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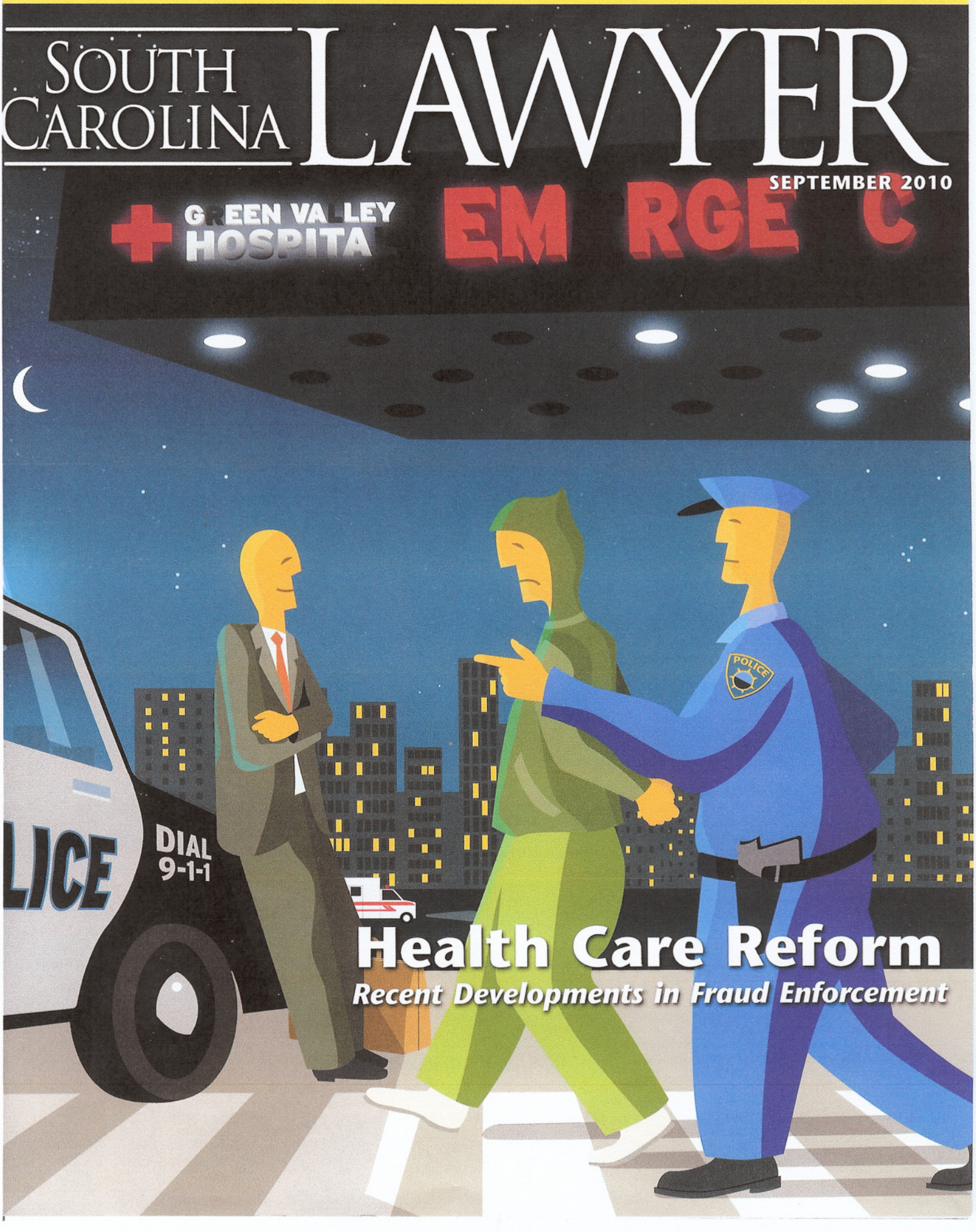

