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# The new frontier: Compliance issues under the Health Care Reform Law

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The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (together known as the Health Care Reform Law), was signed into law by President Barack Obama in March, 2010. The Health Care Reform Law sets forth new compliance obligations for health care providers. Specifically, it contains more than 32 provisions that address health care fraud and abuse issues as well as program integrity. Many of these provisions significantly amend existing criminal, civil, and administrative anti-fraud statutes. The Health Care Reform Law is complex and comprehensive; it includes a myriad of new programs and initiatives and changes to existing programs, policies, practices, and laws. The general complexity of the Health Care Reform Law makes it likely that additional legislation will be proposed, considered, and enacted over time. It will also require the promulgation of a substantial number of regulations with significant effects on the health care industry, which will be subjected to significant new statutory and regulatory requirements and consequently, to structural and operational changes and challenges for the foreseeable future.

Increased compliance and regulatory requirements, disclosure and transparency obligations, quality of care expectations, and extraordinary enforcement provisions that could greatly increase potential legal exposure are all aspects of the Health Care Reform Law. Undoubtedly, compliance professionals and their colleagues will be required to review and to amend their existing policies and procedures. The purpose of this article is to address a few of the potential new areas for compliance obligations as well as some changes to pre-existing compliance requirements under the Health Care Reform Law.

## Fraud and abuse provisions

### Overpayments and liability under the False Claims Act

Under Section 6402(d) of the Health Care Reform Law, a provider

of services who has received an overpayment must report and repay the overpayment to the applicable government contractor, intermediary, carrier, state, or the Secretary of the Department of Health and Human Services (HHS) within 60 days after the overpayment is identified or the date any corresponding cost report is due, whichever is later. Failure to repay any overpayment within the applicable deadline can lead to liability under the False Claims Act (FCA). Namely, retention of any overpayment after the applicable deadline will be considered an "obligation" as defined by the FCA. There is now a direct correlation between the retention of overpayments and liability under the FCA.

Last year, the Fraud Enforcement Recovery Act of 2009 (FERA) expanded exposure under the FCA, adding liability for false claims paid with government funds<sup>1</sup> and for the retention of money owed to the government.<sup>2</sup> Before FERA, the FCA contained a fairly narrow provision for what is commonly referred to as a "reverse false claims" theory. Under that theory, a "reverse false claim" arises when an overpayment exists, even though a false claim was never filed. The reverse false claim approach makes it possible for FCA liability to arise for "using" a false record or statement to "conceal" or "avoid" or "decrease" an "obligation to pay or transmit money or property to the Government." The FCA generally provides for the imposition of treble damages and civil monetary penalties ranging from \$5,500 to \$11,000 per claim for the knowing presentation of false claims to the government.

FERA expanded FCA liability to instances when a person "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government," whether the person uses a false record or statement to do so or not.<sup>3</sup> The FCA defines "knowing" as (1) having actual knowledge of the information; (2) acting in deliberate ignorance of the truth or falsity of the information; or (3) acting in reckless disregard of the truth or falsity of the information.<sup>4</sup> FERA also redefined an "obligation" under

the FCA to include the “retention of overpayments.” Section 6402 of the Health Care Reform Law defines overpayments as “any funds that a person receives or retains under [Medicare] or [Medicaid] to which the person, after applicable reconciliation is not entitled.”

Although, it seems this new provision of the Health Care Reform Law makes it easier to establish FCA liability for the receipt and retention of overpayments, providers may still have some protections available to them. First and foremost, the FCA is a fraud statute; therefore it is intent-based, and the government or a whistleblower must prove that the provider acted knowingly (as knowingly is defined in the FCA). Second, many unanswered questions about the intersection of the Health Care Reform Law, FERA, and the FCA still remain, which leaves room for interpretation on the part of providers until these issues have been litigated or regulations promulgated. The most striking of the unanswered questions include:

- the meaning of “knowingly conceal” or “knowingly and improperly” avoid or decrease an obligation;
- the meaning of an “obligation to pay;”
- the circumstances that give rise to a provider not being entitled to funds it has received; and
- the meaning of having “identified” an overpayment, such that the 60-day reporting period starts to run.

Despite some of these uncertainties about the overpayment requirement under Section 6402(d), the overpayment provision became effective on March 23, 2010. Accordingly, health care providers, through their compliance professionals, should endeavor to ensure that identified overpayments are repaid promptly. It is important for compliance professionals to revisit their compliance programs to make certain that auditing policies and procedures, as well as detailed repayment processes and procedures, are in place. They should also actively monitor the promulgation of regulations addressing overpayments. In the meantime, they should attempt to define the unanswered questions (above) within their policies and procedures and apply them consistently. Last, but certainly not least, the policies should include language that explicitly states that the organization will repay any identified overpayments within 60 days of having identified them. The policies should also include the provider’s interpretation of what “identified” means.

