



# HEALTH CARE FRAUD REPORT



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## **Risky Business: Health Care Reform's Fraud-Fighting Provisions Increase the Potential for Liability for All in the Health Care Industry**

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**A**s most everyone knows by now, President Obama signed the Patient Protection and Affordable Care Act<sup>1</sup> (the Act) on March 25, 2010, and the Health Care and Education Affordability Reconciliation Act of 2010<sup>2</sup> (the Reconciliation), on March 30, 2010.

Although private health insurance reforms dominated the health care reform debate, the Act and the Reconciliation, taken together, also require vast changes to the Medicare and Medicaid programs, including new and strengthened mechanisms for combating fraud, waste, and abuse in the state and federal health care programs.

The inclusion of these provisions comes as no surprise to the health care industry because the Obama ad-

ministration has made health care fraud enforcement one of its highest priorities, stating that it has “zero tolerance” for health care fraud and that fighting and preventing fraud is “a personal priority” for the president.<sup>3</sup> The administration has lived up to its words by, for example, creating the Health Care Fraud Prevention and Enforcement Action Team (known as “HEAT”), and proposing that an unprecedented \$1.7 billion be allocated to the Department of Health and Human Services for fraud-fighting activities in the fiscal year 2011 budget.

Because many of the provisions that target fraud, waste, and abuse became effective upon enactment, the health care industry should begin to understand these provisions immediately. This article highlights key provisions, with a particular focus on the impact the legislation will have on enforcement of the Anti-kickback Statute, the False Claims Act, the Stark law, the Civil Monetary Penalties Law, and new provisions mandating reporting and refunding of overpayments.

### **Changes to the Anti-Kickback Statute and the False Claims Act**

Simply put, changes to the Anti-Kickback Statute (AKS) and the civil False Claims Act (FCA) significantly expand the reach of both statutes. These changes, combined with the overall trend toward increased government enforcement and recent amendments to the False

<sup>1</sup> Pub. L. No. 111-148

<sup>2</sup> Pub. L. No. 111-152

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<sup>3</sup> Department of Health and Human Services Secretary Kathleen Sebelius, Address at the National Summit on Health Care Fraud (Jan. 28, 2010) (transcript available at <http://www.hhs.gov/secretary/speeches/sp20100128.html>)

Claims Act in 2009, will undoubtedly result in more *qui tam* actions and government-initiated investigations.

#### *Expansion of the Anti-Kickback Statute's Intent Standard*

One of the Act's most significant amendments is the adoption of a more expansive criminal intent or *scienter* standard under the AKS.<sup>4</sup>

The AKS is a criminal statute that subjects violators to fines, possible imprisonment, and exclusion from the Medicare and Medicaid programs. To prove a violation of the AKS, the government must show that the defendant acted "knowingly and willfully," which is a standard that courts generally have found imposes a high burden on the government.

For example, in 1995 the U.S. Court of Appeals for the Ninth Circuit held that a party violates the AKS only if he or she: (i) knows that the AKS prohibits offering or paying remuneration to induce referrals, and (ii) engages in the prohibited conduct with the *specific intent* to disobey the law.<sup>5</sup>

However, the Act overrides this (and any other) judicial interpretation by adding the following new provision to the AKS: "[w]ith respect to violations of [the AKS], a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]."<sup>6</sup> With this amendment, Congress wiped out a significant body of case law that had required specific knowledge of and intent to violate the AKS and made it easier for the government to pursue and prove AKS violations.

#### *Recognition of Anti-Kickback Statute Violations as False Claims*

The Act clarifies that an AKS violation may trigger liability under the FCA.<sup>7</sup> In recent years, the government and relators (commonly referred to as "whistleblowers") have brought many FCA suits against providers, suppliers, manufacturers, and others in the health care industry for alleged AKS violations.<sup>8</sup>

These suits typically allege that the defendant violated the FCA by knowingly submitting or causing to be submitted to the government claims that were false because the defendant violated the AKS while rendering the services at issue, and compliance with the AKS was a condition of government payment.<sup>9</sup>

With respect to conduct prior to passage of the Act, a defendant could argue that AKS violations did not re-

sult in the filing of false claims because neither the AKS itself nor any certification statement associated with payment states that compliance is a condition of payment.<sup>10</sup>

The Act amends the AKS by expressly stating that claims for items or services "resulting from" AKS violations are false or fraudulent for purposes of the FCA.<sup>11</sup>

As a result, the government or a whistleblower apparently can now sustain a FCA action by merely alleging that the defendant violated the FCA by knowingly submitting (or causing to be submitted) to the government claims for items or services that were tainted by an underlying AKS violation, and the argument that such claims are not false because AKS compliance is not a condition of payment is substantially weakened.<sup>12</sup>

When combined with the lowered intent requirement for the underlying AKS violation, this amendment will likely generate a flood of new FCA suits and could expose providers and others in the health care industry to additional liability in jurisdictions where courts have not adopted the theory that an AKS violation can serve as the basis for a FCA action.

Nonetheless, whistleblowers, as well as the government, still must prove all elements of the predicate AKS violation, which, overall, remains a high bar, before attempting to establish FCA liability.

