THE IMPACT OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT ON FRAUD PREVENTION AND ENFORCEMENT

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I. INTRODUCTION

The *Patient Protection and Affordable Care Act* (PPACA) was signed into law on March 23, 2010.[2] While the debate centered on issues of the public option and mandatory coverage, everyone agreed that fighting fraud in the health care market was an important means to control rising costs. As a result, reform included a number of provisions that will make it easier for the government to prevent and prosecute fraud and abuse. In addition to the provisions outlined below, the current budget seeks a significant increase in funding for the Department of Justice (DOJ), the Federal Bureau of Investigations (FBI), the Center for Medicare and Medicaid Services (CMS), and the Office of the Inspector General in the Department of Health and Human Services (HHS-OIG).

During the year-long debate, the new Administration focused intensely on efforts to fight fraud, waste and abuse. On May 20, 2009, it established the first Cabinet level working group designed to address issues of fraud, the Health Care Fraud Prevention and Enforcement Action Team (HEAT). That same day, President Obama signed the Fraud Enforcement and Recovery Act (FERA). HEAT was designed to marshal resources within the government to both prevent fraud and to maximize the efforts of law enforcement efforts. Congress responded with a few anti-fraud provisions of its own, and the President was delighted to lend his hand to an broad assortment for new fraud fighting tools and refinements.

While some may see the new fraud and abuse provisions as an ominous reminder of the heavily regulated environment in which we work, others may choose to embrace the words of President Abraham Lincoln when he said, "[t]he pessimist sees the difficulty in every opportunity and the optimist sees the opportunity in every difficulty." Many of the new provisions discussed below create uncertainty in the markets which pose added difficulty. However, those in health care industries must continue to work with government to seek to establish a level playing field where the rules are enforced fairly and equally.

This article extracts several of the key reform provisions for fraud and abuse practitioners for the sole purpose of identifying the issues. The next few months will launch an evolution of the reform provisions both in practice and principle.

II. FUNDS FOR HEALTH CARE FRAUD ENFORCEMENT AND PREVENTION

In fiscal year 2009, Medicare is estimated to cost the federal government $503.1 billion and Medicaid is estimated to cost the federal and state governments $386 billion.[3] Under the current health care system, CMS projects that federal health expenditures will double from approximately $873.2 billion in 2009 to $1.65 trillion in 2018.[4] While there is no accurate calculation of the extent of health care fraud, the FBI reports that estimates of fraudulent billings to public and private health care programs range between three and ten percent of total health care expenditures.[5] Within government, many have sought to keep enforcement spending in lock step with the calculation of losses.

Among all the new provisions, funding is likely to have the most profound impact on enforcement activities at DOJ, the FBI and HHS-OIG. The increases in funding will support a variety of programs that are currently expanding under the watch of HEAT. As a starting point, the Omnibus Appropriations Act of 2009 provided a one-time additional $198 million for joint HHS and DOJ health care fraud programs through an allocation adjustment for new program integrity work. The President's 2010 Budget invests an additional $311 million in 2-year funding to further strengthen the anti-fraud efforts, a 50-percent increase from the 2009 Budget. Further, the President's 2011 Budget seeks additional program integrity funding, with a request for another $250 million to expand HEAT efforts. PPACA increases funding for the Health Care Fraud and Abuse Control (HCFAC) Account for fiscal years 2011 through 2020 by $10 million annually,[6] and the Reconciliation Act added an additional $250 million to the account between 2011 and 2016.[7]

In addition to funding designed to support traditional law enforcement, issues of global compliance and executive liability will be further considerations. In November of 2009, DOJ announced its intention to use the Foreign Corrupt Practices Act[8] (FCPA) to conduct investigations in the pharmaceutical and device industries.[9] DOJ's FCPA unit and health care fraud unit have already begun to work together to investigate potential FCPA violations. According to PhRMA's membership survey, close to $100 billion of total sales for its members were generated outside of the United States, where health systems are operated or financed by government entities.[10] Federal prosecutors have said that FCPA enforcement in health care industries is overdue based on extensive government involvement in foreign health systems. For instance, doctors, pharmacists and lab technicians employed by state-owned facilities could all be considered "government officials" in certain countries and scenarios. The types of corrupt payments targeted by DOJ are similar to those items of value that would violate the Anti-Kickback Statute[11] (AKS) if given within the United States, such as cash, gifts, travel, meals, educational grants, and honoraria.