#### **Permissive exclusion**

Under Section 6402 of the Health Care Reform Law, making false statements or misrepresentations of material facts can lead to permissive exclusion from participation in the federal health care programs. Section 6408 of the Health Care Reform Law authorizes permissive

exclusion from the health care fraud programs if a provider obstructs a government investigation or audit. Previously, 42 U.S.C. § 1320a-7(b) explicitly listed the instances in which an individual or entity could be excluded from participation in any federal health care program. With regard to obstruction of investigations, though, the Office of the Inspector General of the Department of Health and Human Services (OIG) was only allowed to sanction permissive exclusion for obstruction of criminal investigations. The addition of these new Health Care Reform Law provisions now broadens that list and makes it possible for a provider to be excluded from participating in Medicare or Medicaid if any individual or entity “knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a federal health care program” or if any individual or entity obstructs any government investigation or audit. The potential exposure is broad in this era of increased OIG investigations, Medicare Recovery Audit Contractor (RAC) audits, and the like.

Compliance professionals should be aware of their facilities’ and physicians’ Medicare and Medicaid enrollment applications. They should consider enacting policies and providing education that address the possibility of exclusion for knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in a Medicare or Medicaid enrollment application, agreement, bid, or contract or obstructing an investigation or audit. Good reasons exist for instituting or revamping this policy: namely, the existence of a policy related to the prohibition of falsifying Medicare and Medicaid enrollment applications or obstructing any government investigation or audit may be a mitigating factor in the OIG’s exclusion decision.

#### **Civil monetary penalties**

The Social Security Act has long authorized the Secretary of HHS to seek civil monetary penalties (CMPs)<sup>5</sup> and assessments for many different types of conduct,<sup>6</sup> ranging from violations of the Anti-kickback Statute (AKS) to violations of the Emergency Medical Treatment and Active Labor Act (EMTALA). Section 6402 of the Health Care Reform Law has added three additional situations that may now warrant the imposition of CMPs:

- knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a federal health care program;
- knowing of an overpayment and failing to report or return the

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overpayment within the 60-day time period after the overpayment is identified; and

- ordering or prescribing a medical or other item or service during a period in which the provider was excluded from participation in a federal health care program, in the case where the provider knows or should know that a claim for such medical or other item or service will be made under such a program.

OIG is authorized to seek different amounts of CMPs and assessments based on the type of violation at issue.<sup>7</sup> For example, the Health Care Reform Law provides that knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact on any Medicare or Medicaid enrollment application carries with it (1) a CMP of up to \$50,000 for each false statement or misrepresentation of a material fact, or (2) an assessment of not more than three times the total amount claimed for each item or service for which payment was made, based on the application containing the false statement or misrepresentation of a material fact.

Compliance professionals should consider updating their policies and procedures to specifically address all of the circumstances that can give rise to the imposition of CMPs, including these three new situations. The policies should explicitly prohibit certain activities in violation of the fraud and abuse laws, as well as outline examples of non-compliance or the type of conduct that is permissible. Compliance professionals should also educate their facilities' employees about these new instances where CMPs may be imposed and work to deter any such conduct.

### Anti-kickback Statute

The AKS makes it a felony to knowingly and willfully offer, pay, solicit, or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal health care program.<sup>8</sup> The AKS applies to many common health care transactions between entities and persons with which providers do business, including hospital-physician joint ventures, medical director agreements, physician recruitment agreements, physician office leases, and other transactions.

There are two basic elements in a determination of whether the AKS is violated. First, "remuneration" must be involved. A violation of the AKS can occur only where "any remuneration" has been solicited, received, offered or paid. Second, if remuneration is involved, it must be in return for, or to induce, a referral of an individual for, or arranging for, the furnishing of items or services for which payment may be made under a federal or state health care program. The AKS is violated only if both of these elements are present and proven. With

respect to the first element, the term "remuneration" has been broadly interpreted to include practically anything of value. The second element has also been broadly interpreted to include any arrangement that is actually, or could be intended, to influence a person's decision to make referrals (which, obviously, requires that such person be in a position to make such referrals). This second element requires a showing of intent, which is significant in the AKS analysis. In other words, the remuneration must have been solicited, received, offered, or paid "knowingly and willfully" in return for or to induce the referral. Section 6402 of the Health Care Reform Law amends a number of AKS provisions and will have an effect on both of these elements.