#### *Changes to the False Claims Act's Public Disclosure and Original Source Requirements*

The Act also amends the FCA's public disclosure bar, which is intended to prevent so-called "parasitic" *qui tam* suits and has been the subject of extensive litigation.<sup>13</sup> Prior to the Act's amendments, the FCA jurisdictionally barred claims that had been "publicly disclosed" under certain circumstances unless the individual bringing suit was the "original source" of the information.<sup>14</sup> However, the Act makes two important changes to this provision.

First, the Act replaces this jurisdictional bar with a requirement that courts must dismiss FCA claims brought by relators "unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" through specified public proceedings, issuances, or media, unless the relator is the "original source" of the in-

<sup>4</sup> 42 U.S.C. § 1320a-7b.

<sup>5</sup> See, e.g., *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

<sup>6</sup> Pub. L. No. 111-148, § 6402(f); codified at Social Security Act § 1128B(h) (42 U.S.C. § 1320a-7b(h)).

<sup>7</sup> 31 U.S.C. § 3729 *et seq.*

<sup>8</sup> See, e.g., *United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 238 F. Supp. 2d 258, 263-66 (D.D.C. 2002) (upholding False Claims Act (FCA) action based on Anti-Kickback Statute (AKS) and Stark Law violations).

<sup>9</sup> All courts that have considered whether a FCA violation can be based upon failure to comply with another law, such as the AKS, require a connection between the predicate law and the government's decision to pay. Courts have, however, expressed this requirement in various ways. See, e.g., *U.S. v. Bourseau*, 531 F.3d 1159, 1170-71 (9th Cir. 2008) (discussing how it "incorporated a materiality element into the FCA, at least within the context of false certification [i.e. FCA allegations based on violations of other laws] and promissory fraud cases.")

<sup>10</sup> This defense was not always successful. See, e.g., *United States ex rel. Barrett v. Columbia/HCA Health Care Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003) (holding that AKS violations could serve as the basis for a FCA action in part because compliance with the AKS would affect the government's decision to pay the claim).

<sup>11</sup> Pub. L. No. 111-148, § 6402(f); codified at Social Security Act § 1128B(g) (42 U.S.C. § 1320a-7b(g)).

<sup>12</sup> A recent decision published by the U.S. District Court for the District of Massachusetts rejected this theory as applied to manufacturers that do not file claims with the Medicare program. *U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, — F. Supp.2d —, 2010 WL 938361, Civil Action No. 06-11771-WGY (D. Mass., March 12, 2010) (finding that provider certification is specific to the party seeking reimbursement and "creates no obligation on the part of the signatory to determine whether the entire transaction complied with the Anti-Kickback Statute").

<sup>13</sup> See, e.g., *Rockwell International, et al. v. United States*, 549 U.S. 457 (2007).

<sup>14</sup> 31 U.S.C. § 3730(e)(4).

formation.<sup>15</sup> By removing the word “jurisdiction” and allowing the government to oppose the dismissal, Congress changed the public disclosure bar from a mandatory, non-waivable, jurisdictional defense to a substantive defense. This change will have significant consequences for defendants in *qui tam* cases; at minimum, early exploration of the availability of public disclosure defenses will be required.

Second, the Act narrows the types of disclosures that qualify as public. A disclosure that occurs in a criminal, civil, or administrative hearing is considered public under the FCA only if the proceeding is at the federal level and if the government or its agent is a party.<sup>16</sup> Similarly, only federal reports, hearings, audits, or investigations constitute public disclosure.<sup>17</sup> Public disclosure in the news media does, however, remain grounds for dismissal.

On March 30, 2010, the U.S. Supreme Court decided a case directly related to this issue. In *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*,<sup>18</sup> the Court held that non-federal reports, such as those that disclosed the alleged fraud in that case, qualified as public disclosures under the pre-Act version of Section 3730(e)(4)(A) while noting that the amendments to the public disclosure provision do not apply retroactively.<sup>19</sup>

The Act also redefines “original source.” Previously, an “original source” must have had “direct and independent knowledge of the information on which the allegations are based.”<sup>20</sup> But, under the Act, an “original source” must either: (i) prior to a public disclosure, have voluntarily disclosed to the government the information on which allegations or transactions in the action or claim are based, or (ii) have knowledge that is independent of, and that materially adds to, the publicly disclosed allegations or transactions, and have voluntarily provided the information to the Government before filing an action.<sup>21</sup>

The first clause, which is entirely new, apparently adds a temporal requirement to the disclosure by requiring the relator to provide the information to the government before any public disclosure.

The second clause eliminates the requirement that the relator have “direct and independent knowledge,” by instead referring only to “knowledge” of the information that is “independent of” and that “materially adds to” the previously disclosed information about the allegations or transactions.

The meaning of the terms “independent knowledge” and “materially adds” undoubtedly will be the subject of future litigation.

#### *Exchange Payments Subject to the False Claims Act*

The Act also provides that “[p]ayments made by, through, or in connection with a[] [Health Insurance] Exchange are subject to the False Claims Act. . .if those payments include any Federal funds.”<sup>22</sup>

This provision is seemingly unnecessary, as the sweeping changes to the FCA enacted as part of the Fraud Enforcement and Recovery Act of 2009 (FERA) (Pub. L. 111-21) extended the FCA’s reach to encompass all requests or demands for money or property “spent or used on the Government’s behalf or to advance a Government program or interest” if the government provides any portion of the money or property requested or demanded.<sup>23</sup> The application of and reasons for including this language are therefore unclear, with the provision perhaps serving only as a reminder of the FCA’s reach and as an invitation for private enforcement.

