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Implementation of Part D e-prescribing surveyed by OIG

As required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS established electronic prescribing standards to facilitate the communication of prescription information among prescribers (e.g., physicians), Part D plan sponsors, and dispensers (e.g., pharmacies). Three of these standards enable the flow of eligibility, medication history, and formulary and benefits information between plan sponsors and prescribers at the point of care.

These plan-to-prescriber standards are (1) Accredited Standards Committee X12N 270/271, (2) SCRIPT 8.1, and (3) Formulary & Benefits Standard 1.0. The Formulary & Benefits Standard 1.0 consists of four components: (1) Formulary Status List, (2) Formulary Alternatives List, (3) Coverage List, and (4) Copayment List.

CMS required that plan sponsors implement two standards by January 2006 and the remaining standard by April 2009. Between August and September 2008, the Office of Inspector General (OIG) surveyed all Part D plan sponsors for plan year 2008 to determine the extent of their implementation of the standards. The OIG received responses from 262 plan sponsors for a 94 percent response rate.

Survey results. The OIG survey found that: (1) nearly 80 percent of plan sponsors reported at least partial plan-to-prescriber connectivity but few reported complete connectivity; (2) problems implementing Formulary & Benefits Standard 1.0 limit complete plan-to-prescriber connectivity; and (3) only 5.0 percent of plan sponsors reported no plan-to-dispenser connectivity.

Recommendations. OIG recommends that CMS ensure that plan sponsors completely implement the plan-to-prescriber and plan-to-dispenser standards. To achieve this, CMS could continue to educate plan sponsors about e-prescribing requirements, clarify e-prescribing standards exemptions, or use corrective action plans and civil monetary penalties to bring plan sponsors into compliance. OIG also recommends that CMS collaborate with plan sponsors, pharmaceutical benefits managers, and standards-development organizations to address batch-processing problems. CMS could also consider pilot-testing a real-time standard that enables plan sponsors to transmit beneficiary-specific formulary and benefits information.

Although CMS concurred with the OIG recommendations, it asserted there were significant methodological limitations with the OIG data collection and analysis, resulting in inflated findings of plan sponsor noncompliance with e-prescribing standards. Specifically, CMS asserted that the OIG results would have likely been different if the survey had been conducted closer to the implementation deadline. ■

OIG Report, No. OEI-05-08-00320, October 2009

Wolters Kluwer Law & Business

Creation of exclusive nephrology practice did not constitute monopolization, 10th Circuit concludes

A nonprofit hospital did not create a monopoly in violation of the antitrust laws when it established a new practice as the exclusive provider of nephrology services and denied admitting privileges to other nephrologists, according to the U.S. Court of Appeals for the Tenth Circuit.

The district court properly granted summary judgment to the hospital because the hospital had no antitrust duty to share its facilities with another physician at the expense of its own nephrology practice, its failure to share its facilities was evidence of competitive conduct. In addition, whatever injury the physician suffered from his exclusion from the hospital staff was not one remedied by antitrust laws, the court concluded.

The physician's nephrology practice. The physician and his associates have a successful nephrology practice located an hour and a half away from the hospital community. In addition, the physician had consulting privileges at the hospital for many years.

Patients from the hospital's community and a nearby Indian reservation traveled to the physician's office to receive kidney dialysis and other outpatient nephrology services. Because of the distance of the physician's practice and the prevalence of kidney disease in its community, most acutely among members of the Indian tribe, the hospital and the tribe had sought for many years to convince the physician to provide nephrology services in its community, but the physician declined.

The hospital's new practice. Subsequently, the hospital and the tribe decided to recruit another nephrologist. After extensive interviews, the hospital hired a nephrologist on a salaried basis and permitted him serve as the director of an independently owned outpatient dialysis center. Because the hospital expected that the new practice would lose money for many years, the hospital agreed to underwrite losses for a period of seven years, and the tribe created a trust fund to backstop additional losses.

Based on the hospital's bylaws, the new nephrologist's employment automatically terminated the physician's consulting privileges, however, the physician was able to remain a member of the hospital's courtesy staff or become a member of the hospital's active staff. Member of the active staff had to reside within 30 minutes of the hospital to be able to provide emergency care. The hospital refused to grant privileges to the physician he did not meet the residence requirement.

