#### INTRODUCTION

Health care is on the forefront of national and local attention. Health care providers have been, and continue to be, the target of criminal, civil and administrative enforcement actions. Federal and state officials are intent on purging fraud and abuse from the health care delivery system. The targeting of clinical laboratories and other health care providers is driven by the perception that fraud is rampant in the health care system and must be eradicated.

As the government and private sector payors increase the intensity of their efforts to fight health care fraud, the burdens placed upon honest health care providers have also escalated.

1. Health care providers face an increasing public relations challenge to overcome being painted in an unfavorable light—as culprits intent on defrauding the system—even though most providers are more committed to compliance than ever before.
2. As the government accelerates its spending on fraud prevention, health care providers must also increase spending in order to comply with progressively complex laws, regulations and oversight.<sup>1</sup>
3. Providers must withstand increased scrutiny from regulators and law enforcement as well as senior citizens enlisted to fight fraud.<sup>2</sup>

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1 During Fiscal Year (FY) 2009, anti-fraud efforts returned \$2.51 billion to the Medicare Trust Fund; in addition, \$441 million in federal Medicaid money was returned to the Treasury. See the Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2009.

2 Senior citizens are being “trained” by the federal government to combat and report medical fraud. See Stop Medicare Fraud, <http://www.stopmedicarefraud.gov/> (last visited Oct. 5, 2010). In 2010, the Federal Administration on Aging (“AoA”) made grants to expand the Senior Medicare Patrol (SMP). Alaska’s Department of Health and Social Services received a federal grant of \$50,000, the California Health Advocates received a grant of \$430,000 and the Washington State



4. Providers must balance the need to spend limited resources on high quality health care against the increasing cost of regulatory compliance. Regulators continue to embrace the premise that America's health care system can provide better care with fewer resources.<sup>3</sup>

## HEALTH CARE REFORM HAS RESULTED IN A PERILOUS LANDSCAPE: NEW STATUTES, PROCESSES & INVESTIGATIVE TOOLS

The fact that recent health care fraud prosecutions have brought the government enormous bounties at a time when governmental budgets are under strain has not gone unnoticed.<sup>4</sup> One example of government action is the recently enacted Affordable Care Act ("ACA"), also referred to as the Patient Protection and Affordable Care Act ("PPACA"), which was signed into law by President Obama on March 23, 2010.

PPACA raises the government's financial commitment to fighting health care fraud in 2011 to \$1.7 billion. In addition, the PPACA toughens sentencing for criminal activity, enhances Medicare screening and enrollment requirements, encourages increased sharing of data across government, expands overpayment recovery efforts, and provides greater oversight of private insurance abuses.<sup>5</sup> The new law also raises the bar for health care providers who seek to avoid liability for inadvertent non-compliance and limits the entry of new providers (and possibly startup innovation).<sup>6</sup>

PPACA comes on the heels of last year's Fraud Enforcement and Recovery Act ("FERA"), as well as the Health Care Fraud Prevention and Enforcement Action Team (HEAT), an aggressive interagency task force created last year by Attorney General Eric H. Holder Jr. and Health and Human Services Secretary

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Office of the Insurance Commissioner received a \$150,000 grant. See also Administration on Aging, Senior Medicare Patrol, [http://www.aoa.gov/AoARoot/AoA\\_Programs/Elder\\_Rights/SMP/index.aspx#purpose](http://www.aoa.gov/AoARoot/AoA_Programs/Elder_Rights/SMP/index.aspx#purpose) (last visited Oct. 5, 2010) ("Since 1997, AoA has funded SMP projects to recruit and train retired professionals and other senior citizens about how to recognize and report instances or patterns of health care fraud.")

3 President Obama has stated the case as follows: "A growing body of research points to substantial opportunities to improve quality while reducing the costs of care. Health care systems in many parts of the country deliver high quality care to the populations they serve at half the cost of other equally renowned academic medical centers in other parts of the country. The key is to provide information, incentives and support to help physicians and others work together to improve quality of care while reducing costs." Barack Obama and Joe Biden's Plan to Lower Health Care Costs and Ensure Affordable, Accessible Health Coverage for All, available at [www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf](http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf) (last visited Oct. 10, 2010).