## **Expansion of Health Care Fraud Offenses and Enhanced Penalties**

The Act expands the use of federal criminal offenses related to health care fraud and enhances penalties under the Federal Sentencing Guidelines for such offenses, which means that federal criminal prosecutors may soon consider the federal health care fraud provisions their weapon of choice. Further, the Act broadens the types of conduct subject to the Civil Monetary Penalties Law.

#### *Intent Requirement for Health Care Fraud Violations*

With the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. No. 104-191), Congress established various new federal criminal offenses related to health care fraud,<sup>24</sup> each of which is a “federal health care fraud offense.”<sup>25</sup> HIPAA further established that such offenses may subject the target to subpoenas for documents in investigations, injunctions, and the freezing of assets, and can affect how sentences are calculated under the Federal Sentencing Guidelines.<sup>26</sup>

In particular, HIPAA created a new federal offense known as “health care fraud,” which involves the knowing and willful execution of a scheme or artifice to defraud a “health care benefit program” or to obtain, through false or fraudulent means, any money or property from such a program.<sup>27</sup>

The term “health care benefit program” means “any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.”<sup>28</sup> Commission of health care fraud can subject the defendant to substantial penalties, including incarceration and/or fines.

Significantly, the Act lowers the level of intent required prove a violation of health care fraud under 18 U.S.C. § 1347,<sup>29</sup> and thus makes it easier for the government to prove a violation. Similar to revisions made to the AKS, the Act amends the intent requirement and provides that “a person need not have actual knowl-

<sup>15</sup> Pub. L. No. 111-148, § 10104(j)(2); codified at 31 U.S.C. § 3730(e)(4).

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> — S.Ct. —, No 08-304, 2010 WL 1189557, \*12 (2010).

<sup>19</sup> *Id.* At \*1.

<sup>20</sup> 31 U.S.C. § 3730.

<sup>21</sup> Pub. L. No. 111-148, § 10104(j)(2); codified at 31 U.S.C. § 3730(e)(4).

<sup>22</sup> Pub. L. No. 111-148, § 1313(a)(6).

<sup>23</sup> 31 U.S.C. § 3729(b)(2).

<sup>24</sup> Pub. L. No. 104-191, §§ 241-246, codified at 18 U.S.C. §§ 24, 669, 1035, 1518, 1347, 1956(a)(1).

<sup>25</sup> 18 U.S.C. § 24 (defining “federal health care offense”).

<sup>26</sup> 28 U.S.C. § 994; 18 U.S.C. §§ 1345, 3486.

<sup>27</sup> 28 U.S.C. § 1347.

<sup>28</sup> 28 U.S.C. § 24(b).

<sup>29</sup> Pub. L. No. 111-148, § 10606(b), codified at 18 U.S.C. § 1347.

edge of [18 U.S.C. § 1347] or specific intent to commit a violation of [18 U.S.C. § 1347].”<sup>30</sup>

#### *Anti-Kickback Statute and Other Crimes Classified as Federal Health Care Fraud Offenses*

The Act also expands the types of conduct that constitute federal health care fraud offenses to include violations of the AKS and, when the offense is related to a “health care benefit program,” the Federal Food, Drug, and Cosmetic Act<sup>31</sup> and section 501 of the Employee Retirement Income Security Act (ERISA).<sup>32</sup>

#### *Federal Sentencing Guidelines*

The Act makes various changes to the Federal Sentencing Guidelines as they apply to federal health care fraud offenses, including, for example, modification of the manner in which the amount of loss is to be determined for sentencing purposes: “the aggregate dollar amount of fraudulent bills submitted to the Government health care program shall constitute prima facie evidence of the amount of the intended loss by the defendant.”<sup>33</sup>

This provision could make it more difficult for a defendant to argue for sentencing purposes that an AKS scheme caused no loss to the government where, for example, medically necessary services were nonetheless provided.

Further, the Act directs the U.S. Sentencing Commission to:

“...ensure that the Federal Sentencing Guidelines and policy statements [among other things] (i) reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud; and (ii) provide increased penalties for persons convicted of health care fraud offenses in appropriate circumstances.”<sup>34</sup>

It also requires amendment of the Federal Sentencing Guidelines to enhance the penalties for convictions of federal health care offenses<sup>35</sup> relating to government programs. Sentences must be increased follows:

- a 2-level increase in the offense level for a loss between \$ 1 million and \$7 million
- a 3-level increase in the offense level for a loss between \$ 7 million and \$20 million
- a 4-level increase in the offense level for a loss of not less than \$ 20 million.<sup>36</sup>

#### *Civil Monetary Penalties Law*

The Secretary of HHS has long had the authority to impose civil monetary penalties (CMPs) on persons who engage in various types of unlawful conduct.<sup>37</sup> The Act expands the types of unlawful conduct subject to

such penalties by allowing the Secretary of HHS to seek CMPs for:

- failing to provide timely access to the HHS Office of Inspector General (OIG) for audits, investigations, evaluations, or other statutory functions of up to \$15,000 per day;
- knowingly making, using, or causing to be made or used a false record or statement material to a false claim for payment for items or services of up to \$50,000 for each false record or statement;
- knowingly making a false statement, omission, or misrepresentation on an enrollment application, bid, or contract of up to \$50,000 for each false statement, omission, or misrepresentation; and
- ordering or prescribing items or services (including lab tests, drugs, durable medical equipment, etc.) during any period when the person ordering or prescribing has been excluded of up to \$50,000 for each order or prescription.<sup>38</sup>