A brief examination of the background to the AKS intent requirement demonstrates the potentially sweeping impact of the Health Care Reform Law. Courts have consistently applied the so-called "one purpose test" in AKS cases. Under this test, even though a specific transaction may be motivated by numerous legitimate business purposes, if even one of those purposes was the knowing and willful inducement of a referral of Medicare or Medicaid business (i.e., not necessarily the primary purpose), then the AKS has been violated.<sup>9</sup> Despite this articulated test, however, the precise meaning of the "knowingly and willfully" intent component has provoked varying and inconsistent judicial interpretations over the years.

For instance, the Fifth Circuit Court of Appeals in *United States v. Davis*<sup>10</sup> held that "willfully" meant that "the act was committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law." Thus, under the Davis standard, the "willfully" requirement is met if it is proven that the conduct was unlawful and committed with the intent to do something that the law forbids. Yet, in 1995, the Ninth Circuit Court of Appeals in *United States v. Hanlester Network v. Shalala*<sup>11</sup> held that the "knowingly and willfully" language of the AKS required a finding of a specific intent to violate the AKS itself.

Courts in other jurisdictions, however, declined to follow the *Hanlester* ruling and its reasoning. For example, in *United States v. Neufeld*,<sup>12</sup> the court specifically declined to follow the *Hanlester* reasoning and found that the language of the AKS did not require specific intent to violate the law. Similarly, in *United States v. Jain*,<sup>13</sup> the Eighth Circuit Court of Appeals held that to violate the AKS, a defendant must know that his conduct was wrong, but there is no requirement that the government prove that he violated a known legal duty. And further, the Eleventh Circuit Court of Appeals adopted a standard similar to that set forth in the *Jain* case, holding that the AKS requires only that a

defendant know that his conduct is unlawful and does not require that the defendant know that his behavior violates the AKS.<sup>14</sup>

But clarification of the intent requirement—and, at the very least, changes within the Ninth Circuit Courts—are on the horizon with the passing of the Health Care Reform Law, which essentially repudiates the *Hanlester* ruling. One such amendment within the Health Care Reform Law permits an AKS violation to be established without showing that an individual knew of the statute's proscriptions or acted with specific intent to violate the AKS. Section 10606 of the Health Care Reform Law amends the intent requirement contained in the health care fraud criminal statute. Consistent with the amendment to the AKS, the health care fraud criminal statute now provides that proof of actual knowledge of the health care fraud statute or specific intent to violate the statute is not required. The definition of "health care offense" also is amended to include violation of the AKS, the Food, Drug, and Cosmetic Act, and certain Employee Retirement Income Security Act provisions.<sup>15,16</sup>

Thus, it now appears that cases such as *Davis*, *Neufeld*, and *Jain* could be viewed as consistent with the new law, and further, that the intent standard set forth in the Health Care Reform Law could be viewed as consistent with the United States Supreme Court interpretation of willfulness under other federal statutes and application of this term in the AKS context. In *Bryan v. United States*<sup>17</sup> in 1998, the United States Supreme Court addressed the "willfully" language in the context of a federal statute concerning firearms, holding that "willfully" required only proof that the defendant knew his conduct was unlawful and did not require knowledge of the specific law violated. In *United States v. Anderson*,<sup>18</sup> the district court expressly followed *Bryan* and *Starks* in an AKS violation case, and found that the willfulness standard required that the defendant act intentionally and with the knowledge that his actions violate a law, although it does not require that the defendant know that his actions specifically violated the AKS. Accordingly, the new standard set forth in the Health Care Reform Law, depending on how it is interpreted, could significantly expand criminal and civil fraud exposure for transactions and arrangements where there is no specific intent to violate the AKS.

The AKS remuneration requirement was also amended by the Health Care Reform Law. Specifically, Section 6402 redefined remuneration as it relates to the beneficiary inducement provisions under the CMP provisions of 42 U.S.C. § 1320a-7a. The new definition excludes, among other things, any remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs. Compliance professionals will find this change in the definition of remuneration

beneficial, because providers may now be able to engage in certain activities aimed at assisting beneficiaries in gaining access to health care,<sup>19</sup> consistent with the intent of the Health Care Reform Law.

Finally, the Health Care Reform Law further amended the AKS to explicitly provide that a violation of the statute constitutes a false or fraudulent claim under the FCA. For years, the government has tried to create a link between violations of the AKS and the FCA.