4 For fiscal year 2009, the Department of Health and Human Services Office of Inspector General announced that audit, investigation, and evaluation accomplishments resulted in savings and expected recoveries of \$20.97 billion. OIG Reports \$20.97 Billion in Savings and Recoveries in FY 2009, Office of Inspector General News (2009), <http://oig.hhs.gov/publications/docs/press/2009/SemiannualFall2009PressRelease.pdf>.

5 July 16, 2010 News Release from the Department of Health and Human Services, available at <http://www.hhs.gov/news/press/2010pres/07/20100716a.html>, (last visited Oct. 5, 2010).

6 For more guidance on how providers and suppliers can avoid common billing errors and other compliance problem, be sure to consult the CMS' newly developed [Medicare Quality Provider Compliance Newsletter](#). The first issue discusses a wide range of issues affecting various provider types (e.g., inpatient hospitals and skilled nursing facilities' failure to submit request documentation). CMS has also begun to issue a series of [Medicare Learning Network \(MLN\) Matters](#) articles to educate providers about program vulnerabilities identified during the RAC demonstration. These articles address denials based on untimely or insufficient documentation, medical necessity, and certain common coding errors.

Kathleen Sebelius to combat Medicare and Medicaid fraud. Health care providers must meet the current environment of heightened scrutiny and new laws by carefully assessing their compliance risks and then implementing strategies to control those risks. Indeed, PPACA now mandates that providers implement and maintain a compliance program. We strongly advise providers not only to satisfy the new legal requirements, but also to assure that their plans, policies and procedures actually enable them to manage the risks of regulatory compliance.

**The goal of this paper is to state the case for why you should update your compliance program and why you should be proactive about compliance.**

## TEN REASONS TO REVIEW AND UPDATE YOUR COMPLIANCE PROGRAM

There are at least ten reasons why you should update your compliance plan and use it as the core guide for your compliance efforts.

### 1. COMPLIANCE PROGRAMS ARE NOT MERELY ADVISABLE, THEY ARE NOW REQUIRED

As a result of PPACA, providers and suppliers participating in Medicaid or the State Children's Health Insurance Program will be required to establish compliance programs as a condition of enrollment. Those compliance programs must contain certain "core elements." The Secretary of Health and Human Services ("HHS") is directed to identify these "core elements."<sup>7</sup> The core elements will be specific to particular industry and category groupings. For example, the Secretary may decide to treat laboratories as one grouping/industry and physicians as a separate grouping/industry.

As you may be aware, currently Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) requires large Medicaid providers and suppliers (i.e., those with annual revenues in excess of \$5 million) to establish written policies for all employees (including management), and for any contractor or agent with details regarding the process used by the Medicaid provider/supplier to detect fraud, waste and abuse. These policies must include detailed information about the False Claims Act, administrative remedies for false claims, state laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws.

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<sup>7</sup> PPACA § 6401; Social Security Act (hereinafter "SSA") § 1866(j).

It is unclear at this time how the PPACA requirements for compliance programs will compare to Section 1902(a)'s existing requirements. However, it is likely that the core elements required by PPACA will include both the types of policies required by Section 1902(a) and a compliance monitoring process.

We anticipate that the new "core elements" (see chart) will be based, in part, on existing OIG compliance guidance<sup>8</sup> and the elements of a compliance plan as set out in the Federal Sentencing Guidelines.

### LIKELY CORE ELEMENTS OF A COMPLIANCE PROGRAM BASED ON EXISTING OIG COMPLIANCE GUIDANCE AND FEDERAL SENTENCING GUIDELINES

1. Establishment of a chief compliance officer and compliance committee (with a direct reporting relationship between the compliance officer and the board).
2. Written standards of conduct (a code of conduct) and written policies and procedures pertaining to specific areas of health care operation.
3. Education and training programs for affected employees.
4. A process for receiving complaints.
5. A system to respond to allegations of improper conduct and impose appropriate discipline.
6. An auditing/monitoring mechanism.
7. A plan for promptly responding to detected offenses and implementing corrective action.

Providers and suppliers with robust compliance processes will inevitably need to adjust existing compliance programs. Those providers and suppliers whose compliance plans are simply gathering dust on a shelf will likely need to put new compliance processes in place.