#### *Beneficiary Inducement Law*

In 1996, as part of HIPAA, Congress authorized the imposition of CMPs for the offering of remuneration to any beneficiary that the “person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner or supplier any item or service” payable under Medicare or Medicaid.<sup>39</sup> Only narrow exceptions were provided,<sup>40</sup> which has created compliance challenges for providers and suppliers. Congress therefore added the following exceptions:

- any remuneration which promotes access to care and poses a low risk of harm to patients and the Federal health care programs;
- the offer or transfer of items or services for free or at less than fair market value by a person for certain coupons, rebates, or other rewards from a retailer;
- the offer or transfer of items or services for free or at less than fair market value by a person for certain items or services not offered as part of any advertisement or solicitation, that are not tied to the provision of other services reimbursed by Medicare or Medicaid, where there is a reasonable connection between the items or services and the medical care of the individual and where the person provides the items or services after determining in good faith that the individual is in financial need; or
- subject to an effective date specified by the Secretary (but not earlier than Jan. 1, 2011), the waiver by a prescription drug plan sponsor of a prescription drug plan under Medicare Part D or an MA organization offering an MA-PD plan under Medicare Part C of any copayment for the first fill of a covered Part D drug that is a generic drug for in-

<sup>30</sup> Pub. L. No. 111-148, § 10606(b), *codified at* 18 U.S.C. § 1347(a)-(b).

<sup>31</sup> 21 U.S.C. § 331 *et seq.*

<sup>32</sup> Pub. L. No. 111-148, § 10606(c), *codified at* 18 U.S.C. § 24(a).

<sup>33</sup> Pub. L. No. 111-148, § 10606(a)(2) (directing the Federal Sentencing Commission to amend the Federal Sentencing Guidelines).

<sup>34</sup> Pub. L. No. 111-148, § 10606(a)(3).

<sup>35</sup> 18 U.S.C. § 24.

<sup>36</sup> Pub. L. No. 111-148, § 10606(a)(2)(C).

<sup>37</sup> Social Security Act § 1128A (42 U.S.C. § 1320a-7a).

<sup>38</sup> Pub. L. No. 111-148, §§ 6402(d)(2), *codified at* Social Security Act § 1128A(a) (41 U.S.C. § 1320a-7a(a)), and 6408(a), *codified at* Social Security Act § 1128A(a) (41 U.S.C. § 1320a-7a(a)).

<sup>39</sup> Social Security Act § 1128A(a)(6) (42 U.S.C. § 1320a-7a(a)(6)).

<sup>40</sup> Social Security Act § 1128A(i)(6) (42 U.S.C. § 1320a-7a(i)(6)).

dividuals enrolled in the prescription drug plan or MA-PD plan, respectively.<sup>41</sup>

While these new exceptions offer expanded protection for certain, specific arrangements, other common—and legitimate—arrangements do not fall within the parameters of this statute. For example, the new exception for “coupons, rebates, or other rewards,” applies on its face only to retailers even though providers, suppliers, health plans, and other entities also offer such benefits to beneficiaries.

### Marketing Violations

The Social Security Act authorizes the HHS Secretary to impose sanctions and penalties on Medicare Advantage and Medicare Part D plans that engage in certain unlawful behavior, such as falsifying information required to be furnished to HHS and failing to provide medically necessary services that are contractually required to be provided.<sup>42</sup>

The Act protects federal health care program beneficiaries from predatory marketing practices by expanding this existing authority by allowing for the imposition of penalties and sanctions on plans that:

- enroll individuals in a plan without their consent (subject to certain limited exceptions);
- transfer individuals from one plan to another without their consent or solely for the purpose of earning a commission;
- fail to comply with applicable marketing restrictions; and
- employ or contract with any person who engages in conduct prohibited by the intermediate sanctions provisions.<sup>43</sup>

According to the plain language of the Act, these new intermediate sanctions became effective as of Jan. 1, 2010.<sup>44</sup> It is unclear, however, whether Congress actually intended for these provisions to be retroactive.

### Changes to the Stark Law

The Act and the Reconciliation also make changes to certain exceptions under the Stark law and create a self-disclosure protocol for Stark law violations.

#### Self-Referral Disclosure Protocol and Compromise of Penalties

Since the implementation of the Stark law, providers and suppliers have struggled to understand its implications and to comply with its numerous prescriptive rules.

This situation is complicated by the fact that strict compliance is necessary because even *de minimus* violations, such as failing to ensure that both parties sign agreements or to renew agreements in a timely way, have the potential to result in significant overpayments and even FCA liability. For years, providers and suppliers have searched for meaningful relief, which the Act has, hopefully, provided.

First, the Act directs the Secretary of HHS, in cooperation with the HHS OIG, to develop a self-referral disclosure protocol (the SRDP) within six months of enact-

ment to enable health care providers and suppliers to self-disclose actual or potential Stark law violations.<sup>45</sup> Congress presumably imposed this requirement on the Secretary of HHS to address the fact that the OIG announced in March 2009 that it would no longer accept self disclosures of Stark law violations pursuant to its Self-Disclosure Protocol unless “a colorable [AKS] violation” was involved.<sup>46</sup>

Since that time, providers and suppliers have had difficulty determining whether to report Stark law violations to the Centers for Medicare & Medicaid Services (CMS), which is responsible for enforcing the Stark law, or to the Medicare Administrative Contractor (MAC) responsible for processing its claims. How or whether the SRDP will relate to the OIG’s Self-Disclosure Protocol remains to be seen.