Health Care Reform

Recent Developments in Fraud Enforcement

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By Matthew R. Hubbell, Joseph P. Griffith Jr. and E. Bart Daniel

Introduction

Notorious bank robber Willie Sutton's advice was, "Go where the money is ... and go there often." Willie Sutton & Edward Linn, WHERE THE MONEY WAS: THE MEMOIRS OF A BANK ROBBER (The Viking Press 1976). Today no bank could hold the enormous amount of government money spent on health care in just one year. In 2010, combined federal and state health care spending is projected to exceed $800 billion. Acting Deputy Attorney General Gary Grindler, Address at The American Bar Association's 20th Annual National Institute on Health Care Fraud (May 13, 2010). The U.S. Department of Justice (DOJ) cites external studies estimating that the amount of fraud associated with that level of spending is between three and 10 percent, or $27 to $80 billion in 2010 alone. *Id.* The big money, and hence big-time fraud, is now found in the health care industry.

The recently passed Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010), and the Healthcare and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (the "Act"), enacted sweeping changes to health care, including important anti-fraud measures that will significantly boost the federal government's prosecution of civil and criminal fraud cases. Although these anti-fraud provisions were largely obscured by the sound and fury of the health care reform debate,

health care law practitioners and their clients must be aware of these significant changes in the landscape of health care law. Specifically, the Act provides substantial federal funding to finance fraud enforcement efforts, creates powerful new investigative tools, lowers the bar for prosecutors and qui tam plaintiffs, establishes new criminal offenses, and increases the punishment for violations.

A stimulus package for health care prosecutors

The Act provides an additional $350 million to fight fraud. Pub. L. No. 111-148 § 6402(i)(1)(A), 124 Stat. 119, 761 (2010); Pub. L. No. 111-152, § 1303(a)(1)(A), 124 Stat. 1029, 1057-8 (2010). These funds supplement a robust $464 million expenditure in fiscal year 2009 for the Health Care Fraud and Abuse Control Account. Dep't. of Health & Human Servs. & Dep't of Justice, Health Care Fraud and Abuse Program Annual Report for Fiscal Year 2009 at 4 (May 2010) (the "Report"). This account, which is administered jointly by the Attorney General and the Secretary of the U.S. Department of Health and Human Services (HHS), funds anti-fraud programs. *Id.* at 3. The programs include aggressive prosecution strike forces operating in Medicare fraud "hot spots" such as Miami and Los Angeles. *Id.* at 10. Recently these strike forces have made mass arrests, indicted hundreds of individuals and secured more than 250 guilty pleas that resulted in around 200 sentences of imprisonment. *Id.* at 10-11.

In fiscal year 2009, the combined anti-fraud efforts of the DOJ and HHS provided a fantastic return on the government's investment, including: approximately $2.5 billion in deposits to the Medicare Trust Fund; $1.6 billion in judgments and settlements; more than 1,000 newly opened criminal health care fraud investigations; and nearly 900 new civil health care fraud investigations. *Id.* at 1.

The proof of the incredible magnitude of health care fraud is in the pudding: record-smashing fines or penalties obtained by the government from pharmaceutical manufacturers, physicians, pharmacies and hospitals. Pfizer, for example, paid $2.3 billion to resolve criminal and civil liability arising out of the alleged illegal promotion of pharmaceutical products. *Id.* at 15. This was the highest settlement ever for a health care fraud case. *Id.* Eli Lilly paid $1.4 billion for a global settlement of criminal, civil and administrative liability in connection with the alleged illegal marketing of the antipsychotic drug Zyprexa in violation of the federal Food, Drug and Cosmetics Act (FDCA). *Id.*

New administrative enforcement tools

To aid the government in administrative proceedings to exclude violators from participation in the Medicare program, the Act authorizes the secretary of HHS to delegate a testimonial subpoena power in exclusion-only cases to the HHS Inspector General. This

power can be used to obtain information from any individual, including a beneficiary, provider, supplier, grant recipient, contractor, manufacturer, distributor or other entity, for the purposes of protecting the integrity of Medicare and Medicaid, including supporting documentation necessary to validate Medicare and Medicaid payments. Pub. L. No. 111-148, § 6402(e), 124 Stat. 199, 759 (2010); 42 U.S.C. § 1320a-7(f)(4). This follows enactment of a similar provision in the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 121-21, 123 Stat. 1617 (2009) (28 C.F.R. Pt. 0, Subpt. Y, App., Sec. 5), which gave U.S. Attorneys the power to subpoena documents and take depositions before filing suit under the False Claims Act.