## 2. FRAUD ENFORCEMENT: YOU AND YOUR COMPANY ARE TARGETS

In order to effect organizational change, the government has frequently chosen to hold corporate officers responsible for company missteps. This is exactly what the Office of Inspector General has announced it intends to do in the health care industry.

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<sup>8</sup> See Compliance Program Guidance for Clinical Laboratories (PDF) (63 FR 45076; August 24, 1998), available at website for U.S. Dept of Health and Human Services, Office of Inspector General, Compliance Guidance, <http://oig.hhs.gov/fraud/complianceguidance.asp> (last visited Oct. 13, 2010).

Thus, not only is an organization subject to civil and/or criminal liability based on its policies and procedures, its officers, high-level managers, and employees also are exposed to personal responsibility. In the absence of specific statutory authority, state and federal prosecutors and regulators routinely have relied on two legal theories to hold individuals responsible for the organization's conduct: (1) accomplice liability, and (2) the "Responsible Corporate Officer" doctrine.

We draw your attention to the following comments of Daniel R. Levinson, Inspector General of the Department of Health & Human Services, which were delivered at the Health Care Compliance Association Annual Compliance Institute on April 19, 2010, and posted on the internet under the heading – **Individual Accountability**.<sup>9</sup>

### INDIVIDUAL ACCOUNTABILITY

The OIG is focused on holding Responsible Corporate Officials accountable for health care fraud.

- ▶ Under the "responsible corporate officer" doctrine, corporate officers are subject to both civil and criminal liability for corporate violations of statutes affecting public welfare.
- ▶ Liability as a responsible corporate officer does not turn upon a corporate officer's approval of wrongdoing, but rather on whether the officer had, by reason of his or her position in the corporation, responsibility and authority either to prevent, or promptly correct, the violation at issue, and the officer failed to do so.
- ▶ The doctrine has been applied extensively in a variety of criminal cases involving public welfare statutes. For example:
  - OIG recently excluded the chairman of a large nursing home chain for his responsibility in the alleged provision of substandard care to residents of his facilities, including failure to protect residents from accidents, neglect, and abuse, exacerbated by chronic understaffing.
  - OIG excluded for 12 years the CEO, General Counsel, and Chief Medical Officer of Purdue Frederick based on their misdemeanor convictions related to misbranding of oxycontin.

Compliance is personal; D&O and umbrella insurance may not cover your inaction.

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<sup>9</sup> See <http://oig.hhs.gov/testimony.asp>.

### 3. THE GOVERNMENT HAS DEDICATED MORE ENFORCEMENT RESOURCES

The Health Care Fraud and Abuse Control (“HCFAC”) Program was established by HIPAA in 1996. HCFAC is a national program designed to combat fraud committed against all health plans, both public and private. HCFAC coordinates federal, state and local law enforcement activities. HCFAC operates under the joint direction of the U.S. Attorney General and the Secretary of HHS acting through the Department’s Inspector General (“HHS/OIG”).

In recent years, HCFAC’s resources have expanded. In 2011, the total commitment for HCFAC’s anti-fraud programs is \$1.7 billion. Meanwhile, HHS’ OIG Office of Investigations has roughly 500 investigators and approximately 75 attorneys (up from only 14 twenty-five years ago).<sup>10</sup> These enforcement officials have been busy—last year their work resulted in 1,014 new criminal investigations and 886 new civil investigations.<sup>11</sup>

#### HCFAC BUDGET HIGHLIGHTS

- ▶ Omnibus Appropriations Act of 2009 provided a one-time additional \$198 million
- ▶ 2010 budget invests \$311 million in two-year funding (50% increase over FY09)
- ▶ 2011 budget seeks \$250 million to expand HEAT
- ▶ PPACA increases HCFAC Account for FY11-20 by \$10 million per year
- ▶ Reconciliation Act added an additional \$250 million to the account between 2011 and 2016

### 4. FRONT-END FOCUS

Attorney General Eric Holder and HHS Secretary Kathleen Sebelius have made it clear: the focus of health care anti-fraud efforts has shifted from recovering illegal payments to preventing questionable payments at the front end. Likewise, PPACA authorizes more

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10 Lew Morris, Chief Counsel to HHS-OIG. AHLA “Reflections,” August 2010, pp. 1, 36 and 37.