Second, the Act authorizes the Secretary of HHS to reduce the penalty amounts for Stark law violations.<sup>47</sup> Going forward, when assessing penalties under the Stark law, the Secretary may consider the nature and extent of the improper practice, the timeliness of self-disclosure, the cooperation in providing additional information related to the disclosure, and any other factors that the Secretary considers appropriate.

Among other issues, CMS, which has responsibility for enforcing the Stark law and which will design and implement the SRDP, will need to consider whether providers and suppliers must disclose violations within a certain timeframe after discovery; whether preliminary disclosures followed by a complete internal investigation will be permitted; whether it will require written reports similar to those accepted by the HHS OIG through its Self-Disclosure Protocol; and whether it will limit the compromise of penalties only to matters disclosed under the SRDP.

#### Disclosures Under the In-Office Ancillary Services Exception

The Act adds a requirement that physicians making self-referrals under the in-office ancillary services exception to the Stark law, which is the exception commonly used by physicians who offer laboratory testing and certain other services from which they receive a financial benefit,<sup>48</sup> must make certain disclosures to patients. In particular, such physicians must inform patients, at the time of referral, that the services can be obtained from someone other than the: (i) referring physician, (ii) a physician who is a member of the referring physician’s practice group, or (iii) an individual who is directly supervised by the referring physician or another physician in the referring physician’s practice group.<sup>49</sup> The group practice must also provide a list of “suppliers” who furnish such services in the area in which the individual resides.

Although this provision provides an effective date of Jan. 1, 2010, the amendment refers back to a provision of the exception that gives the HHS Secretary the authority to specify “such other requirements as the Sec-

<sup>41</sup> Pub. L. No. 111-148, § 6402(d)(2)(B); *codified at* Social Security Act § 1128A(i)(6)(F)-(I) (42 U.S.C. § 1320a-7a(i)(6)(F)-(I)).

<sup>42</sup> Social Security Act § 1857(g) (42 U.S.C. § 1395w-27(g)).

<sup>43</sup> Pub. L. No. 111-148, § 6408(b)(2), *codified at* Social Security Act § 1857(g)(1) (42 U.S.C. § 1395w-27(g)(1)).

<sup>44</sup> Pub. L. No. 111-148, § 6408(d).

<sup>45</sup> Pub. L. No. 111-148, § 6409(a).

<sup>46</sup> <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>.

<sup>47</sup> Pub. L. No. 111-148, § 6409(b).

<sup>48</sup> Social Security Act § 1877(b)(2) (42 U.S.C. § 1395nn(b)(2)).

<sup>49</sup> Pub. L. No. 111-148, § 6003; *codified at* Social Security Act § 1877(b)(2) (42 U.S.C. § 1395nn(b)(2)).

retary may impose by regulation as needed to protect against program or patient abuse.”<sup>50</sup> Thus, CMS likely will issue rules to implement this authority. Clarifying rules could be helpful by addressing issues such as:

- to which designated health services disclosure obligations will apply;
- a description of the sources that should be used to compile the list of alternative suppliers;
- whether group practices will be authorized to expand the list beyond alternative “suppliers” to include local hospitals that provide these ancillary services;
- the criteria that group practices should use when developing the lists; and
- how a patient’s service area should be determined.

#### *Physician-Owned Hospitals*

Under the Act and the Reconciliation, physician-owned hospitals will no longer be able to participate in the Medicare program unless the physicians holds an ownership interest and the hospital had a provider agreement by Dec. 31, 2010.<sup>51</sup> This provision effectively bans physician-owned hospitals created after that date from participating in the Medicare program and prohibits the expansion of then existing physician-owned hospitals except under two limited exceptions.<sup>52</sup> Further, Congress imposed significant new rules on pre-existing relationships by requiring, for example, the following:

- disclosures to patients of the physician’s investment interest,
- annual reporting by hospitals to HHS,
- compliance with safe-harbor-like requirements to assure that the physician’s investment interest is *bona fide*, and
- assurances of patient safety.<sup>53</sup>

### **Transparency Provisions**

The Act advances the trend toward increased transparency in the health care industry by imposing disclosure obligations on drug, medical device, and certain other manufacturers and on group purchasing organizations (GPOs) related to payments and transfers of value.

Congress has considered this approach, commonly known as the “Sunshine Act,” for some time. The Act imposes myriad additional disclosure obligations on pharmacy benefit managers (PBMs), drug manufacturers, distributors, nursing facilities, and physicians.

#### *Sunshine Act*

Drug, device, biological, and medical supply manufacturers will be required to report annually to the Sec-

<sup>50</sup> *Id.*

<sup>51</sup> Pub. L. No. 111-148, § 6001(a)(3), *codified at* Social Security Act § 1877(i) (42 U.S.C. § 1395nn(i)); Pub. L. No. 111-152, § 1106, *codified at* Social Security Act § 1877(i) (42 U.S.C. § 1395nn(i)).