In addition, for financial reasons, including concerns that granting privileges staff privileges to other nephrologists would reduce the volume of patients for its practice and increase anticipated losses and exhaust its reserves prematurely, the hospital made the nephrology practice the sole provider of nephrology services to the hospital.

Finally, the hospital was concerned that the physician's intentions were to destroy the hospital's practice rather than increase the quantity and quality of nephrology services available in the community.

Antitrust analysis. The physician filed a complaint alleging that the hospital's refusal to grant staff privileges to nephrologists other than those employed by the hospital amounted to monopolization. The hospital's refusal to share its facilities with the physician did not constitute anticompetitive conduct sufficient to sustain a claim for monopolization, the court stated, adding that the hospital is entitled to recoup its investment without sharing its facilities with a competitor.

Further, the members of the community now have greater access to nephrology services and more options. In addition, the evidence showed that the hospital refused to deal with the physician to avoid an unprofitable relationship and to protect and maximize the chances of profitability in the short term, the court said. Finally, by asking the court to order the hospital to grant him privileges, the physician sought to share rather than undo the hospital's alleged monopoly, the court concluded. ■

Four Corners Nephrology, 10th Cir., Sept. 29, 2009, Health Care Compliance Reporter, ¶800,744

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Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

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New tips offered to prevent identity theft and Medicare fraud

New tips and information to help seniors and Medicare beneficiaries were recently introduced by HHS Secretary Sebelius, Assistant Attorney General Tony West, and Inspector General Daniel R. Levinson.

"When criminals steal from Medicare, they are stealing from all of us. That's why fighting Medicare fraud is one of the Obama Administration's top priorities," said Secretary Sebelius. "Preventing medical identify theft is an important part of our work to stop Medicare fraud, and these tools will give seniors important information about how to deter, detect and defend against ID theft and fraud."

"This Administration is committed to guarding Medicare against fraud and abuse," noted Assistant Attorney General West. "The Department of Justice (DOJ), in collaboration with our partners at the Department of Health and Human Services (HHS), will continue to protect the integrity of the nation's public health programs and vigorously pursue those who seek to take advantage of our most vulnerable citizens."

Brochure. The new tips and a printable brochure were produced by the HHS Officer of the Inspector General and are available at http://www.stopmedicarefraud.gov/.

Identity theft. The materials include steps to help "deter, detect, and defend" against medical identity theft. The brochure reminds beneficiaries to beware of offers of free medical equipment, services, or goods in exchange for their Medicare numbers, and also encourages beneficiaries to regularly review their Medicare Summary Notices, Explanations of Benefits statements, and medical bills for suspicious charges and to report suspected problems. The brochure also describes common fraud schemes, such as people who offer free services, groceries, transportation, or other items in exchange for beneficiaries' Medicare numbers, or telephone marketers who claim to be from Medicare or Social Security and ask for payment over the phone or Internet.

Medicare fraud. Other efforts to prevent fraud include the Health Care Fraud Prevention and Enforcement Action Team (HEAT), which identify, investigate, and prosecute ongoing Medicare fraud with data analysis techniques and community policing. HEAT's efforts have expanded from South Florida and Los Angeles to additional cities including Detroit and Houston. Beginning October 1, 2009, CMS required all durable medical equipment suppliers, except for pharmacies, to be certified by Medicare, to assure beneficiaries that their suppliers are valid businesses.

SMP programs. Secretary Sebelius also highlighted the SMP program, formerly known as the Senior Medicare Patrol program. SMPs, funded by HHS' Administration on Aging, help Medicare and Medicaid beneficiaries prevent, detect, and report health care fraud. SMPs recruit and train nearly 5,000 volunteers every year to help in this effort. ■

CCH Chicago Bureau, Oct. 15, 2009

Tenth Circuit affirms dismissal of qui tam action for pleading deficiencies

The district court properly dismissed a case manager's *qui tam* suit under the False Claims Act (FCA) against a corporation that operated several long-term care facilities for mentally retarded adults because the case manager failed to either state a claim or plead the allegations with particularity. After the case manager had worked for the corporation for 5 years, the corporation terminated her employment. The case manager's suit alleged that: (1) the corporation had presented false and fraudulent claims to the government under the Medicare, Medicaid, and Social Security programs; (2) used false or fraudulent records; (3) conspired to get false or fraudulent claims paid; and (4) terminated her employment in retaliation for reporting these false claims. The district court granted the corporation's motion to dismiss due to its pleading deficiencies. The case manager subsequently appealed to the Tenth Circuit Court of Appeals.

