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Compliance

Report



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For Hospitals, Laboratories and Physician Practices

Supreme Court Upholds Ruling on Forensic Lab Testimony

The U.S. Supreme Court has dismissed a challenge to its ruling last year that lab analysts and other forensic specialists must be available to testify in person at trials. The court ordered the case, *Briscoe v. Virginia*, back to state court for further consideration.

In a Jan. 25 one-line order, the court said, "We vacate the judgment of the Supreme Court of Virginia and remand the case for further proceedings not inconsistent with the opinion in *Melendez-Diaz v. Massachusetts*."

Last year, in *Melendez-Diaz v. Massachusetts*, the court ruled, 5-4, that analysts who create crime lab reports must be available to be cross-examined on how they reached those results. Prosecutors can no longer rely on the crime lab report as prima-facie evidence of what they assert. The ruling applies to testing for blood alcohol, narcotics, or any substance whose results are included in a crime lab report and to the qualifications and skills of personnel who produce the test results cited in the report.

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Proposed Federal Budget Seeks \$250 Million for Increased Anti-Fraud Efforts, Strike Force

Federal health care anti-fraud efforts at the Department of Health and Human Services (HHS) would receive a boost of \$250 million in funding over last year's budget request, and the Medicare Fraud Strike Force program would be expanded, under the proposed fiscal year 2011 budget, released Feb. 1.

"This budget sends a clear message to those who commit fraud: stop stealing from seniors and taxpayers, or we'll put you behind bars," Health and Human Services Secretary Kathleen Sebelius said at a press conference Feb. 1 announcing the budget request.

Mandatory, nondiscretionary spending on fraud programs, which include Medicare integrity program activity and Federal Bureau of Investigation fraud and abuse control, would remain at \$1.2 billion, unchanged from FY 2010, while discretionary spending would jump 80 percent, from \$311 million in 2010 to \$561 million in 2011.

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The majority opinion, written by Justice Antonin Scalia, held that a criminal defendant has the right under the Sixth Amendment “to be confronted with the witnesses against him.” Cross-examination of witnesses “is designed to weed out not only the fraudulent analyst, but the incompetent one as well” and “forensic evidence is not uniquely immune from the risk of manipulation.”

Scalia dismissed dissenters’ arguments that producing analysts in court would be burdensome and costly. “The confrontation clause may make the prosecution of criminals more burdensome, but that is equally true of the right to trial by jury and the privilege against self-incrimination.”

Issue in *Briscoe* Legal Challenge

The issue in *Briscoe v. Virginia* was whether the state met its obligation under the confrontation clause by giving a defendant the right to call the lab expert as his own witness, and if the defendant declines to do so, must the state present the lab expert for cross-examination.

The defendant was convicted on cocaine charges based in part on “certificates of analysis” from the state lab attesting to the amount and type of drugs found during his arrest. During the trial, the defense argued that the drug evidence needed to be presented in live testimony to allow for cross-examination, but the judge admitted the testimonials. The defense did not call the lab analyst as its own witness.

Scalia dismissed dissenters’ arguments that producing analysts in court would be burdensome and costly. “The confrontation clause may make the prosecution of criminals more burdensome, but that is equally true of the right to trial by jury and the privilege against self-incrimination.”

The conviction was upheld by a state appellate court, which consolidated the case with a similar appeal (*Magruder v. Commonwealth*), and subsequently by the Virginia Supreme Court, which stated, “Because the defendants in these appeals failed to call the lab experts, they waived the challenges under the confrontation clause to the admissibility of the certificates of analysis.”

The U.S. Supreme Court in *Melendez-Diaz* indicated that an approach like Virginia’s, shifting the burden of calling the witness to the defendant, would not satisfy the state’s obligation under the Sixth Amendment confrontation clause. 🏛️

Lab, Pathology Groups Urge Quick Legislative Action to Revive ‘Grandfather’ Protection for TC Billing

Eight national laboratory and pathology professional and scientific groups have urged congressional leaders to act quickly to restore the pathology “grandfather” protection that expired Dec. 31, 2009, saying it is needed to maintain quality testing and access to testing by Medicare beneficiaries, especially in rural areas.

The protection allows independent clinical labs to bill Medicare directly for the technical component (TC) of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare and Medicaid Services (CMS) first proposed eliminating separate billings. Congress has repeatedly blocked the agency from going ahead with this policy change.