In fact, there have been dozens of cases that have settled due to the tenuous and uncertain relationship between the two. On May 21, 2010, the U.S. Department of Justice announced a settlement with The Health Alliance of Greater Cincinnati (Alliance) and a former member hospital, The Christ Hospital, located in Mount Auburn, OH, to resolve allegations that they violated the AKS and the FCA.<sup>20</sup> The government claimed that the Alliance and The Christ Hospital, in what the government refers to as a "pay-to-play" scheme, unlawfully paid remuneration to doctors in exchange for referring cardiac patients to The Christ Hospital by rewarding referring cardiologists with the opportunity to work in an outpatient cardiology testing unit that provided non-invasive heart procedures. Specifically, the government alleged that referring cardiologists whose referrals contributed to at least 2% of The Christ Hospital's yearly gross revenue were provided with a corresponding percentage of opportunity time in the cardiology testing unit. The government further alleged that the increased time enabled the cardiologists to generate additional income.

In 2007, OIG entered into a settlement under which five orthopaedic implant vendors agreed to pay \$311 million to resolve allegations of AKS and FCA violations related to alleged sham consulting and other payments to physicians that were disguised kickbacks.<sup>21</sup>

The health care amendments establishes a link between the AKS and the FCA. In light of this development, compliance professionals should consider enacting policies and procedures related to relationships and transactions that may be subject to the AKS. These policies should track the particular requirements of relevant safe harbors under the AKS; as well as specifically enumerate what is and is not considered to be remuneration under the statute.

### Nonprofit hospitals

Section 9007 of the Health Care Reform Law sets forth a number of changes applicable to nonprofit hospitals which are exempt under Section 501(c)(3) of the Internal Revenue Code. These changes include:

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- new eligibility requirements for 501(c)(3) hospitals to maintain exemption, coupled with an excise tax for failures to meet certain of those requirements;
- mandatory review by the Internal Revenue Service (IRS) of hospitals' entitlement to exemption under 501(c)(3); and
- new hospital reporting requirements involving community health needs assessments and audited financial statements.

Section 10903 modifies the limitation on the amount that can be charged by a nonprofit hospital for emergency or medically necessary services from the "lowest amount charged" to individuals who have insurance to the amount generally billed. Section 10903 appears to be a direct result of Senator Chuck Grassley's (R-Iowa) continued pressure on nonprofit hospitals since May 2005 as part of a long-running investigation into whether nonprofit hospitals are doing enough to keep their tax-exempt status.

These requirements are set forth in a new Internal Revenue Code Section 501(r). In multi-hospital systems, each hospital must meet these requirements in order to retain that hospital's exempt status. In particular, nonprofit hospitals must:

- conduct a community health needs assessment at least once every three years;
- establish written policies on financial assistance and emergency medical care;
- limit the amounts charged for emergency or other medically necessary care provided to individuals eligible for assistance under the financial assistance policy; and
- refrain from "extraordinary collection efforts" such as collection actions, unless the organization has made reasonable efforts to determine whether the individual is eligible for assistance under the organization's financial assistance policy.

Requirements relating to community health needs assessments will become effective for taxable years beginning after March 23, 2012, while the other requirements became effective on the date the Health Care Reform Law was effective. Failure to comply with the community needs assessment by the taxable year including March 2012 could lead to penalties of up to \$50,000 per year for each hospital.

Many organizations probably already have some of these practices in place, such as written financial assistance policies and conducting community need assessments. Compliance professionals at nonprofit hospitals should review their policies and procedures to ensure that existing protocols match the new requirements of 501(r) for

community input and implementation of the results. If they do not, compliance professionals should update any such policies accordingly.

Section 9007 also imposes additional reporting requirements on the Secretary of the Treasury regarding

- charity care levels,
- bad debt expenses,
- unreimbursed costs for services with respect to non-means tested and means-tested government programs, and
- costs incurred by nonprofit hospitals regarding costs incurred for community benefit.

The Secretary of the Treasury will be required to make an annual report on charity care to certain committees of the House and the Senate, including the Senate Finance Committee with regard to nonprofit, taxable, and government-owned hospitals. The Secretary of the Treasury may have this information readily available to it for nonprofit hospitals from the IRS Form 990 and accompanying Schedules. It is not clear how the Secretary of the Treasury will obtain this information from taxable hospitals and government-owned hospitals, which are not required to file tax returns that contain this information.

IRS Form 990 is used by 501(c)(3) nonprofit organizations to submit information required by the federal government for tax-exemption. On December 20, 2007, the IRS released a revised Form 990 that requires detailed public disclosure of compensation practices, corporate governance, loans to management and others, joint ventures and other types of transactions, political campaign activities, and other areas the IRS deems to be compliance risk areas. The redesigned Form 990 also requires the reporting of detailed community benefit information on Schedule H to the Form, and establishes uniform standards for the reporting of charity care. The mandate to complete the entire Schedule H has been in place since taxable year 2009. The redesigned Form 990 also contains a separate schedule requiring detailed reporting of information relating to tax exempt bonds, including compliance with the arbitrage rules and rules limiting private use of bond-financed facilities, including compliance with the safe harbor guidance in connection with management contracts and research contracts. The redesigned Form 990 results in enhanced transparency as to the operations of exempt organizations. It is also likely to result in enhanced enforcement, as the redesigned Form 990 will make available a wealth of detailed information on compliance risk areas to the IRS and other stakeholders, including state attorneys general, unions, plaintiff's class action attorneys, public watchdog groups, and others.