Failure to plead with particularity. Federal Rules of Civil Procedures require that a relator must state the who, what, when, where and how of an alleged fraud as well as a time, place, contents of the false representation and the party making the false statement. After reviewing the complaint, the Tenth Circuit concluded that the case manager failed to plead her FCA claims with the requisite particularity.

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On The Front Lines

RACs and HEAT and TARP – Oh, My! – Part 1

by Michael E. Clark, JD

Whether health care professionals and providers know it or not, they face escalating legal dangers that increase the likelihood of serious consequences. In this two part article, the author discusses five recent developments that have created this dangerous environment for those working in the health care industry. In Part 1, Mr. Clark discusses the first two of the five developments, and in Part 2 he discusses the remaining three developments.

While it may be an overstatement to call the situation a "perfect storm," the following are five recent developments that have created this dangerous environment for those working in the industry:

- The Obama Administration's efforts to revamp how healthcare is financed in this country, along with the renewed regulatory focus on controlling healthcare costs and ramping up anti-fraud and abuse efforts, including more focused federal investigations and prosecutions of healthcare providers in major metropolitan areas considered to be rampant with Medicare and Medicaid fraud as part of the U.S. Department of Justice's Health Care Fraud Prevention and Enforcement Action Team;
- Increasing numbers of audits conducted by bounty hunter auditors operating as part of the Recovery Audit Contractor ("RAC") program[1] approved by the Centers for Medicare and Medicaid Services ("CMS");
- Heightened compliance and reporting obligations for federal contractors imposed by Federal Acquisition Regulation ("FAR") 52.203-13 ("Contractor Code of Business Ethics and Conduct") which put a new mandatory disclosure policy into operation;[2]
- Strict terms and conditions tied to funds obtained from stimulus funds provided under the Emergency Economic Stabilization Act of 2008's Troubled Assets Relief Program ("TARP");[3] and
- *Substantial* amendments to the federal civil False Claims Act ("FCA")[4] will make it easier for whistleblower actions to be brought and succeed under the FCA's qui tam provisions.[5]

The Administration's Efforts to Revamp Healthcare Financing and Renewed Focus on Controlling Costs, Including Ramped up Anti-Fraud and Abuse Efforts

When the Democrats last controlled the Executive and Legislative Branches, during the Clinton Administration, not only was there a concerted effort to broadly change how our nation's healthcare is financed (changes which were *incrementally* made after the broader, more ambitious Clinton Plan was rejected), but, notably, the U.S. Department of Justice ("DOJ") also announced that combating healthcare fraud was its major white collar crime priority.[6]

The Obama Administration's efforts to reform healthcare spending appear to be very similar. President Obama has emphasized the federal government's need to control costs, remarking that "the biggest threat to our nation's balance sheet is the skyrocketing cost of health care."[7] Now, as before, a significant part of the government cost control efforts will involve having federal regulators target those who are committing fraud and abuse of the federal healthcare benefit programs. To that end, on May 20, 2009, Eric Holder, the U.S. Attorney General, and Kathleen Sebelius, the Secretary of the U.S. Department of Health and Human Services ("HHS"), announced the New Interagency **H**ealth Care Fraud Prevention & **E**nforcement **A**ction **T**eam ("HEAT"), which expanded the Medicare Fraud Strike Force operations from those operating in South Florida[8] and Los Angeles to Detroit and Houston. In a prepared press release announcing the creation of HEAT, the DOJ and HHS emphasized the amount of money earmarked by the Obama Administration in its proposed 2010 budget for these anti-fraud and abuse efforts:

> Fraud prevention efforts are also strengthened in President Obama's proposed Fiscal Year 2010 budget. The President's budget invests $311 million – a 50 percent increase from 2009 funding – to strengthen program integrity activities within the Medicare and Medicaid programs. Combined, the anti-fraud efforts in the President's budget could save $2.7 billion over five years by improving oversight and stopping fraud in the Medicare and Medicaid programs, including the Medicare Advantage and Medicare prescription drug programs.[9]

The dangers to healthcare providers from having such significant funds invested in increasing the anti-fraud and abuse efforts by the principal Medicare fraud regulators and

federal prosecutors should be evident. To get a good idea of where the Office of the Inspector General ("OIG") for HHS will be emphasizing its efforts during the next fiscal year, it is worth carefully reviewing the lengthy, recently published OIG Work Plan for Fiscal Year 2010.[10] Among the many stated areas in which the agency will be focusing attention, three of the "Department-wide Issues" are worth underscoring since they demonstrate how serious the Obama Administration is about ensuring that TARP funds aren't misused, as well as the increasing importance of whistleblower actions to its anti-fraud and abuse efforts:

1. **Integrity of Recovery Act Expenditures**
   We will review and evaluate credible allegations relating to improper expenditures of Recovery Act funds to identify cases in which criminal investigations will be opened and appropriate enforcement actions pursued. The Recovery Act funding will result in a significant increase in the number of grants and contracts awarded by HHS. Accordingly, we anticipate an increase in the number of complaints and referrals of grant- and contract-related fraud allegations. The Recovery Act requires transparency and accountability in the awarding and spending of funds.[11]
2. **Enforcement of Whistleblower Protections**
   We will review and evaluate credible allegations relating to reprisals perpetrated against whistleblowers by entities or individuals receiving Recovery Act funds to identify cases in which criminal investigations will be opened and anti-reprisal enforcement actions pursued. Section 1553 of the Recovery Act extends whistleblower protection to employees who reasonably believe they are being retaliated against for reporting misuse of Recovery Act funds received by their non-Federal employers.[12]
3. **Pre-award Screening of Potential Grant Recipients**
   We will develop and implement a process whereby HHS granting agencies will be able to quickly consult with OIG to determine whether there are any ongoing OIG or other criminal investigations before making awards. Through this mechanism, we will reinforce HHS's efforts to ensure integrity in the awarding of funds under the Recovery Act.[13]

Increasing Numbers of Audits Conducted by Bounty Hunter Auditors Operating as Part of the RAC Program

The RAC program incentivizes special Medicare contractors by paying them a contingency fee (nine to twelve and one-half percent) based on the amounts which they help recoup or that were underpaid by enrolled providers. The RACs are tasked with detecting improper Medicare payments and correcting improper payments by collecting overpayments from providers and paying back underpayments to providers.[14]

Significantly, "RACs can use statistical sampling and extrapolate findings to calculate the overpayment."[15] While statistical sampling techniques[16] are widely used and accepted, they can be applied unfairly—and arguably so by RAC contractors since they stand to increase their contingency rewards by inflating the claimed amount of monies owed to the government by indiscriminately using statistical sampling techniques.

In 2003, reported abuses of statistical sampling led Congress to place limitations on the use of such extrapolations.[17] Consequently, CMS revised Chapter 3 of the Medicare Program Integrity Manual.[18] This announced policy change describes the limits of statistical sampling placed by the MMA for assessing overpayments. As CMS explained, there must be a sustained or high level of payment error or evidence that educational intervention has failed to correct the payment error before extrapolation can properly be used to determine overpayment amounts which can be recovered.

Affected providers will have to follow a *protracted* administrative appeals process to obtain relief.[19] Notably, during the three year demonstration project that preceded the permanent RAC program, many providers who were subjected to RAC audits in New York, Florida, and California expressed concerns about the fairness of these audits. "In addition, some of the tactics used by the RACs also have come under fire, such as their reportedly unfair process of forcing providers to pay overpayments or the risk accrued interest, garnishing Medicare paychecks, or taking away Medicare billing privileges."[20]

Conclusion

Part I of this article has examined the Obama Administration's efforts to reform healthcare, with an emphasis on the federal government's need to control costs through the prevention and prosecution of healthcare fraud; and the RAC program's efforts to detect and correct improper Medicare payments by collecting overpayments and paying back underpayments to providers. Part II will examine federal contractors' compliance obligations under the Federal Acquisition Regulations, including the new self-reporting obligations; the conditions on the stimulus funds under the Troubled Asset Relief Program; and amendments to the federal civil False Claims Act that expand liability on certain claims and extend the statute of limitations, among other things.