Meanwhile, the FDA made it clear in a March 4, 2010 letter that it would begin using misdemeanor prosecutions and exclusion provisions to hold corporate executives personally accountable for fraud and abuse violations that occur on their watch.[12] The basis of personal liability was laid out by the Supreme Court when it concluded that the government may establish a *prima facie* violation of FDCA when "it introduces evidence…that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."[13] OIG has already begun using this exclusionary power to target individual pharmaceutical executives convicted of Federal Food, Drug, and Cosmetic Act and other violations. Three top executives at Purdue were excluded for 12 years.[14]

III. IGNORANCE OF THE LAW NO LONGER AN EXCUSE IN NINTH CIRCUIT

Since 1991, tax evasion cases have largely hinged on jury instructions derived from *Cheek v. United States*.[15] Prior to PPACA, violations of the AKS were according the same type of *Cheek* instructions in the Ninth Circuit. PPACA settles a Federal circuit split about the definition of "willfully" as applied to the AKS's intent requirement.

In *Hanlester Network* v. *Shalala*,[16] the Ninth Circuit interpreted the Anti-Kickback Statute's "willfully" intent requirement to mean that the government had to prove that a defendant knew that the AKS prohibited the conduct at issue.[17] Other Circuits disagreed.[18] The debate is now resolved as the reform legislation makes clear that the AKS does not require a heightened scienter standard.[19] Likewise, the new law makes clear that the Health Care Fraud Statute,[20] which makes it unlawful to knowingly and willfully defraud or attempt to defraud any healthcare benefit program, does not require proof that the defendant had actual knowledge of the Statute.[21]

An example of the impact of PPACA can be seen in the oft-cited *Alvarado Hospital* case where the U.S. Attorney in the Southern District of California charged multiple entities and individuals with violating the AKS.[22] The trial court found that the Ninth Circuit "construed the scienter requirement of the AKS to require proof that the defendants knew that the AKS prohibited paying remuneration to induce referrals." [23] Implementation of the PPACA will require the Ninth Circuit to pattern "willfully" language in accordance with the other Circuits[24] and preclude it from instructing juries that an AKS violation requires knowledge of a "known legal duty."[25] Removing this burden in the Ninth Circuit allows prosecutors to charge and present cases based on a substantially reduced evidentiary foundation and may encourage increased utilization of the AKS.

IV. CLAIMS RESULTING FROM ANTI-KICKBACK VIOLATIONS ARE FALSE CLAIMS

Beyond making it easier to establish anti-kickback claims, PPACA also transforms many anti-kickback claims into potential False Claims Act (FCA) cases by codifying certain court decisions holding that an anti-kickback violation can establish the "falsity" of a claim under the FCA.[26] The new law amends the AKS to provide that "a claim that includes items or services resulting from a violation [of the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]."[27] Thus, reform clarifies that items or services resulting from an AKS violation are false for purposes of the FCA.

PPACA puts to rest the courts' struggle to ascertain when and under what circumstances violations of the AKS can be penalized under the FCA.[28] No longer will courts have to hinge a theory of FCA liability on a false assertion of compliance with the AKS.[29] The PPACA clearly narrows future courts' ability to adopt the rationale articulated in *U.S. ex rel. Thomas v. Bailey*.[30]

This amendment will undoubtedly lead to an increase in FCA litigation involving a myriad of issues. For example, PPACA's state-run exchanges are designed to increase competition among health insurers by creating a market for certain individuals to purchase health care policies. PPACA specifies that payments made "by, through, or in connection with" an exchange are subject to the FCA if the payment includes federal funds.[31] As FCA violations are subject to treble damages plus penalties, counsel will be watching exchange-related activities for opportunities to bring claims. In addition, the FERA amendments redefined obligation under the FCA to include "the retention of any overpayment." This amendment poses an added litigation risk for providers who knowingly retain overpayments.[32] Now, PPACA requires providers to report and return overpayments within 60 days.[33]

V. NARROWING FALSE CLAIMS ACT'S PUBLIC DISCLOSURE BAR

PPACA also significantly narrows the FCA's "public disclosure bar." Traditionally, the bar prohibited *qui tam* suits based on information that previously had been disclosed to the public, unless the whistleblower qualified as an "original source" of the information. First, PPACA narrows the types of information that could trigger the public disclosure bar. Under the new law, a whistleblower suit cannot be barred unless "substantially the same allegations or transactions were publicly disclosed" in: (1) "a Federal criminal civil or administrative hearing in which the government or its agent was a party;" (2) "a congressional, [GAO], or other Federal report, hearing, audit, or investigation," or (3) "from the news media."[34]

Before PPACA, the public disclosure bar was far broader, applying to disclosures at both the state and local level as well. Ironically, the Supreme Court decided on March 30, 2010, one week after President Obama signed PPACA, that whistleblower allegations based on publicly disclosed information in state or local reports are barred.[35] The Court acknowledged the PPACA's change but said that the amendment would not be retroactive and stated that the decision applied to the pre-PPACA FCA.[36]