The Act also expands the Recovery Audit Contractor (RAC) program, which is an outsourced component of the government's anti-fraud effort. Under the RAC program, the federal government contracts with private contractors (RACs) who analyze claims data to identify overpayments and underpayments. Dep't of Health & Human Servs., Recovery Audit Contractors' Fraud Referrals 1 (Feb. 2010). RACs receive a negotiated contingency fee, historically 18 to 35 percent, based on the amount of identified erroneous payments. *Id.* at 3. Pursuant to new mandatory provisions of the Act, the RAC program will be expanded dramatically to include Medicare Parts C (private plans) and D (prescription drugs) with a requirement that these programs have anti-fraud plans in effect. Pub. L. No. 111-148, § 6411(b), 124 Stat. 119, 775 (2010). The Act also mandates that by December 31, 2010, states must contract with RACs to identify and recoup Medicaid overpayments. Pub. L. No. 111-148, § 6411(a), 124 Stat. 119, 773-4 (2010).

RACs are required to report fraud to Centers for Medicare and Medicaid Services (CMS) (the federal agency that administers Medicare and Medicaid). Dep't of Health & Human Servs., Recovery Audit Contractors' Fraud Referrals 1 (Feb. 2010). During a three-year RAC demonstration project conducted in just a few states, RACs identified more than $1.03 billion in improper Medicare payments at a cost to the government of only 20 cents on the dollar. *Id.* at 5. Due to the expanded scope of the RAC program and the massive government spending on health care, fraud referrals should only increase in the future.

False Claims Act amendments

The False Claims Act, 31 U.S.C. §§ 3729-3733 (FCA), is a powerful weapon used by the DOJ and private whistleblowers to civilly prosecute those who perpetrate frauds upon the United States through false and fraudulent claims for payment. The FCA provides for treble damages and civil monetary penalties to be awarded to the federal government, and the qui tam plaintiff, often called a "relator," may recover up to 30 percent of the award, plus statutory attorney's fees.

The FCA was amended by the Act to make it easier for whistleblowers to bring qui tam suits on behalf of the federal government by lowering the "public disclosure" standard. Prior to the Act, a qui tam plaintiff who was not an original source was jurisdictionally barred from bringing an FCA suit if the fraudulent conduct of the defendant had been previously disclosed in the public domain through the media; federal, state or local reports; audits and investigations; or criminal, civil and administrative hearings and proceedings. *See Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S.Ct. 1396 (2010) (upholding the dismissal of FCA claim for lack of jurisdiction based on prior public disclosure of fraud in county audit reports).

Under the amendments of the Act, public disclosures under the FCA are now more limited and only include: a *federal* criminal, civil and administrative hearing in which the government or its agent is a party; congressional, Government Accounting Office or other *federal* report, hearing, audit or investigation; or the news media. *See* 31 U.S.C. § 3730(e)(4)(A). This means that state and local audits, reports, investigations and hearings, as well as litigation between private parties, can now be used as the sole source of information for an FCA suit for defrauding the federal government.