Michael E. Clark, a partner with Hamel Bowers & Clark LLP, is an attorney, author, and part-time academic. His national law practice involves federal court matters, including administrative, civil, and white collar defense–along with corporate governance matters, such as internal investigations and compliance. Mr. Clark developed and serves as the Editor-in-Chief of Pharmaceutical Law: Regulation of Research, Development, and Marketing (BNA/ABA Section of Health Law (2007) (now in supplementation). He is a member of the Planning Committee for the ABA's National Institute on Securities Fraud and the ABA's National In-House

Counsel and Internal Investigations Institute. Mr. Clark is an Adjunct Professor of Law at the University of Houston Law Center; a NITA faculty member, and a member of the CCH Health Law Compliance Board.

[1] As ably explained in the Proposed "America's Healthy Future Act of 2009": [RACs] ... are private organizations that contract with [CMS] ... to identify and collect improper payments made in Medicare's fee-for-service (FFS) program. Congress originally required the Secretary of Health and Human Services to conduct a three-year demonstration program using RACs in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173). In December 2006, Congress passed the Tax Relief and Health Care Act of 2006 (TRHCA, P.L. 109-432), which made the program permanent and mandated the expansion of RACs nationwide by 2010. CMS began the national rollout of the permanent program in 19 states in March 2009.

Chairman's Mark, "America's Healthy Future Act of 2009" (scheduled for Markup by the Senate Committee on Finance on September 22, 2009), at 228, *available at* http://www.washingtonpost.com/wp-srv/nation/documents/Americas_Healthy_Future_Act_amended_100209.pdf.

[2] The revised suspension and debarment regulations and revised contract clause were required by the "Close the Contractor Fraud Loophole Act," PubLNo 110-252 (June 30, 2008) and took effect on December 12, 2008. *See* http://edocket.access.gpo.gov/2008/pdf/E8-26953.pdf. *See also* Carol A. Poindexter, *Battling Health Care Fraud: Criminal & Civil Perspectives*, West LegalEdCenter (Dec. 17, 2008).

[3] *See* PubLNo 110-343, 122 Stat. 3765 (enacted Oct. 3, 2008) (formerly titled "An Act To provide authority for the Federal Government to purchase and insure certain types of troubled assets for the purposes of providing stability to and preventing disruption in the economy and financial system and protecting taxpayers, to amend the Internal Revenue Code of 1986 to provide incentives for energy production and conservation, to extend certain expiring provisions, to provide individual income tax relief, and for other purposes.").

[4] *See* 31 U.S.C. §§ 3729-3733

[5] *See* Alston & Bird, *Government Investigations, Health Care and Government Contracts Advisory* (June 1, 2009) ("On May 20, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act of 2009 (FERA) [S.386, 111th Cong. §4 (2009) (enrolled)], *available at* http://thomas.loc.gov/cgi-bin/query/z?c111:S.386] that significantly amends the federal … [FCA] and expands the potential liability for all companies doing business with the government.").

[6] *See generally*, Michael E. Clark, *Whether the False Claims Act is a Proper Legal Tool for the Government to Use for Improving the Quality of Care in Long-Term Care Facilities*, 15 NO. 1 HEALTH LAW. 12, 12 (2002) ("In the mid-1990's our elected officials dodged their accountability for not having properly addressed the problem of escalating health care costs by … blam[ing] … doctors and other professionals … for being too greedy and corrupt. Also during this time, when the [DOJ] … announced that its top White Collar crime priority program would be fighting health care fraud, Congress dedicated substantial funding for federal agencies to use in fighting health care fraud through landmark legislation. In the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress provided funding through 2003 that … enabled the DOJ and the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) to increase the number of investigators and prosecutors dedicated to combating health care fraud. HIPAA was quickly followed by the Balanced Budget Act of 1997 (BBA). The BBA not only increased the punishment that could be imposed on wrongdoers, but it also required HHS to implement strict austerity measures on program spending.").