<sup>52</sup> The Act directs the Secretary to implement a process for granting exceptions to the expansion prohibition for certain rural hospitals while the Reconciliation includes an addition expansion exception for “high Medicaid facilities.” See Pub. L. No. 111-148, § 6001(a)(3), *codified at* Social Security Act § 1877(i) (42 U.S.C. § 1395nn(i)); Pub. L. No. 111-152, § 1106(2), *codified at* Social Security Act § 1877(i) (42 U.S.C. § 1395nn(i)).

<sup>53</sup> Pub. L. No. 111-148, § 6001(a)(3), *codified at* Social Security Act § 1877(i) (42 U.S.C. § 1395nn(i)).

retary of HHS, beginning on March 31, 2013, and on the 90<sup>th</sup> day of every calendar year thereafter, certain information on payments and other transfers of value to “covered recipients.”<sup>54</sup> The term “covered recipients” includes physicians (other than physician employees of the manufacturer) and teaching hospitals.<sup>55</sup> The Act provides detailed specifications regarding the types of payments that must be reported, including but not limited to:

- consulting fees, compensation for services other than consulting, and direct compensation for serving as faculty or as a speaker for a medical education program;
- honoraria and gifts;
- entertainment, food, and travel (including the specified destinations);
- education and research;
- grants and charitable contributions; and
- royalties or licenses.

The Act does contain numerous exceptions and exclusions to the reporting requirements, such as:

- a transfer to a covered recipient of anything with a value of less than \$10, unless the aggregate amount to the same covered recipient during the calendar year exceeds \$100 (inflation adjustments will apply as of calendar year 2013);
- product samples that are not intended to be sold and are intended for patient use;
- educational materials that directly benefit patients or are intended for patient use;
- the loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient;
- items or services provided under a contractual warranty; and
- in-kind items used for the provision of charity care.

Further, manufacturers, as well as GPOs, must disclose certain ownership or investment interests held by physicians. Interests held in the form of a publicly traded security or through a mutual fund are not covered by this requirement.

All information submitted to the Secretary of HHS will be made available on the Internet, and the Act sets forth requirements for the content and format. The Secretary of HHS also must submit an annual report to Congress and to the states.

Penalties for failure to report may be substantial. CMPs for each payment or other transfer of value or ownership or investment interest not reported will range from \$1,000 to \$10,000, up to \$150,000 per annual submission. A knowing failure to report can be more costly; CMPs for such violations will range from \$10,000 to \$100,000, up to a total of \$1,000,000.

More details on this new process will be forthcoming. The Secretary of HHS is required to establish reporting procedures no later than Oct. 1, 2011.

#### *Other Disclosure/Transparency Rules*

Other, less onerous disclosure requirements apply to various other segments of the health care industry:

<sup>54</sup> Pub. L. No. 111-148, § 6002, *codified at* Social Security Act § 1128G (42 U.S.C. § 1320a-7g).

<sup>55</sup> Pub. L. No. 111-148, § 6002(e), *codified at* Social Security Act § 1128G(e) (42 U.S.C. § 1320a-7g).

- Each **drug manufacturer and authorized distributor** must submit to HHS by April 1st of each year, beginning in 2012, (i) the identity and quantity of drug samples requested, and (ii) the identity and quantity of drug samples distributed during that year.<sup>56</sup>
- **Health benefit plans and PBMs** that contract with a Prescription Drug Plan (PDP) sponsor or a MA organization offering an MA-PD plan under Medicare Part D, or that contract with qualified health benefits plans must report certain information, such as generic dispensing rates and negotiated price concession amounts, to the plans with which they contract and the Secretary of HHS.<sup>57</sup> The required information is confidential and may not be disclosed in a manner that identifies the specific PBM, plan, or prices charged for drugs.<sup>58</sup> This provision, which does not include an effective date, presumably became effective upon enactment.
- **Skilled nursing facilities and nursing facilities** must immediately begin collecting information about ownership and control of the facility, which must be disclosed after the Secretary of HHS promulgates implementing regulations. This information includes: (i) members of the governing body of the facility, (ii) officers, directors, members, partners, trustees, or managing employees of the facility, and (iii) other “disclosable” parties, including those who exercise operational, financial, or managerial control over the facility, lease property to the facility, or provide management, administrative, clinical consulting, or financial services to the facility.
- As discussed above, as part of amendments to the Stark Law, **physicians** must disclose to patients that in-office ancillary services can be obtained from someone other than the referring physician or his group.<sup>59</sup>

These transparency provisions—especially those applicable to drug, device, biological, and medical supply manufacturers—add to the growing number of required disclosures under state and federal law and will require entities to navigate sometimes differing obligations.

Several states, including Massachusetts, have enacted laws requiring pharmaceutical and medical device manufacturers to disclose payments made or economic benefits provided to certain recipients in connection with sales and marketing activities.

Although the Act explicitly preempts state laws that require identical manufacturer disclosures of payments or value transfers made as of Jan. 1, 2012, the entities subject to them must nevertheless proceed carefully to ensure they fully satisfy both state and federal disclosure obligations.

The Act will not preempt any State laws that require the disclosure or reporting of, among other things, information “not of the type required to be disclosed or

<sup>56</sup> Pub. L. No. 111-148, § 6004, *codified at* Social Security Act § 1128H (42 U.S.C. § 1320a-7h).

<sup>57</sup> Pub. L. No. 111-148, § 6005, *codified at* Social Security Act § 1150A.

<sup>58</sup> Pub. L. No. 111-148, § 6005, *codified at* Social Security Act § 1150A.