The Act also changed the jurisdictional nature of the public disclosure provisions. Before the new law was enacted, a violation of the public disclosure requirements of the FCA was a jurisdictional defect that could be raised by a party at any time or *sua sponte* by the court. Under the Act, a qui tam complaint that violates the public disclosure provision can be dismissed pursuant to a Rule 12(b)(6) motion, unless such dismissal is "opposed by the Government." *Id.*

The Act also amended the "original source" provisions of the FCA. Prior to the Act, a relator who was an original source could bring an FCA suit regardless of whether there was a previous public disclosure. This meant that a relator had to have "direct and independent knowledge" of the information on which the fraud allegations were based and had voluntarily provided the information to the government before filing an FCA action that was based on the information. Now, under the Act, the "direct and independent knowledge" requirement has been eliminated, and an original source is an individual who voluntarily discloses the frauds to the government prior to a public disclosure or "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). Thus, as long as the relator has information about the government frauds that are independent of publicly disclosed information, even if the relator did not have "direct" information usually derived from personally witnessing the fraudulent conduct, an FCA suit may proceed.

The limiting of the public disclosure provisions and the broadening of the original source provisions of the FCA will surely lead to an increase in the filing of qui tam lawsuits. While the change in the jurisdictional aspect of the public disclosure provisions ostensibly helps qui tam relators, it remains to be seen whether the government will develop a policy towards or against FCA suits in which Rule 12(b)(6) motions have been filed based upon prior public disclosures.

The Act also amended the Anti-Kickback Statute (AKS) to make violations subject to the civil enforcement provisions of the FCA. 42 U.S.C. § 1320a-7b(g). This amendment was in response to a line of qui tam cases that have held that kickbacks involving federal health care programs were not covered by the FCA under an implied certification theory. In an implied certification case, the relator alleges liability of the defendant based upon the very act of submitting a claim for reimbursement because the defendant has impliedly certified compliance with governing federal rules that were a precondition to payment. Several courts had held that no FCA liability could attach under an implied certification theory involving kickbacks because neither the AKS statute nor regulation expressly stated that compliance was a precondition to Medicare or Medicaid payments. *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, No. 06-11771-WGY, 2010 WL 938361 (D. Mass. Mar. 12, 2010). With this new legislation, implied certification FCA cases will likely become more prevalent.

The Act further expanded the scope of "reverse false claims" under the FCA with respect to the retention of Medicare and Medicaid overpayments. In the 2009 Fraud Enforcement and Recovery Act (FERA), Congress eliminated the requirement of an affirmative false statement to the government for liability to attach in reverse false claims cases. *See* 31 U.S.C. § 729(a)(1)(G) (liability for

a person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government"). The Act amended the Social Security Act to provide that Medicare and Medicaid overpayments become an actionable "obligation" under the FCA when the deadline for repayment expires. Such overpayments must be reported and returned to the federal government within 60 days of the later of the date the overpayment was identified or the date a corresponding cost report is due.

Finally, the Act creates potential FCA liability for private exchange insurers. The Act establishes private insurer "exchanges" to provide individuals with options for the purchase of health insurance. If the private insurer's exchange plans include any federal funding, then the payments made by, through or in connection with the plan are subject to the FCA. However, the effective date of this provision is January 1, 2014, so there will be a significant delay in its implementation.

Anti-Kickback and other health care fraud criminal statutes

The Act significantly lowers the bar for prosecutors charging AKS violations under 42 U.S.C. § 1320a-7b by revising the intent standard. The AKS is a criminal statute that prohibits the offer or receipt of remuneration to induce referrals that may be covered by Medicare, Medicaid or any other federally funded health care program. Prior to the Act's amendments, the government was required to prove that the defendant acted "knowingly and willfully." However, as amended by the Act, the AKS now provides that "a person need not have actual knowledge of this section or specific intent to violate this section" in determining whether a violation occurred. Pub. L. No. 111-148, § 6402(f)(2), 124 Stat. 119, 759 (2010); 42 U.S.C. § 1320a-7b(h). These revisions will of course make it easier to prosecute violations of the AKS, which are felonies punishable by fines and imprisonment for up to five years. *Id.* at § (b)(1).

The Act also amends the general criminal health care fraud statute by lowering the standard of intent necessary for prosecution. 18 U.S.C. § 1347. Under the amendments, neither the specific intent to violate the health care fraud statute nor actual knowledge of the statute are required. Pub. L. No. 111-148, § 10606(b), 124 Stat. 119, 1008 (2010).