[7] Remarks at the Opening of the White House Forum on Health Reform (March 5, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-Opening-of-the-White-House-Forum-on-Health-Reform.

[8] "The Miami Strike Force was publicly announced on May 9, 2007, after 28 defendants were arrested by FBI and HHS-OIG agents. Through September 30, 2007 in Dade County, Florida, the task force's operations have resulted in 130 defendants being indicted, over 100 convictions obtained, and 130 defendants awaiting trial." Michael E. Clark, Health Care Fraud Redux?, BUSINESS CRIMES BULLETIN (July 2008), *available at* http://www.law.com/jsp/law/LawArticleFriendly.jsp?id=1202423030517. *See also* "Strike Force Targets Medicare Fraud by Los Angeles Area Health Care Companies," *available at* http://www.usdoj.gov/opa/pr/2008/May/08-crm-399.html.

[9] *See* U.S. Department of Justice, Office of Public Affairs, Press Release, "Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention & Enforcement Action Team" (May 20, 2009), *available at* http://www.usdoj.gov/opa/pr/2009/May/09-ag-491.html.

[10] The OIG's Work Plan for Fiscal Year 2010 is available at http://oig.hhs.gov/publications/docs/workplan/2010/work_plan_fy_2010.pdf.

[11] OIG Work Plan for Fiscal Year 2010, Appendix A, at 109.

[12] *Id.*

[13] *Id.* at 109-10.

[14] *See Recovery Audit Contractors: Everything You Wanted to Know About RACs ... but Were Afraid to Ask*, Teleconference Materials, ABA Health Law Section and Center for CLE. *See also* CMS' Overview of Recovery Audit Contractor Program, *available at* http://www.cms.hhs.gov/rac/ and "The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration," *available at* http://www.cms.hhs.gov/RAC/Downloads/RAC_Demonstration_Evaluation_Report.pdf.

[15] Arent Fox, *Recovery Audit Contractors (RAC): The Essentials* (Aug. 12, 2009), *available at* http://www.arentfox.com/publications/index.cfm?fa=legalUpdateDisp=2054

[16] *See generally*, David H. Kaye and David A. Freedman, "Reference Guide on Statistics," REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, Second Edition (Federal Judicial Center 2000).

[17] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (PubLNo 108-173) § 935 ("Recovery of Overpayments") and *Medicare Program Integrity Manual*, Pub. 100-08, Transmittal No. 115 (June 10, 2005), explaining that "[t]he MMA Section 935(a)(4) allows contractors to request documentation for a limited sample of submitted claims, after overpayments have been identified, in order to ensure the practice leading to the overpayments has ceased. The MMA Section 935(a)(8) requires CMS to establish a standard methodology for contractors to use when selecting sample claims for review in the case of an abnormal billing pattern."

[18] *Medicare Program Integrity Manual*, Pub. 100-08, Transmittal No. 115, June 10, 2005.

[19] *See* Arent Fox, *Recovery Audit Contractors (RAC): The Essentials* (Aug. 12, 2009) and *Recovery Audit Contractors: Everything You Wanted to Know About RACs ... but Were Afraid to Ask*, Teleconference Materials, ABA Health Law Section and Center for CLE.

[20] Arpana Narain, David J. Butler, Rita Isnar, and Deborah Rubbens Hutchinson, CCH 2009 RECOVERY AUDIT CONTRACTORS WORKBOOK (Wolters Kluwer Law & Business), at 20.

The case manager alleged a scheme in which the corporation submitted bills at the beginning of each month to patients and to Medicare, Medicaid, and Social Security Administration programs seeking payment for services to be performed for patients during that month before services were even provided. However, the case manager failed to supply any specific details concerning any particular false claim for payment submitted or how the scheme was implemented. The Tenth Circuit concluded that the case manager's broad-ranging allegations about forward billing were properly dismissed.

Another claim alleged that the corporation billed the government for reimbursement at the per diem rate for days after patients died; when patients were absent from the facility; and when a patient moved out a state, among other things. The claim however omitted any details concerning the dates and amounts involved, which specific government programs were not reimbursed after the alleged patient deaths, the number of times the alleged overbilling occurred, or the estimate of the total number of patients involved. For these and other reasons, the per diem billing claim was properly dismissed.