11 2009 Health Care Fraud and Abuse Control Program Report to Congress.

stringent processes and requirements, with the goal of preventing enrollment by unethical health care providers. Unfortunately, those same measures may slow reputable providers who are enrolling in Medicare and Medicaid. PPACA provides for the following possible changes:

- ▶ Increased enrollment screening;<sup>12</sup>
- ▶ Temporary enrollment moratoria;<sup>13</sup>
- ▶ Enhanced oversight, such as prepayment review and payment caps for newly enrolled Medicare/Medicaid and CHIP providers;<sup>14</sup>
- ▶ Shared information databases;<sup>15</sup>
- ▶ Required use of National Provider Identifier on Medicare and Medicaid claims and on enrollment applications;<sup>16</sup>
- ▶ Unscheduled and unannounced site visits, including pre-enrollment site visits;
- ▶ Database checks (including such checks across states); and
- ▶ Payment suspensions pending the completion of an investigation.<sup>17</sup>

As required by PPACA, CMS recently issued proposed regulations governing the Medicare, Medicaid and CHIP enrollment (and re-enrollment) process for providers and suppliers.<sup>18</sup> In setting screening requirements, the proposed regulations group health care providers into three categories of risk for fraud, waste and abuse: limited, moderate and high. Publicly-traded providers (including laboratories) are designated “limited risk,” as are physicians and physician groups (presumably physician-owned labs and pathology groups). Privately-owned independent clinical laboratories are deemed “moderate” risk for screening purposes due to “a number of potentials for fraud, not the least of which is the sheer volume of service and

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12 PPACA § 6401; SSA § 1866(j).

13 Medicare: PPACA § 6401; SSA § 1866(j). Medicaid: PPACA § 6401; SSA § 1902(a).

14 PPACA § 6402; SSA § 1128J.

15 PPACA § 6402; SSA § 1128J.

16 PPACA § 6402; SSA § 1128J.

17 PPACA § 6402; SSA § 1128J.

18 PPACA § 6401; SSA § 1866(j). Proposed regulations published at 75 Fed. Reg. 58024 (Sept. 23, 2010). Required screening will include verification of provider-specific Medicare requirements and licensure, database checks, unscheduled site visits, and, in some cases, criminal background checks and fingerprinting.

associated billing generated by these entities.”<sup>19</sup> Neither category requires background checks or fingerprinting, but the “moderate” risk classification mandates unscheduled site visits.

## 5. NEW MEDICAID EXCLUSIONS

PPACA requires state Medicaid programs to exclude anyone who is terminated by Medicare or another state’s program.<sup>20</sup> Additionally, Medicaid programs must exclude anyone that fails to repay overpayments. PPACA also requires Medicaid programs to implement many of the federal fraud and abuse regulations.

## 6. NEW SELF-POLICING REQUIREMENTS

PPACA creates a clear obligation to report and repay overpayments; thus removing any doubt whether an inadvertent overpayment must be repaid. An overpayment is defined as any Medicare or Medicaid funds that a person receives or retains to which the person, after “applicable reconciliation,” is not entitled.<sup>21</sup>

Laboratories must report and return overpayments to the appropriate agency no later than 60 days after the date the overpayment was “identified.”<sup>22</sup> Additionally, PPACA requires providers/suppliers to provide a writing describing the reason for the overpayment.<sup>23</sup> As discussed below, a failure to comply with these requirements can result in liability under the Civil Monetary Penalties law and/or the False Claims Act.

Unfortunately, PPACA does not define what the term “identified” means, nor does it state what meaning to attach to the term “after applicable reconciliation,” therefore, it is difficult to know, presently, when the 60 day notice period begins or ends.

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19 75 Fed. Reg. 58211 (Sept. 23, 2010)

20 PPACA § 6502; SSA § 1902(a).

21 PPACA § 6402; SSA § 1128J.

22 PPACA § 6402; SSA § 1128J.

23 PPACA § 6402; SSA § 1128J.

## 7. THE GOVERNMENT WILL HAVE AN EASIER TIME PROVING FRAUD

The FCA was amended in 2009 to remove some of the language that had been used by criminal defense lawyers to avoid FCA convictions. Lawyers have often argued that defendants did not act with culpable knowledge. Briefly, the changes in 2009 re-defined what constitutes a knowing violation of the law. As amended, the FCA defined “knowing” to mean that the provider (1) had actual knowledge of the information; (2) acted in deliberate ignorance of the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information.