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As a result of the increased scrutiny of community benefit activity by the IRS, nonprofit hospitals may be required to increase the resources they spend on qualifying activities.

On May 27, 2010, the IRS released Notice 2010-39 requesting comments on these new provisions, including whether any guidance is needed at all. The specific areas on which the IRS solicited comments are:

- the appropriate requirements for a community health needs assessment;
- what constitutes “reasonable efforts” to determine whether a patient is eligible for financial assistance; and
- application of the new provision for loss of exemption as to individual facilities that do not meet the requirements of Section 501(r), including what the tax consequences should be for a failure to meet the requirements of Section 501(r) with respect to some but not all of an organization’s hospitals and the proper tax treatment in future periods.

The comments were due by July 22, 2010. Compliance professionals should monitor any subsequent guidance released by the IRS later this year in order to better understand what the IRS is requiring of nonprofit hospitals as it relates to these new requirements. At that time, it may be necessary for compliance professionals of nonprofit hospitals to reconcile their policies and procedures with the IRS guidance.

#### False Claims Act *qui tam* public disclosure bar

Section 10104(j) of the Health Care Reform Law makes a significant change to the “public disclosure” bar of the FCA—one of the most widely used tools by providers who are targeted by relators through *qui tam* suits under the FCA—the public disclosure bar. For a long time, the public disclosure bar was “jurisdictional,” meaning that a court lacked the power to hear an FCA case if the allegations had been publicly disclosed in a criminal, civil, or administrative proceeding; a congressional, administrative, or Government Accountability Office report, hearing, audit, or investigation; or the news media.<sup>22</sup> As such, the public disclosure bar required dismissal of such a *qui tam* suit. Before the Health Care Reform Law, Section 31 U.S.C. § 3730(e)(4)(A) of the FCA provided that “no court shall have jurisdiction over an action based on the public disclosure of allegations or transactions.” The Health Care Reform Law removes this jurisdictional bar, and instead requires that, “the court shall dismiss an action or claim under this section unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed.” This change gives great power to the government to quash a provider’s motion to dismiss a *qui tam* suit based on the public disclosure bar.

The Health Care Reform Law further limits the use of the public dis-

closure bar only with respect to

- federal criminal, civil, and administrative proceedings in which the government or its agent is a party; and
- federal reports, hearings, audits, or investigations.

Before the passage of the Health Care Reform Law, it was unclear as to whether state reports, hearings, audits, or investigations were included as public disclosures under the FCA. This amendment may be seen as different from the United States Supreme Court’s decision in *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*,<sup>23</sup> which was issued shortly after the enactment of the Health Care Reform Law. The Graham County court reversed the lower court’s ruling extending the scope of the public disclosure bar to include state proceedings. The Graham County court held that the reference in Section 3730(e)(4)(A) to “administrative” reports and audits was not limited to federal sources. The Graham County court also specifically noted that because the FCA amendments within the Health Care Reform Law (enacted on March 23, 2010) did “not mention retroactivity, which would be necessary for its application to pending cases” including the case at hand, the court stated that the public disclosure amendments of the Health Care Reform were not retroactive.<sup>24</sup> Accordingly, the public disclosure amendments do not apply to cases pending on or before March 23, 2010.

The FCA provides that where a public disclosure has taken place, the relator can only proceed with the action if he or she is the original source of the information.<sup>25</sup> Before the amendments to the FCA contained in the Health Care Reform Law, to qualify as an original source, the relator had to have direct and independent knowledge of the allegations that were allegedly publicly disclosed. The amendments to the FCA contained in the Health Care Reform Law have made it easier for a relator to qualify as an “original source.” In fact, the relator does not have to have direct knowledge of the publicly disclosed allegations. In order to qualify as an original source under the new law, the relator may arguably establish and maintain his status in a case by (1) simply voluntarily providing to the government information on which the claims or transactions of the case are based prior to the public disclosure; or (2) having information which is independent of, and materially adds to, the publicly disclosed allegations. This amendment to the original source exception reduces another mechanism used by defendants to defend against frivolous *qui tam* suits.

These amendments to the FCA public disclosure bar and the definition of original source will allow more *qui tam* suits to proceed past the motion to dismiss stage and ultimately cause providers to have to

deal with more frivolous law suits. It is important that compliance professionals understand the risks relators pose to their organizations, especially with many of the provisions under the FCA being relaxed in the relator's favor.