A claim that the corporation used false records to substantiate false claims to the government was also properly dismissed, because the case manager failed to allege a link between the alleged falsifications and the alleged false claims.

Failure to state a claim. The Tenth Circuit affirmed the dismissal of the remaining claims because all of them failed to state a claim. The FCA claim that the corporation included improper expenses, such as personal groceries, gas, and liquor, in their annual cost reports to obtain Medicare or Medicaid payments failed, because the case manager failed to allege that the annual cost reports had the required relationship to a payment request necessary to support an FCA claim. In essence, the cost reports would not have led the government to make a payment not otherwise authorized to the corporation.

The case manager's claim that certain facilities owned by the corporation engaged in improper self-referral failed because the case manager did not allege there was any remuneration made in exchange for the self-referrals.

The retaliatory discharge claim was properly dismissed because the case manager failed to allege that she was fired for actions taken prior to termination in furtherance of an FCA action. Given that she failed to plead the requisite elements of a retaliatory discharge claim, the Tenth Circuit affirmed the district court's dismissal of her claim. ■

U.S. ex rel. Lacy v. New Horizons, Inc., 10th Cir., Oct. 9, 2009, Health Care Compliance Reporter ¶800,751

False Claims Act suit involving sham DME company survives dismissal

A district court granted in part and denied in part motions to dismiss a *qui tam* complaint alleging that a durable medical equipment (DME) supplier, its parent company, a "sham" DME company, and several nursing home chains violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the False Claims Act (FCA), 31 U.S.C. § 3729, *et seq.*, because certain claims satisfied the pleading requirements of Federal Rules of Civil Procedure 9(b) and 12(b)(6), while the remaining claims did not. The complaint alleged an arrangement in which, among other things: (1) the DME supplier submitted claims for DME services in nursing homes under the supplier number of a sham DME company owned by a nursing home chain, (2) the nursing home chain profited substantially from the sham company's Medicare reimbursements, and (3) the DME supplier and its parent received valuable referrals from the nursing home chain.

Pleading with particularity. The district court dismissed certain FCA claims because they failed to satisfy Rule 9(b)'s requirement to plead with sufficient particularity. For example, the complaint failed to allege any fraudulent conduct on the part of two nursing homes named in the complaint, and also failed to identify by name all of the nursing home entities that engaged in kickback schemes. Accordingly, all fraud claims against those two nursing homes were dismissed, and the allegations relating to the unnamed nursing homes were stricken from the complaint.

Other FCA claims in the complaint did pass muster under Rule 9(b) by alleging the "who, what, when, where and how" of each claim. For instance, the government's FCA claim that the DME supplier violated §3729(a)(1) by submitting false claims through the sham company survived dismissal because it: (1) alleged sufficient detail of the scheme involving the creation of the sham DME provider and the alleged kickbacks from the supplier to the nursing home chain, and (2) provided reliable indicia that led to the strong inference that false claims were actually submitted, such as quotations from internal memoranda, specific documents evidencing the fraud, and the supplier's filing of over 56,000 claims, which totalled over $23 million worth of Medicare reimbursements.

Stating a claim. The district court also dismissed certain claims in the complaint because they failed to satisfy Rule 12(b)(6)'s requirement to state a claim upon which relief could be granted. The false records claims relating to the nursing home chain or the supplier's alleged conspiracy with their wholly-owned subsidiaries were dismissed because a parent corporation and its wholly owned subsidiary were legally incapable of forming a conspiracy with one another. Other claims, however, did survive dismissal under Rule 12(b)(6), such as the claim that the DME supplier, its parent, and the sham company violated the FCA by filing or causing to file false Medicare certification statements that the sham company would be in compliance with the law. The complaint alleged that the sham company knew that, at the time it signed the certifications, it intended to conduct kickback schemes in conjunction with the DME supplier, its parent, and a nursing home chain. Accordingly, the allegations sufficiently stated a claim under the FCA. ■

U.S. ex rel Jamison. v. McKesson Corp., N.D. Miss., Sept. 29, 2009, Health Care Compliance Reporter, ¶800,743

Fraud & Abuse

Upward sentencing adjustments require actual pecuniary loss by victims

The sentence of a business owner who was convicted of health care fraud was vacated and remanded because the district court erroneously made an upward victim adjustment when the victims suffered no pecuniary harm. The owner had established a business which purported to provide psychological counseling services, and set himself up to be reimbursed for providing services to Indiana Medicaid recipients by using an enrollment application that bore the signature of a doctor who never signed the application. The owner billed Medicaid for over 84,000 counseling sessions using the identification numbers of over 2,500 Medicaid recipients. The owner was ultimately convicted of health fraud and was sentenced the statutory maximum, 120 months.