<sup>59</sup> Pub. L. No. 111-148, § 6003, *codified at* Social Security Act § 1877(b)(2) (42 U.S.C. 1395nn(b)(2)).

reported under” the Act. For instance, the Act would likely not preempt Massachusetts’s requirement for disclosure of payments to pharmacists because such disclosures are not required by the Act.<sup>60</sup>

Further, entities not subject to the Act’s reporting requirements should not assume their State law disclosure obligations are preempted by the new federal law.

## Mandatory Compliance Programs

Although the HHS OIG and other enforcement authorities already expect providers, suppliers, and others to have compliance programs in place, and the HHS OIG has issued numerous compliance guidance documents making this expectation clear, the adoption of a corporate compliance program is currently voluntary for most providers and suppliers.<sup>61</sup>

However, the Act makes the establishment of a compliance program a condition of enrollment under the Medicare, Medicaid, and SCHIP programs. The Act further requires the Secretary of HHS to establish “core elements” for a compliance program for providers and suppliers and directs providers and suppliers to establish compliance programs containing those core elements.<sup>62</sup>

## Changes to Payment-Related Provisions

### *Disclosing and Repaying Overpayments & Penalties for Failure to Timely Repay*

For the first time, disclosure and repayment of Medicare and Medicaid overpayments is now an express legal requirement.<sup>63</sup> “Overpayment” is broadly defined to mean any Medicare or Medicaid funds that a person receives or retains to which the person, after applicable reconciliation, is not entitled under the Medicaid or Medicaid laws.<sup>64</sup>

The overpayment must be returned to the appropriate party (HHS, the State, an intermediary, a carrier, or a contractor) and must include a written explanation of the reason for the overpayment. The report must be submitted, along with the refund, 60 days after identifying the overpayment or on the date any corresponding cost report is due, whichever is later. The overpayment provisions explicitly apply to providers, suppliers, Medicaid managed care organizations, Medicare Advantage organizations, and Part D sponsors.

The Act specifies that any overpayment retained after the deadline is an “obligation” for purposes of the FCA. The FCA, as amended by FERA, imposes liability on any person who “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or

<sup>60</sup> Mass. Gen. L. 111N § 6.

<sup>61</sup> See, e.g., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003). In addition, providers subject to the Medicaid compliance policy requirements imposed under Section 6032 of the Deficit Reduction Act of 2005 and laws of certain states, such as New York, are required to adopt compliance programs.

<sup>62</sup> Pub. L. No. 111-148, § 6401, *codified at* Social Security Act § 1866(j) (42 U.S.C. § 1395cc(j)).

<sup>63</sup> Pub. L. No. 111-148, § 6402(a); *codified at* Social Security Act § 1128J(d) (42 U.S.C. § 1320a-7j(d)).

<sup>64</sup> The Act also defines “knowing” and “knowingly” as having the same meanings given to those terms under the FCA. However, neither term is used in the overpayment section and so the reason for their inclusion is unclear.

transmit money or property to the Government.”<sup>65</sup> The Act also creates CMPs for any knowing failure to report<sup>66</sup> and permissive Medicaid exclusion authority for providers that fail to refund overpayments.<sup>67</sup> Thus, individuals and entities accepting government funds for health care services must be especially diligent in their accounting and should review their policies and procedures related to overpayment detection.

This provision raises a number of questions. For example, the Department of Justice and the HHS OIG have historically opposed any settlement of overpayments during the pendency of a fraud investigation. For this reason, parties subject to any type of enforcement action should seek clarification from the investigating agency or agencies about the application of this requirement.

#### *DME and Home Health Services*

The Act imposes additional restrictions on those seeking reimbursement for durable medical equipment (DME) or home health services—two areas that have been the subject of numerous fraud enforcement actions in recent years. One study found that nearly one in three claims for DME paid by Medicare in fiscal year 2006 was erroneous.<sup>68</sup> Home health services is another area that enforcement agencies believe is rife with abuse.<sup>69</sup>

The Act attempts to address these problem areas by requiring physicians and certain other health care providers to have had a face-to-face patient encounter within the six months prior to submitting a request for reimbursement for home health services or DME and allows the HHS Secretary to expand this requirement to items and services beyond DME and home health services if such expansion will help mitigate fraud.<sup>70</sup>

In addition, the HHS Secretary can withhold payment to newly enrolled DME suppliers for 90 days after the DME supplier submits an initial claim for payment if the Secretary has identified a significant risk of fraud among DME suppliers in a specific category or geographic area.<sup>71</sup>

#### *Increase in Authority to Conduct Pre-Payment Reviews*

The Reconciliation eliminates certain limitations on pre-payment reviews by Medicare Administrative Contractors (MACs).<sup>72</sup> Before removal of these limitations, MACs could conduct random pre-payment reviews only for select reasons, were required to use standard proto-

cols when conducting such reviews, and could only conduct non-random pre-payment reviews if there were a likelihood of sustained or high-volume payment errors. The Reconciliation’s deletion of these restrictions will likely result in an increase in the number of pre-payment reviews.

#### *Expansion of the Recovery Audit Contractor Program*

Consistent with the Obama administration’s interest in using contingency fees to recover federal funds,<sup>73</sup> the Act expands the Recovery Audit Contractor (RAC) program to Medicaid and Medicare Parts C and D.<sup>74</sup>

The RAC program began in 2005 as a regional Medicare demonstration project that became nationwide and permanent this year. Under the Act, the RAC program is scheduled to expand to Medicaid and the Medicare Advantage (“MA”) and Medicare prescription drug benefit (“Part D”) programs by Dec. 31, 2010.