PPACA defines the terms ‘knowing’ and ‘knowingly’ in other provisions of law by adopting the definition under the FCA. This is a significant change.

For example, it is likely that courts will interpret the FCA as now allowing a conviction when a provider retains monies which it received from a private company, even if the provider did not realize that the private company received some portion of those monies from the government. (As indicated above, PPACA clarifies that a failure to return an overpayment is a violation of the FCA.)<sup>24</sup>

In addition, this change will also make it easier for the government to obtain a conviction under the Anti-kickback Statute (“AKS”). Formerly, some (but not all) courts had determined that an AKS violation required proof that the defendant both knew about the law and intended to violate it. PPACA now provides that claims submitted while a provider is violating the AKS constitute fraudulent claims under the FCA, and that a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS.

PPACA thus changed the standard of proof such that ignorance of the AKS is no longer an excuse—an AKS violation may occur even though the defendant did not know (1) about the law, or (2) that his/her actions violate the AKS.

PPACA's clarification of the relationship between the AKS and the FCA also makes AKS claims subject to qui tam suits and FCA penalties (treble damages and civil penalties of \$5,500-\$11,000 for each false claim) as well as AKS penalties (up to 5 years in prison, a \$25,000 criminal fine, a \$50,000 civil fine, and exclusion).

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24 PPACA § 6402; SSA § 1128J.

The AKS was also amended by PPACA so that liability now attaches to a false statement that is merely “material to a false or fraudulent claim” (i.e., a statement that has the capacity to influence a payment).<sup>25</sup> Consequently, prosecutors are no longer required to show that a provider took affirmative actions to conceal an overpayment or that the government was misled by the false claim.

Finally, PPACA also lowered the standard of proof under the Health Care Fraud Statute (“HCFS”), a criminal statute, by specifying that a person need not have actual knowledge of the HCFS or specific intent to commit a violation of the HCFS to violate the law.<sup>26</sup>

## 8. EXPECT MORE QUI TAM LAWSUITS

### ‘Qui Tam Relator’

A private citizen who files a lawsuit in the name of the federal government.

Qui tam allegations already account for 80% of health care fraud investigations. After PPACA, it will be easier for qui tam relators to bring FCA lawsuits, for the following reasons:

- ▶ First, the government is now authorized to share Civil Investigative Demand (“CID”) information with relators.
- ▶ Under prior law, qui tam lawsuits were dismissed if the claims were based on publicly-disclosed information. PPACA provides that the court will allow the case to go forward if the government opposes dismissal. Therefore, relators are no longer required to have direct knowledge of the FCA violations and do not even need to be an original source of the information. Finally, the amendments protect whistleblowers who disclose information to the government after a public disclosure but before officially filing a complaint.<sup>27</sup>

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25 PPACA § 6408; SSA § 1128A(a).

26 PPACA § 10606; 18 U.S.C. § 1347.

27 PPACA § 10104; 31 U.S.C. § 3730(e).

- ▶ PPACA reverses court decisions that held that state and local government proceedings involving the behavior underlying the qui tam lawsuit (e.g., employment litigation, shareholder suits, etc.) could not form the basis of a qui tam suit. Thus, these types of decisions will no longer result in a dismissal of a qui tam action.
- ▶ Finally, PPACA narrows the FCA's "public disclosure bar" (see below). Qui tam suits are now only prohibited by the public disclosure bar if the public disclosure of allegations or transactions occurs via: a federal hearing in which the federal government is a party; a congressional report, or federal audit, report or investigation; or a news media report.

### FCA Public Disclosure Bar

Prevents private plaintiffs from bringing qui tam lawsuits if the lawsuit is based upon the public disclosure of allegations or transactions via certain defined sources.

## 9. EXPANDED INVESTIGATIVE TOOLS

**Civil Investigative Demand ("CID"):** A potent tool for investigators examining violations of the FCA since 1986, CIDs can include requests for documents, demands for depositions, or interrogatories. Prior to PPACA, only the Attorney General was authorized to issue CIDs. After PPACA, the law allows the Attorney General to delegate this authority. Finally, CIDs are now accompanied by two new punches: (1) failure to allow the OIG timely access to requested materials or testimony will be punished by a \$15,000 per day penalty; and (2) those who fail to maintain and provide HHS access to documents can be excluded.