The ruling that he was responsible for the $9 million he billed to Medicaid was not in error, in light of the fact that the enrollment documents listed him as the only owner of the business, and that he managed all of the money.

The owner's argument that he received 25 percent less than he actually billed did not nullify his intent to recover the full amounts he billed Medicaid. Contrary to the government's assertion, however, the owner's crime had only two victims—Indiana Medicaid and CMS—not the 2,500 individuals whose Medicaid numbers he used without their knowledge. Since loss is defined as pecuniary harm that is monetary in nature, the individuals whose numbers he used to bill were not victims, as none of them actually paid for a service they did not receive. Therefore, while the conviction was not in error, no upward adjustment of the sentence was inappropriate.■

U.S. v. Sutton, 7th Cir., Sept. 28, 2009, Health Care Compliance Reporter, ¶800,742

In the News

DMEPOS Competitive Bidding Program reopened

On October 21, 2009, CMS reopened the competitive bidding program for medical equipment and supplies. Medicare-approved medical equipment suppliers will have 60 days from October 21 to submit bids for the Round One Rebid of the Medicare Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in nine communities. CMS is accepting bids from accredited and bonded medical equipment suppliers after implementing a number of modifications to the program and conducting a supplier outreach and education effort. Some of these measures include the Early Comprehensive Bidder Education Program, which helps suppliers understand all aspects of the bid submission and evaluation processes, and the user-friendly bid submission process, which provides a new on-line bidding system, upgraded Request for Bids instructions, and a special process for suppliers to have their financial bid documents reviewed for completeness. For additional information about the Medicare DMEPOS Competitive Bidding Program, please visit: http://www.cms.hhs.gov/DMEPOSCompetitiveBid/.

CCH Chicago Bureau, Oct. 21, 2009

HIV/AIDS patient access settlement reached

An orthopaedic surgeon in Texas entered a settlement agreement with HHS' Office for Civil Rights (OCR), in which the surgeon agreed that he and his staff will not deny or withhold medically appropriate treatment from patients solely because they are HIV-positive. The settlement followed OCR's investigation of an administrative complaint filed by a patient living with HIV. The patient, a Medicaid beneficiary, sought medical treatment for a knee injury and informed the surgeon of his HIV status. The surgeon referred the patient to another surgeon located over 200 miles away. OCR found that the Austin surgeon violated Section 504 of the Rehabilitation Act of 1973 by refusing to perform the surgery and instead referring the patient to another surgeon. The settlement agreement required the surgeon to establish a non-discrimination policy, make reasonable modifications to his procedures to avoid discrimination against individuals living with HIV/AIDS, and inform patients of their right to file a complaint with OCR, among other things.

CCH Chicago Bureau, Oct. 16, 2009

"Meaningful use" of EHRs definition forthcoming

David Blumenthal, the National Coordinator for Health Information Technology, recently discussed the term "meaningful use" of electronic health records (EHRs), and specifically noted that an electronic health information system would ultimately help facilitate, inform, measure and sustain improvements in the quality, efficiency, and safety of health care available to every American. Blumenthal reiterated the fact that, under the Health Information Technology for Economic and Clinical Health Act, doctors and hospitals are incentivized to adopt and meaningfully use health information technology. CMS is expected to publish a formal definition of "meaningful use" by December 31, 2009. It is anticipated that "meaningful use" of EHRs will enable providers to reduce the amount of time spent on duplicative paperwork and gain more time to spend with their patients throughout the day. Information on the discussion of meaningful use criteria is available at http://healthit.hhs.gov/meaningfuluse.

CCH Chicago Bureau, Oct. 1, 2009