In letters sent Jan. 28 to House speaker Nancy Pelosi and chairmen of the House health committees and to Senate majority leader Harry Reid and chairmen of the Senate health committees, the groups support extending the “grandfather” protection for two years, effective Jan. 1, 2010.

To expedite action, they further support attaching the extension to urgent legislation such as the debt limit bill or the Medicare physician fee update fix needed to block a 21 percent cut scheduled for March 1.

Signing the letter were the American Medical Technologists, American Association for Clinical Chemistry, American Clinical Laboratory Association, American Society for Clinical Laboratory Science, American Society for Clinical Pathology, American Society for Microbiology, College of American Pathologists, and the National Rural Health Care Association.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

A Quandary for Qualified Providers

Since the start of the year, providers that qualify under the protection have been left in suspense about whether they will get paid. CMS has advised them to hold TC claims, but this was premised on the expectation that Congress would enact an extension as part of comprehensive health care reform legislation. The House reform bill included a two-year extension, the Senate bill a one-year reprieve.

CMS told providers “to hold, to the extent possible, claims for services furnished on or after Jan. 1, 2010. If legislation is enacted, claims submission for affected services may resume. Otherwise, claims submitted with dates of service on or after Jan. 1 will not be paid.”

CMS has repeatedly sought to end “grandfathered” TC billings, contending that the TC is paid through the hospital’s inpatient diagnosis-related groups (DRG) and labs should seek reimbursement from the hospital, not the Part B program.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology. 

ACLA Makes Recommendations on Exchange of Electronic Laboratory Data

The American Clinical Laboratory Association (ACLA) is recommending several changes to the Clinical Laboratory Improvement Amendments (CLIA) and its interpretive guidelines that it believes will help facilitate the exchange of electronic laboratory data.

In testimony presented before the Clinical Laboratory Improvement Advisory Committee, which met Feb. 9-10, ACLA President Alan Mertz noted that the

transmission of electronic laboratory data presents a number of challenges.

“The first challenge is that laboratories must visually verify that CLIA-compliant result reports are being displayed on the screens of end users of lab result interfaces,” said Mertz. “While CLIA does not currently specify the manner in

‘The clinical laboratory’s responsibility for the result report should end once the result is provided to the destination intended by the clinical laboratory transmitting the result or to an intermediary contractually obligated to send the results to the intended destination.’

—Alan Mertz, ACLA

which interface verification must occur, there is currently no automated verification method, so as a practical matter, visual verification is required to ensure compliance.”

This requirement is resource-intensive and hampers access to electronic lab data exchange, he said. CLIA and the interpretive guidelines should clarify that a results interface will be deemed verified if results are sent to an electronic health record (EHR) certified under require-

ments by the secretary of Health and Human Services.

The second challenge labs face when exchanging laboratory data occurs when an EHR vendor makes changes in the test result report before providing it to the physician by configuring the EHR to modify the result report display. The clinical laboratory is still responsible for the content of that report.

“The clinical laboratory’s responsibility for the result report should end once the result is provided to the destination intended by the clinical laboratory transmitting the result or to an intermediary contractually obligated to send the results to the intended destination,” said Mertz. “The interpretive guidelines should make clear that the laboratory is not responsible for subsequent modifications of test result information made by the physician or other third parties.”

The third challenge laboratories are facing is that in many states, if a health information exchange (HIE) or any person other than the ordering physician who ordered the test wishes to receive test results from the laboratory, the lab may not be permitted to make the disclosure without ordering physician authorization.

Under the definitions in CLIA, the lab can only furnish the test result to an “authorized person,” or the “individual responsible for using the test results,”

or the laboratory that requested the test, if applicable. An “authorized person” is whoever is permitted to order the test or receive the test results under state law, which is often restricted to the ordering physician. There is no definition of “individual responsible for using the test results.”

“To resolve this third CLIA issue, ACLA proposes that CMS amend the definition of ‘authorized person’ to include not only a person authorized under state law to receive the test results but also the authorized person’s agent and other legitimate recipients of the results,” said Mertz. “Alternatively, CMS could define ‘individual responsible for using the results’ in a similar manner or revise the section governing result delivery accordingly.” 🏛️

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What the Government's Increased Enforcement Efforts Could Mean for Health Care Providers