In addition, PPACA broadens the definition of "original source." Previously, an original source needed "direct and independent knowledge of the information on which the allegations were based" and must have voluntarily provided that information to the government before filing an FCA suit based on that information. PPACA expands the definition of "original source" to also include any individual who has knowledge that is "independent of and materially adds to the publicly disclosed allegations or transactions, and who voluntarily provided the information to the government" before filing the suit.[37]

Third, in contrast to the prior rule that courts lacked jurisdiction to hear *qui tam* cases where the relator does not qualify as an original source, PPACA provides that if the whistleblower suit is based on publicly disclosed information and the whistleblower does not qualify as an original source then "the court shall dismiss [the suit], unless opposed by the government."[38] Thus, PPACA seems to allow whistleblower suits that would otherwise be barred if the Government opposes dismissal of the suit. The ultimate effect of this provision will depend on its utilization by the Government and the interpretation it is given by the courts, and its development will be particularly interesting to watch.

These changes, coupled with FERA, which made it easier for the government to obtain information from an FCA defendant, and share that information with a whistleblower and counsel, all but removes one of the most substantial restrictions on whistleblower suits. In short, FERA invites cases testing the new bounds of FCA liability, while PPACA expands the rights of the group most likely to test those limits. If the Government chooses to arm whistleblowers with extensive information from civil investigative demands (CIDs), and free them from the public disclosure bar, the number of FCA cases is certain to increase dramatically.

VI. EXPANDED EXCLUSION LEVERAGE

PPACA contains provisions clarifying or amending the current law regarding exclusion of entities from participation in federal healthcare programs for violations of healthcare fraud statutes. The new law expands HHS-OIG's permissive exclusion authority under section 1128 of

the Social Security Act (SSA) to apply in instances of obstruction of program audits and investigations.[39]

The rules of exclusion from the state Medicaid programs have also been dramatically updated. PPACA requires States to terminate individuals or entities from their State Medicaid programs if they have been terminated from Medicare or another State's Medicaid program. State Medicaid programs must also exclude an individual or entity that owns, controls, or manages another entity that has failed to repay overpayments, been suspended, terminated, or excluded from Medicaid participation, or is affiliated with any such entity.[40]

VII. DIRECTION TO EXTEND PRISON TERMS

It is generally understood that community knowledge of substantially longer sentences adds to the perception of punitive risk and creates deterrence. The new law is designed to boost deterrence by updating the advisory sentencing guidelines applicable to persons convicted of federal healthcare offenses involving federal healthcare programs. The U.S. Sentencing Commission will be required to update the guidelines to provide increased penalties. The Commission has been directed to increase the offense levels for defendants by 20 to 50 percent for crimes that involve more than $1 million in losses.[41]

Another purpose of sentencing is to hold a defendant accountable for his crimes, and with respect to fraud cases, that includes what the defendant intended to accomplish with his fraudulent scheme. Courts have been split on whether allowed amount or the billed amount is the appropriate basis to calculated intended loss. As with most white collar cases, the key driver of a healthcare fraud sentence, when applying the guidelines, is the amount of "intended loss." Arguably, the best evidence of a defendant's intent is the action that he undertook. In the healthcare fraud case, the act of filing a claim requires that a person knowingly and willfully place an amount into electronic or paper claim form. In most cases, this act is the best evidence of the amount the person intends to take from the federal healthcare program. The new law codifies a number of Circuit court opinions that supported this approach,[42] specifying that in applying the sentencing guidelines, the aggregate dollar amount of fraudulent bills submitted to a government healthcare program shall constitute *prima facie* evidence of the amount of the "intended loss" by the defendant.[43]

VIII. UPDATED DEFINITIONS

PPACA updates and broadens the definition of "health care fraud offense" under 18 U.S.C. § 24(a) to include violations of the AKS, the Food, Drug and Cosmetic Act (FDCA), and certain provisions of the Employee Retirement Income Security Act (ERISA).[44] These changes impact enforcement by: (1) making the proceeds of these offenses subject to criminal forfeiture; (2) rendering obstruction of an investigation of these offenses a crime; (3) including these offenses as specified unlawful activity for purposes of money laundering; and (4) authorizing the use of administrative subpoenas for the production of documents.