The amendments have also expanded the definition of "federal health care offense" under 18 U.S.C. § 24(a) to encompass violations of the AKS, FDCA and Employee Retirement Income Security Act of 1974 (ERISA). Pub. L. No. 111-148, § 10606(c), 124 Stat. 119, 1008 (2010). The Section 24 amendments thereby enable criminal forfeitures under 18

U.S.C. § 982(a)(7) for an expanded list of health care fraud violations while at the same time expanding the list of health care frauds subject to the money laundering provisions of 18 U.S.C. § 1956(c)(7)(F).

Multiple employer welfare arrangements

The Act imposes a new stiff penalty concerning misrepresentations regarding multiple employer welfare arrangements (MEWAs). ERISA, at 29 U.S.C. § 1002(1), defines a MEWA as:

> any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer or by an employee organization, or by both, to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, or vacation benefits, apprenticeship or other training programs, or day care centers, scholarship funds, or prepaid legal services, or (B) any benefit described in section 186(c) of this title (other than pensions on retirement or death, and insurance to provide such pensions).

The Act creates a new penalty in ERISA by incorporating Section 519. This section is designed to protect MEWAs by prohibiting a:

> False statement or false representation of fact, knowing it to be false, in connection with the marketing or sale of such plan or arrangement [MEWA] ... concerning (1) the financial condition or solvency of such a plan or arrangement; (2) the benefits provided by such plan or arrangement; (3) the regulatory status of such plan or other arrangement under any

> Federal or State law governing collective bargaining, labor management relations, or intern union affairs; or (4) the regulatory status of such plan or other arrangement regarding exemption from state regulatory authority under this Act.

Pub. L. No. 111-148, § 6601, 124 Stat. 199, 779 (2010). A conviction under this new penalty can result in 10 years federal imprisonment or a fine under Title 18, or both. *Id.*

Federal Sentencing Guidelines amendments

The Act instructs the U.S. Sentencing Commission to amend the U.S. Federal Sentencing Guidelines (Guidelines) to ensure that they "reflect the serious harms associated with heath care fraud." Pub. L. No. 111-148, § 10606(a)(3)(A)(i), 124 Stat. 119, 1007 (2010). It also requires specific amendments to the Guidelines to increase penalties for federal criminal health care fraud offenses.

Under the Guidelines, the greater of the actual or intended loss to the federal health care program determines the offense level and ultimately the sentence of imprisonment. Section 10606(a)(2)(B) of the Act directs the Sentencing Commission to amend the Guidelines to provide that "the total aggregate 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." 124 Stat. 119, 1007 (2010).

Under the Act, the offense level for any offense causing a loss of between $1,000,000 and $7,000,000 is increased by two levels. *Id.* Similarly, the Act imposes a three level increase for any offense involving a loss between $7,000,000 and $20,000,000 and a four level increase for an offense involving a loss greater than $20,000,000. *Id.* At the lower loss threshold, these amendments will add at least an additional year to the Guideline sentence of imprisonment.

Conclusion

Under the Act, life is good for federal prosecutors, government agencies and qui tam plaintiffs targeting fraud in the health care industry. On the other hand, crooks defrauding federally funded health care programs will face more investigations and harsher penalties. In the middle, however, well-intentioned hospitals, doctors and other providers will struggle to comply with a byzantine maze of health care laws while competing in an increasingly difficult economic environment. Unfortunately for good faith providers, the Act increases the risk of draconian civil and even criminal punishment for alleged technical offenses that may bear no resemblance to old-fashioned fraud comprised of lyin', cheatin' and stealin.'

Matthew R. Hubbell, Joseph P. Griffith Jr. and E. Bart Daniel, former federal prosecutors, are co-authors of Health Care Fraud and Collateral Consequences, 2nd Edition, *to be published by the S.C. Bar this fall.*