The first two months of 2010 have seen the political stars align for the passage of stand-alone health care fraud legislation. First came the election of Sen. Scott Brown (R-Mass.) on Jan. 19, 2010, which delivered a serious blow to passage of the Senate's comprehensive health care reform bill and therewith the sweeping health care fraud initiatives contained within that bill. Second came the president's fiscal year 2011 budget, which called for \$1.7 billion for the Department of Health and Human Services (HHS) to fight fraud, including \$561 million in Health Care Fraud and Abuse Control (HCFAC) discretionary funding.¹ This 80 percent increase in discretionary funds² includes \$60.2 million for the Department of Justice (DOJ) to use in the investigation and litigation of health care fraud cases.³

Attorney General Eric Holder and HHS Secretary Kathleen Sebelius announced at the Jan. 28, 2010, National Summit on Health care Fraud that the increased investments called for in the president's FY 2011 budget will be used to support anti-fraud efforts in the field, including the Health Care Prevention and Enforcement Action Team (HEAT) initiative introduced in May 2009.⁴ In keeping with those efforts, DOJ increased the public fisc in FY 2009 by \$2.4 billion as a result of False Claims Act recoveries, with \$1.6 billion contributed by the health care industry, the second largest recovery in U.S. history.⁵ Health care fraud legislation is not likely to face opposition by either party; in fact, it may constitute one of the few areas of common ground in the current debate on health care reform.

Particularly poised for passage is Senate Bill 1959, the Health Care Fraud Enforcement Act of 2009,⁶ which was introduced by Sen. Ted Kaufman (D-Del.) following an Oct. 28, 2009, Senate Judiciary Committee hearing titled "Effective Strategies for Preventing Health Care Fraud." S. 1959 was described as being aimed at ensuring that those who "steal" from the federal government's investment in health care will face swift prosecution and substantial punishment.⁷

¹ Press release, Department of Health & Human Services, "HHS Budget Makes Smart Investments, Protects the Health and Safety of America's Families" (Feb. 1, 2010), <http://www.hhs.gov/news/press/2010pres/02/20100201a.html>.

² Kathleen Sebelius, secretary, Department of Health & Human Services, Remarks to the National Health Care Fraud Summit (Jan. 28, 2010), www.hhs.gov/secretary/speeches/sp20100128.html.

³ U.S. Department of Justice, FY 2011 Budget Request Fact Sheet: "Restore Confidence in Our Markets, Protect the Federal Fisc, and Defend the Interest of the United States," www.justice.gov/jmd/2011factsheets/pdf/defend-interests-unitedstates.pdf.

⁴ Press release, Department of Health & Human Services, "Health & Human Services Secretary Kathleen Sebelius, Attorney General Eric Holder Convene National Summit on Health Care Fraud, Unveil Historic Commitment to Fighting Fraud in President's FY 2011 Budget" (Jan. 28, 2010), www.hhs.gov/news/press/2010pres/01/20100128a.html (hereinafter "Health Care Fraud Summit Press Release"). The HEAT initiative has been promoted as an effort to strengthen existing programs to combat fraud and invest new resources and technology. HEAT initiative efforts include the expansion of joint DOJ-HHS Medicare Fraud Strike Force teams to Detroit and Houston, Brooklyn, N.Y., and Baton Rouge, La. (other teams are operating in South Florida and Los Angeles). These teams use a data-driven approach to identify unexplainable billing patterns and investigate these providers for possible fraudulent activity. See www.hhs.gov/news/press/2009pres/05/20090520a.html.

⁵ Press release, "Department of Justice, Justice Department Recovers \$2.4 Billion in False Claims Cases in Fiscal Year 2009; More Than \$24 Billion Since 1986" (Nov. 19, 2009), www.justice.gov/opa/pr/2009/November/09-civ-1253.html.

⁶ S. 1959, 111th Cong. (2009).

⁷ Health Care Fraud Enforcement Act of 2009, Section-by-Section Justification, available at: http://kaufman.senate.gov/press/press_releases/release/?id=5e8767a9-e711-4f7a-8a52-27ad23e8fb53.

In the senator's words, S. 1959 is designed to "strengthen the government's capacity to investigate and prosecute waste, fraud, and abuse in both government and private health insurance."⁸ Sen. Kaufman's description is lockstep with the current administration's statements, particularly those of AG Holder, that the FY 2011 budget requests and the fraud initiatives, including HEAT, are key in combating crime and recovering stolen resources.⁹

S. 1959 has strong provisions that would assist AG Holder, who has already charged 200 defendants,¹⁰ in his efforts to prosecute health care fraud. Indeed, S. 1959 would increase the offense level in the federal sentencing guidelines for "federal health care offenses," redefine "federal health care offense," reduce the bar necessary to prove intent under the health care fraud statute, declare all kickbacks as "false" for purposes of the federal False Claims Act, and increase funding for health care fraud prevention and enforcement efforts.