IX. CIVIL MONETARY PENALTIES FOR SLOW OR FALSE RESPONDERS

The new law provides civil monetary penalties (CMPs) for slow or false responders to HHS-OIG inquiries. HHS-OIG has been empowered to impose CMPs of $15,000 per day for those who fail to grant timely access for purposes of audits, evaluations, investigations, or other statutory functions.[45] Plus, PPACA authorizes CMPs of up to $50,000 for any false claim or false statement submitted to or made to any federal healthcare program.[46]

X. INCREASED SUBPOENA AUTHORITY

PPACA also provides the Justice Department with subpoena authority for investigations conducted pursuant to the Civil Rights for Institutionalized Persons Act,[47] allowing the government to seek to protect the health and civil rights of individuals living in institutional facilities, such as nursing homes, mental health institutions, facilities for persons with disabilities, residential schools for children with disabilities, as well as jails and prisons.[48]

The law also amends an obstruction statute, 18 U.S.C. § 1510, so that obstruction of criminal investigations involving administrative subpoenas under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is treated in the same manner as obstruction of criminal investigations involving grand jury subpoenas.[49]

XI. DRUG PRICING IMPACT

Among other pricing provisions, PPACA imposes new reporting obligations on manufacturers with regard to the Section 340B drug pricing program, which requires manufacturers to charge at or below a specified ceiling price to eligible safety net providers. The legislation requires the Health Resources Services Agency (HRSA) to "improve" manufacturer compliance with the 340B program, including (a) amending the Pharmaceutical Pricing Agreement (PPA) to require drug manufacturers to provide HRSA with quarterly reports of the

ceiling price for each covered outpatient drug subject to the agreement; (b) requiring that manufacturers offer each covered entity covered drugs for purchase at or below the ceiling price if such drug is made available to any other purchaser at any price; (c) establishing a process to verify the accuracy of 340B ceiling prices calculated by manufacturers and charged to covered entities; (d) creating a process for evaluating any discrepancies between ceiling prices and manufacturer pricing data and taking corrective action in response to such discrepancies; (e) adopting mechanisms for manufacturers to report rebates and other lagged discounts provided by manufacturers to purchasers subsequent to the sale of drugs to 340B entities and to issue credits and refunds to covered entities if the rebates would lower the ceiling price for the relevant quarter; and (f) developing a process for manufacturers to issue refunds in the event there is an overcharge to 340B covered entities.[50] The legislation authorizes CMPs if a manufacturer "knowingly and intentionally" charges a covered entity a price that exceeds the 340B ceiling price, not to exceed $5,000 for each instance of overcharging that may have occurred.[51]

XII. SUNSHINE PROVISIONS

The reform legislation also included the Physician Payment Sunshine Act. In particular, it requires manufacturers of drugs, biologics, devices, or medical supplies that provide payments (or other transfers of value) to a physician or teaching hospital to submit information about those payments to HHS beginning March 31, 2013.[52] Payments or other transfers of value include any transfers of value unless excluded by the statute; however, transfers of value do not include a transfer made indirectly to a covered recipient through a third party where the manufacturer is unaware of the identity of the covered recipient. These "transparency" reports must include the name and address of the physician/recipient; the amount, date and a description of the payment; the identity of the drug, device, or medical supply to which the payment relates (if related to the promotion of a particular item); and other information.[53]

The transparency provisions contain the following exemptions: (1) transfers of value less than $10, unless the aggregate amount exceeds $100 during the calendar year; (2) educational materials that directly benefit patients or are intended for patient use; (3) the loan of a covered device for less than 90 days for evaluation by the covered recipient; (4) items or services provided under a contractual warranty; (5) a transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in a professional capacity; (6) discounts (including rebates); (7) in-kind items used for the provision of charity care; (8) profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund; (9) payments for the provision of healthcare to employees under a self-insured plan; (10) a transfer of value to a licensed non-medical professional if the transfer is payment solely for non-medical professional services; and (11) a transfer of value to a physician if the transfer is payment solely

for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.[54]

Although product samples are exempt from the transparency report, beginning April 1, 2012, and annually thereafter, drug manufacturers must report distributions of drug samples to practitioners, separate from the transparency report.[55] The information reported must be made publicly available by HHS on an Internet website, in a searchable format.

Additionally, PPACA requires HHS to establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP as well as subjects them to new disclosure requirements.[56]

The new law also requires HHS to enter into data-sharing agreements with other agencies to help identify fraud, waste, and abuse. HHS-OIG and DOJ will have access to this data for the purposes of conducting law enforcement and oversight activities.[57]

XIII. CONCLUSION

This article has merely touched on a few of the recent fraud and abuse provisions that were signed into law in March of 2010. The implications of these reforms are just beginning to be discussed and analyzed. As counsel to health care providers, we can advise our clients on how to navigate this more heavily regulated landscape, as well as work with the government to ensure fair and equal application of the significantly strengthened government enforcement arsenal.