### Stark Law self-disclosure protocol

Section 6409 of the Health Care Reform Law creates a new statutory self-disclosure protocol for violations of the Stark Law (the Stark Law Protocol), especially for those categories that do not fall within the purview of the OIG Provider Self-Disclosure Protocol (the SDP).<sup>26</sup> OIG developed its Protocol in 1998 for providers who were not currently under investigation for the particular conduct to be disclosed.<sup>27</sup> OIG intended that the SDP would be a more open-ended process that did not set limitations on the conditions under which a health care provider could disclose potential non-compliance to OIG. Subsequently, OIG issued two open letters—in April 2006 and April 2008—encouraging health care providers to use the SDP to resolve violations of both the Stark Law and the AKS. The Stark Law prohibits, subject to limited exceptions, a physician who has a financial relationship, or whose immediate family member has a financial relationship, with entities providing “designated health services” (DHS) from referring Medicare or Medicaid patients to such entities for the furnishing of such DHS.<sup>28</sup>

The introduction of the Stark Law Protocol is very timely. Just last year, on March 24, 2009, OIG announced two policy changes to the SDP that limited a provider's use of the SDP for the reporting of Stark Law violations.

In particular, the March 2009 guidance served to (1) clarify when the SDP should be used to address potential Stark Law violations; and (2) narrow the applicability of the OIG's April 24, 2006 Open Letter.<sup>29</sup> OIG encouraged health care providers to resort to the SDP for potential Stark Law violations only if there were also potential AKS violations. OIG also stated that it will impose a minimum CMP of \$50,000 for noncompliance with the Stark Law and the AKS reported under the SDP. Accordingly, the March 2009 Open Letter left many health care providers without an avenue to disclose and to resolve potential Stark Law violations.

This new Stark Law Protocol will provide for agency discretion to resolve Stark Law violations and authorizes HHS to reduce the amount due and owing for all violations under the Stark Law. HHS may consider such factors as:

- the nature and extent of the improper practice;

- the timeliness of the disclosure;
- cooperation by the disclosing party; and
- other factors within HHS' discretion.

The Stark Law is a strict liability statute, which means that the government does not need to prove that a provider acted with intent to violate the Stark Law.<sup>30</sup> The Stark Law generally applies to physician referrals of DHS to entities with which they have financial relationships. Reimbursement received by an entity based on a prohibited referral may result in an overpayment. Because the new provisions within Section 6402 of the Health Care Reform Law relate to when overpayments may become obligations subject to the FCA, the establishment of the Stark Law Protocol should be beneficial to health care providers because it may be a way to disclose and resolve Stark Law violations, while escaping liability under the FCA.

The Stark Law Protocol is supposed to be developed within six months of the effective date of the Health Care Reform Law. That means the Centers for Medicare & Medicaid Services (CMS) is expected to publish the process for the Stark Law Protocol by the end of September 2010. When CMS establishes the process, compliance professionals should revisit their policies and procedures regarding disclosures of Stark Law violations to ensure they are consistent with the Stark Law Protocol.

### Recovery Audit Contractor activities

Under Section 6411 of the Health Care Reform Law, RAC audits of providers will increase and also expand to Medicare Parts C and D as well as the Medicaid program by December 31, 2010. The Medicare Modernization Act established the RAC program initially as a demonstration program to identify and correct improper Medicare fee-for-service payments. The 3-year RAC demonstration program was designed to determine whether the use of RACs would be a cost-effective means of adding resources to ensure correct payments were being made to providers and suppliers, and therefore, protect the Medicare Trust Fund. Section 302 of the Tax Relief Health Care Act of 2006 made the RAC Program permanent and required the Secretary of HHS to expand the program to all 50 states by no later than 2010.

RACs are required to identify both overpayments and underpayments. They are paid on a contingency fee basis, receiving a percentage of the improper provider overpayments and underpayments they identify. Initially, RACs were contracted to review the last four years of provider claims for the following types of services: hospital inpatient and outpatient, skilled nursing facility, physician, ambulance, and laboratory,

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as well as durable medical equipment. The RACs use automated software programs to identify potential payment errors in such areas as duplicate payments, fiscal intermediaries' mistakes, medical necessity, and coding. The RAC program identified significant overpayments for collection in the demonstration states.