The Act contains special requirements for MA and Part D program RACs, requiring them to ensure that each MA and Part D plan has an anti-fraud plan in effect and to review the effectiveness of such plans. Further, RACs will examine claims for reinsurance payments under Part D and will review estimates relating to the enrollment of high-cost beneficiaries.

#### **Provider Screening Requirements**

The Act requires the HHS Secretary to establish additional screening procedures for providers and suppliers and to impose a fee for the screening.<sup>75</sup> The new screening measures must include licensure checks and may also include criminal background checks, fingerprinting, unscheduled and unannounced site visits, database checks, and other appropriate screening measures as determined by the Secretary. These screening requirements will not apply to new providers before March 2011 or to current providers before March 2012.

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#### **Conclusion**

Congress and the Obama administration undoubtedly intended to send a message to the health care industry with these significant changes to the various laws governing health care fraud and abuse and state and federal health care program integrity.

Congress has made it easier for enforcement authorities to prove health care fraud violations by:

- lowering the intent standard of both the AKS and the federal health care fraud statute;
- stripping the FCA of the jurisdictional defense of prior public disclosure;

<sup>73</sup> Four months after issuing Executive Order 13520, “Reducing Improper Payments,” President Obama issued a memorandum to direct all federal departments and agencies to expand the use of payment recapture audits. See “Presidential Memorandum Regarding Finding and Recapturing Improper Payments,” March 10, 2010, available at <http://www.whitehouse.gov/the-press-office/presidential-memorandum-regarding-finding-and-recapturing-improper-payments>

<sup>74</sup> Pub. L. No. 111-148, § 6411, codified at Social Security Act § 1902(a)(42) (42 U.S.C. § 1396a(a)(42)) and Social Security Act § 1893(h) (42 U.S.C. § 1395ddd(h)).

<sup>75</sup> Pub. L. No. 111-148, § 6401, codified at Social Security Act § 1866(j) (42 U.S.C. § 1395cc(j)).

<sup>65</sup> 31 U.S.C. § 3729(a)(1)(G).

<sup>66</sup> Pub. L. No. 111-148, § 6402(d)(2); codified at Social Security Act § 1128A(a)(10) (42 U.S.C. § 1320a-7a(a)(10)).

<sup>67</sup> Pub. L. No. 111-148, § 6502; codified at Social Security Act § 1902(a)(78) (42 U.S.C. § 1396a(a)(78)).

<sup>68</sup> Coalition Against Insurance Fraud. *Go Figure: fraud data*. Available at:

<http://www.insurancefraud.org/medicarefraud.htm>

<sup>69</sup> Assistant Attorney General Tony West, Remarks at HHS Press Conference (Oct. 15, 2009). Available at: <http://www.stopmedicarefraud.gov/west.pdf>

<sup>70</sup> Pub. L. No. 111-148, § 6407, codified at Social Security Act § 1814(a)(2)(C) (42 U.S.C. § 42U.S.C. 1395f(a)(2)(C)); Social Security Act § 1835(a)(2)(A) (42 U.S.C. § 1395n(a)(2)(a)); Social Security Act § 1834(a)(11)(B) (42 U.S.C. 1395m(a)(11)(B)).

<sup>71</sup> Pub. L. No. 111-152, § 1304, codified at Social Security Act § 1866(j) (42 U.S.C. § 1395cc(j)).

<sup>72</sup> Pub. L. No. 111-152, § 1302 (repealing Social Security Act § 1874A(h)).

- declaring AKS violations to be FCA predicate acts;
- expanding the types of conduct that constitute federal health care fraud offenses;
- broadening the grounds for imposition of CMPs;
- adding to the list of Medicare Part C and Part D marketing violations that can trigger enforcement;
- expressly requiring the return of overpayments within a certain time period and declaring the non-disclosure and retention of overpayments to be grounds for FCA recovery;
- tightening scrutiny of payments to DME suppliers and home health agencies;
- eliminating restrictions on pre-payment reviews; and
- extending the reach of RACs to Medicare Part C and Part D and to Medicaid.

Congress also took steps to ensure that enforcement authorities have the financial resources necessary to accomplish their goals. The Act authorizes \$10 million in increased Health Care Fraud and Abuse Control (HC-

FAC) program funding for each year through 2020,<sup>76</sup> and the Reconciliation provides an additional \$250 million through 2017 to the HCFAC program, beginning with a \$95 million boost in 2011.<sup>77</sup>

Finally, the Act takes the view that “sunshine is the best disinfectant” and imposes a variety of disclosure obligations on various health care entities ranging from pharmaceutical and medical device manufacturers to skilled nursing facilities.

The effectiveness of such disclosures remains to be seen, but, without question, the health care industry will be required to collect and report more information than ever before, and failure to report such information completely and accurately could carry its own enforcement risk.

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<sup>76</sup> Pub. L. No. 111-148, § 6402, *codified at* Social Security Act § 1817(k) (42 U.S.C. § 1395i(k)).

<sup>77</sup> Pub. L. No. 111-152, § 1303, *codified at* Social Security Act § 1817(k) (42 U.S.C. § 1395i(k)).