ENDNOTES

1. Messrs. Ogrosky and Kracov are Partners in the FDA and healthcare practice. Prior to joining the firm, Mr. Ogrosky served as Deputy Chief in the Fraud Section of the Criminal Division at the U.S. Department of Justice. Mr. Kracov leads the firm's FDA and healthcare practice, and handles product and compliance-related enforcement matters and Congressional investigations. Messrs. Ogrosky and Kracov express their gratitude to Catherine Brandon, an associate in the Washington office for her assistance in the preparation of this article. Ms. Brandon is a member of the FDA and healthcare practice and a 2009 graduate of the University of Pennsylvania School of Law.

2. Pub. L. No. 111-148 (2009). Since the Government Printing Office (GPO) has not published a final version of the public law at the time of this writing, citations to H.R. 3590, 111th Cong. (2009) will cover relevant provisions of both the PPACA and H.R. 4872, 111th Cong. (2010), the Health Care and Education Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152 (2010). Generally, references to PPACA should be treated as inclusive of HCERA.

3. Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Expenditure Projections 2008-2018, 5 tbl. 3 (2007), available at http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf.

4. Id.

5. Federal Bureau of Investigation, Financial Crimes Report to the Public: Fiscal Year 2007 (2007), available at http://www.fbi.gov/publications/financial/fcs_report2007/financial_crime_2007.htm#health.

6. H.R. 3590, §6402.

7. H.R. 4872 §1303(a).

8. 15 U.S.C. §§ 78dd-1, et seq.

9. Lanny A. Breuer, Assistant Attorney General, Criminal Division, Prepared Keynote Address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009).

10. Id.

11. 42 U.S.C. §1320a-7b(b).

12. Letter from Margaret A. Hamberg, Commissioner of Food and Drugs, to Senator Charles E. Grassley (March 4, 2010).

13. United States v. Park, 421 U.S. 658, 673-74 (1975).

14. PBS, Nightly Business Report, Mar. 19, 2010, available at http://video.pbs.org/video/1445614974/.

15. 498 U.S. 192 (1991).

16. 51 F.3d 1390, 1400 (9th Cir. 1995).

17. Id.

18. See, e.g., United States v. Starks, 157 F.3d 833, 838-39 (11th Cir. 1998).

19. H.R. 3590 §6402 ("with respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section").

20. 18 U.S.C. § 1347.

21. H.R. 3590 §10606(b).

22. United States v. Weinbaum, et al., Case No. 03-CR-1587-L (S.D.C.A. 2005).

23. Weinbaum, Case No. 03-CR-1587-L, at 14 (citing Hanlester, 51 F.3d at 1400).

24. H.R. 3590 §6402.

25. See Weibaum, Case No. 03-CR-1587-L, at 14 (interpretation of the scienter requirement overturned by PPACA).

26. See, e.g., United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009).

27. H.R. 3590 §6402.

28. See, e.g., U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 565 F. Supp. 2d 153 (D.D.C. 2008); U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28 (D.D.C. 2003); U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997).

29. See, e.g., U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 2010 WL 938361 (D.Mass. Mar. 12, 2010); U.S. ex rel. Thomas v. Bailey, 2008 WL 485630 (E.D.Ark. Nov. 6, 2008).

30. Id.

31. H.R. 3590 §1313(a)(6).

32. 31 U.S.C. § 3729(a)(1)(G) (2010).

33. H.R. 3590 §6402(a).

34. H.R. 3590 §1303(j)(2).

35. Graham County Soil and Water Conservation District v. U.S. ex rel. Wilson, 08-304, 2010 WL 1189557 (March 30, 2010).

36. Id. at *2, fn. 1.

37. Id.

38. Id.

39. H.R. 3590 §6408(c).

40. H.R. 3590 §6501.

41. H.R. 3590 §10606(a)(2)(C).

42. See, e.g., United States v. Miller, 316 F.3d 496 (4th Cir. 2003).

43. H.R. 3590 §10606(a)(2)(B).

44. H.R. 3590 § 10606(c).

45. H.R. 3590 §6408 (a)(2)-(3).

46. Id.

47. 42 U.S.C. § 1997 et seq.

48. H.R. 3590 §10606(d)(2).

49. H.R. 3590 §10606(d)(1).

50. H.R. 3590 §7102(a).

51. Id.

52. H.R. 3590 §6002.

53. Id.

54. Id.

55. H.R. 3590 §6004.

56. H.R. 3590 § 6401.

57. H.R. 3590 §6402.