With the expansion of the RACs to Medicare Parts C and D as well as the Medicaid program, health care providers should have RAC Committees that conduct routine internal audit activities and take ownership of the responses to the various RAC requests. The RAC Committee should develop corrective action plans based on the internal audits. It should also review the facility's compliance plan, policies, and procedures and make sure they are all up-to-date. The RAC Committee should, among other things, maintain organized files related to the RAC audits, document all interactions with RAC representatives, and prudently respond to the RAC requests.<sup>31</sup>

### Government's expanded subpoena power

Under Section 10606 of the Health Care Reform Law, the subpoena power of HHS is expanded to apply to cases involving allegations that a party is defrauding federal health care programs. The Secretary of HHS may delegate this subpoena power to OIG.

Compliance professionals should check their policies regarding government investigations—namely subpoenas—and make sure they have procedures in place that detail what an employee is to do if presented with a subpoena by HHS or OIG. In particular, employees should be directed to notify the Legal department as well as the compliance office and allow the Legal department to respond to the subpoena requests.

### Program integrity provisions

The new and revised program integrity provisions of the Health Care Reform Law will require compliance professionals to update several other policies and procedures. Some of these provisions, if violated, may be a basis for an overpayment or fraud liability. These provisions include, but are not limited to:

- new transparency and reporting requirements related to financial interests and activities;
- reimbursement requirements; and
- new financial disclosure requirements.

### Office of the Inspector General authority

Section 6402(b) of the Health Care Reform Law, allows OIG to obtain information from any individual or entity (including a provider) related to claims of payment or the payment of claims

under Medicare or Medicaid. Namely, OIG may obtain supporting documentation necessary to validate claims for payment or payments including a prescribing physician's medical records. This expanded reviewing authority may lead to hospitals giving to OIG documents that contain patients' protected health information (PHI), which is generally protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HIPAA Privacy Rule provides federal protections for PHI belonging to patients and held by covered entities (including health care providers), and permits disclosure of PHI only in certain circumstances.

Under the HIPAA privacy regulations, OIG is considered to be a health oversight agency: an agency or authority of the United States authorized by law to oversee the health care system or government programs in which health information is necessary to determine eligibility or compliance.<sup>32</sup> Health care providers shall disclose information to a health oversight agency for those oversight activities which are authorized by law,<sup>33</sup> based on the "minimum necessary standard" which requires health care providers to make reasonable efforts to limit disclosures of PHI to the minimum extent necessary to accomplish the intended purpose of the use, disclosure, or request. Accordingly, compliance professionals should review their policies and procedures and adjust or develop criteria designed to limit the PHI disclosed to OIG to the minimum necessary to comply with the OIG's request.

### National Provider Identifier

Pursuant to Section 6402(e) of the Health Care Reform Law, all providers who qualify for a national provider identifier (NPI) number must include their NPI on all applications for enrollment and on all claims for payment submitted to the Medicare and Medicaid programs.

HIPAA required the adoption of a standard NPI. The NPI Final Rule was issued January 23, 2004. The NPI is a 10-digit, intelligence free numeric identifier (10 digit number). "Intelligence free" means that the numbers do not carry information about health care providers, such as the state in which they practice or their provider type or specialization. The NPI replaces health care provider identifiers used in HIPAA standard transactions. Those numbers include Medicare legacy IDs (UPIN, OSCAR, PIN, and National Supplier Clearinghouse or NSC). The provider's NPI will not change and will remain with the provider regardless of job or location changes. CMS started issuing NPIs on May 23, 2005. By May 23, 2008, all providers were supposed to obtain NPIs, because CMS instructed that it would not accept claims with legacy IDs.

The Secretary of CMS is required to promulgate a regulation no later than January 1, 2011 detailing the rules related to NPIs and penalties related to failure to submit NPIs with claims for payment or enrollment applications. Compliance professionals should ensure that policies and procedures are in place that ensure that all enrollment applications and claims for payment include an NPI. A failure to include the NPI could result in denial of claims, denial of enrollment into the program, or possibly penalties.

### Hospital reporting requirements

Sections 6001 and 10601 of the Health Care Reform Law limit the Whole Hospital exception under the Stark Law to hospitals that have Medicare provider agreements and physician ownership and investment as of December 31, 2010. Specifically, the new law prohibits physician-owned hospitals from participating in Medicare if they do not have provider agreements in place by December 31, 2010. There are also new reporting obligations for such physician-owned hospitals. These hospitals must submit an annual report to HHS describing the identity of each physician owner or investor of the hospital and the nature and extent of all ownership investment interests in the hospital. This information will be published on a public website maintained by CMS. Hospitals are required to implement policies and procedures requiring physician owners and investors to disclose their interests to patients. In addition, all public advertising of the hospital (whether on its website or otherwise) must clearly state that the hospital is partially owned or invested in by physicians.