**RAC Auditors:** Since 2006, RAC auditors were contracted to audit and detect improper payments on a contingent fee basis. Now, Medicaid programs must employ their own RAC auditors.<sup>28</sup>

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28 PPACA § 6411; SSA § 1902(a)(42).

## 10. NEW STARK SELF-DISCLOSURE PROTOCOL

PPACA required HHS (in cooperation with OIG) to establish a disclosure protocol to be used by health care providers/supplier to report violations of the Stark law (“SRDP”).<sup>29</sup> The Stark law is a federal statute which prohibits physicians from making referrals for certain medical services (referred to as “designated health services”) to an entity with which the physicians (or members of the physicians’ family) have a financial relationship, unless the financial relationship falls within certain exceptions.<sup>30</sup> In exchange for self-disclosure, the Secretary of HHS is authorized to reduce the amount due and owing for Stark violations.

As stated above, PPACA established a deadline for reporting and returning overpayments (i.e., (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable). However, if a SRDP is filed, the obligation under PPACA to return any potential overpayment within 60 days will be suspended until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP.

On September 23, 2010, HHS issued the SRDP and posted it on the internet.<sup>31</sup> The SRDP is applicable only to disclosures of actual or potential violations of the self-referral law (i.e., Stark) and must include the following:

- ▶ All relevant information, including names, dates, identification numbers, and a detailed description of the issue, its discovery, investigation, resolution, and any corrective actions (including the restructuring of the disclosed arrangement), as well as a financial assessment of the overpayment. The SRDP must be certified by an organization’s Chief Executive Officer, Chief Financial Officer, or other authorized representative.
- ▶ Parties who are already the subject of a government inquiry (including investigations, audits, or routine oversight activities) are not automatically precluded from the SRDP, although they must notify CMS of any ongoing investigations of which they are aware.
- ▶ As a condition of remaining in the SRDP, disclosing parties must agree to not appeal any overpayment assessed as party of a settlement agreement.

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29 PPACA § 6409.

30 42 U.S.C. § 1395nn; 42 C.F.R. § 411.350 et seq.

31 PPACA § 6409. See CMS Voluntary Self-Referral Disclosure Protocol (2010), [http://www.cms.gov/PhysicianSelfReferral/Downloads/6409\\_SRDP\\_Protocol.pdf](http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf).

- ▶ The disclosure must be submitted electronically to 1877SRDP@cms.hhs.gov. In addition, an original and 1 copy must be mailed to the Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Mailstop C4-25-02, Baltimore, MD 21224-1850. (CMS will acknowledge receipt via email.)

CMS is not bound to resolve a disclosure in any particular fashion or for any specific amount (for instance, CMS is not obligated to reduce a claimed overpayment by any specified percentage) although it will look to the mitigation factors provided in PPACA:

- ▶ The nature and extent of the improper legal practice;
- ▶ The timeliness of self-disclosure;
- ▶ The cooperation in providing additional information relating to the disclosure;
- ▶ The litigation risk associated with the matter disclosed; and
- ▶ The financial position of the disclosing party.

Any reduction based on these factors will be based on an individual appraisal of the facts and circumstances of each disclosed violation. CMS may treat matters discovered outside the scope of the matter initially disclosed as outside the SRDP. Parties are expected to cooperate fully with CMS' verification process.

Parties may not include any repayments as part of their SRDP submission and may not make repayments during CMS' verification without CMS' permission. Parties are encouraged, however, to place reserved payments in an interest bearing escrow account to ensure adequate resources remain available at settlement. CMS also notes that amounts collected from individuals billed in violation of Stark must be refunded to those individuals on a timely basis. The SRDP does not explicitly state how such repayment will occur in connection with a compromised settlement.

## RECOMMENDATIONS

In light of these very significant changes brought about by the health care reform bill, executive leadership at health care enterprises should review existing compliance programs (both written policies and compliance procedures) to assure that the enterprise is ready to fully comply with the new rules which apply to it.

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