Compliance professionals should scrutinize physician relationships and start keeping a log of the identity of each physician owner and investor and the nature and extent of all ownership investment interests in hospitals or related entities. They should periodically update the list so that it captures the latest information. They should also implement policies and procedures that requiring physicians to disclose their ownership or investment interest to patients. Failure to abide by these disclosure requirements can result in fines or penalties.

### Mandatory compliance plan

Under Sections 6102 and 6401 of the Health Care Reform Law, all suppliers and providers enrolled in Medicare and all providers enrolled in Medicaid are required to implement a compliance plan that contains core elements that will be laid out by the Secretary of HHS as a condition of enrollment in the federal health care programs. There is no guidance at this time related to what types of provisions must be included in the compliance plans.

For the last 12 years, OIG has promoted the voluntary adoption of compliance programs throughout the health care industry. OIG has published compliance guidance tailored to specific health care industry segments, including hospitals.<sup>34</sup> OIG has used mandatory contractual compliance programs in the form of Corporate Integrity Agreements (CIAs) when settling matters involving civil fraud allegations. These sanctioned CIAs usually reflect the OIG's perspective on what it deems as appropriate elements and activities of a compliance program. These compliance program guidance and CIAs may serve as the basis for what HHS will consider when developing mandatory compliance program requirements. This new mandate significantly raises the bar for health care provider compliance measures.

### Next steps

Due to the lack of definitions and agency guidance, compliance professionals need to closely monitor any implementation efforts by the agencies. Rule-making notices and comment opportunities will likely be published in the Federal Register throughout this year and beyond. Such guidance will help compliance professionals to draft and execute new and improved policies and procedures that address the changes brought about by the Health Care Reform Law. Compliance professionals should also consult with their Legal departments or outside counsel with regard to the many compliance obligations that have been created by the Health Care Reform Law. ■

*The views in this article are the personal views of the author and do not necessarily reflect the views of Jones Day, its lawyers, or its clients.*

1 31 U.S.C. § 3729(a)(1)(A).  
2 31 U.S.C. § 3729(a)(1)(G).  
3 The Fraud Enforcement and Recovery Act of 2009 § 4 (Pub. L. No. 111-21).  
4 31 U.S.C. § 3729(b).  
5 42 U.S.C. § 1320a-7a(a).  
6 See 42 C.F.R. § 1003.102.  
7 See 42 C.F.R. § 1003.103.  
8 42 U.S.C. § 1320a-7b.  
9 See, e.g., U.S. v. Greber, 760 F.2d 68, 71 (3d Cir. 1985); U.S. v. Bay State Ambulance and Hospital Rental Service, Inc., 874 F.2d 20 (1st Cir. 1989).  
10 132 F.3d 1092 (5th Cir. 1998).  
11 51 F.3d 1390, 1400 (9th Cir. 1995).  
12 908 F. Supp. 491 (S.D. Ohio 1995).  
13 93 F.3d 436, 441 (8th Cir. 1996).  
14 United States v. Starks, 157 F.3d 833 (11th Cir. 1998).  
15 18 U.S.C. § 1347 and 18 U.S.C. § 24(a).  
16 The Patient Protection and Affordable Care Act § 6402 (Pub. L. No. 111-148) (2010).  
17 118 S. Ct. 1939 (1998).  
18 85 F. Supp. 2d 1047.  
19 42 U.S.C. § 1320a-7a(i)(6) and (7).  
20 Press Release, U.S. Dept. of Justice, The Health Alliance of Greater Cincinnati and The Christ Hospital to Pay \$108 Million for Violating Anti-Kickback Statute and Defrauding Medicare and Medicaid (May 21, 2010). Available at <http://www.justice.gov/opa/pr/2010/May/10-civ-602.html>.  
21 Press Release, U.S. Dept. of Justice, Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring (Sept. 27, 2007). Available at <http://www.usdoj.gov/usa/o/nj/press/files/pdffiles/hips0927.rel.pdf>.  
22 31 U.S.C. § 3730(e)(4)(A).  
23 559 US \_\_\_, 130 S. Ct. 1396 (2010).  
24 Id. at n.1.  
25 31 U.S.C. § 3730(e)(4)(B).  
26 The Patient Protection and Affordable Care Act § 6409 (Pub. L. No. 111-148) (2010).  
27 See Notice, 63 FR 5839, Oct. 30, 1998.  
28 42 U.S.C. § 1395nn.  
29 OIG Open Letter to Providers, March 24, 2009.  
30 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d).  
31 42 U.S.C. §§ 1396a(a)(42) and 1395ddd(h).  
32 45 C.F.R. § 164.501.  
33 45 C.F.R. 164.512(d).  
34 See e.g., OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4,858 (Jan. 31, 2005); OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987 (Feb. 23, 1998).