Although, S. 1959 authorizes only the "modest" annual appropriation of an additional \$20 million for 2011 through 2016 to be used in investigating and prosecuting health care fraud, S. 1959 specifically allocates an additional \$10 million per year to the U.S. attorneys' offices and \$5 million each to the civil and criminal divisions of the Department of Justice.

S.1959 Proposes Significant Changes

In addition to expanded annual appropriations, S. 1959's substantive provisions increase the potential sanctions, including criminal sanctions, that can be imposed upon health care entities while at the same time lowering the scienter (intent) requirement necessary to successfully prosecute health care fraud. The specific provisions include the following.

Proposed amendments to the federal sentencing guidelines would result in increased sentences for persons convicted of federal health care offenses in two ways:

- ❖ By increasing the offense level range by two to four levels for federal health care offenses according to the following tiers of monetary loss: a two-level increase for losses of \$1 million or more, a three-level increase for losses of \$7 million or more, and a four-level increase for losses of \$20 million or more;
- ❖ By "clarifying" that the definition of "intended loss includes the aggregate dollar amount of all claims submitted." This proposed "clarification" is significant because under Section 2B1.1 of the sentencing guidelines, monetary loss is determined as the greater of actual loss or intended loss. Since actual loss will rarely exceed intended loss, intended loss is a key driver of sentences for federal health care offenses, and some courts have limited intended loss to the amount actually paid by the government or payable under government fee schedules.¹¹ By allowing "intended losses" to include claims submitted (as opposed to actually paid) the sentences received for health care fraud are sure to be longer.

Proposed amendments to 18 U.S.C. § 24(a), the provision defining federal health care offense, would add violations of the anti-kickback statute as well as health care-related offenses under the federal Food, Drug and Cosmetic Act (FDCA) and Employee Retirement Income Security Act (ERISA) to the definition. Violations of the newly included sections would allow the proceeds of these offenses to be subject

⁸ *Id.* S. 1959 is co-sponsored by Judiciary Committee Chairman Leahy (D-Vt.) and Committee members Specter (D-Pa.), Kohl (D-Wis.), Schumer (D-N.Y.), and Klobuchar (D-Minn.).

⁹ *Health Care Fraud Summit Press Release (Jan 28, 2010).*

¹⁰ Eric H. Holder Jr., U.S. attorney general, *Remarks to the National Health Care Fraud Summit (Jan. 28, 2010)*, www.justice.gov/ag/speeches/2010/ag-speech-100128.html.

¹¹ *Health Care Fraud Enforcement Act of 2009, Section-by-Section Justification.*

The possibility of more severe penalties under the FCA and federal sentencing guidelines combined with the potential lowering of the AKS intent requirement proposed in other legislation means that it will be imperative for providers to review their financial relationships with potential referral sources to try to align these relationships as closely as possible with a safe harbor or statutory exception.

to criminal forfeiture, render obstruction of an investigation a crime, include these offenses as “specified unlawful activity” for purposes of money laundering, and authorize the use of administrative subpoenas to investigate such violations.

Proposed amendments to 18 U.S.C. § 1347, the health care fraud statute, would add a definition of willful conduct which specifies that a defendant need not act with actual knowledge of the law in question or specific intent to violate that law. Rather, the willful intent requirement would be met if the defendant acted voluntarily and purposefully to do the act prohibited under the law.

Proposed amendments to 42 U.S.C. § 1320a-7b, the law that enumerates criminal penalties for acts involving federal health care programs, including the anti-kickback statute, would provide that all claims submitted in violation of this law constitute a false

or fraudulent claim under the False Claims Act, allowing the trebling of damages. Importantly, if the amendments are adopted, a tainted claim would constitute both a prohibited kickback and a false claim, even when the claims are submitted by someone other than the payer or recipient of the kickback.

Bill Would Augment Other Fraud Enforcement Initiatives

In addition to the increased criminal penalties and sanctions proposed above, passage of the Health Care Fraud Enforcement Act would augment earlier federal government efforts to intensify health care fraud enforcement, including the Fraud Enforcement and Recovery Act of 2009 (FERA),¹² which President Obama signed into law on May 20, 2009. Specifically, FERA already expanded the scope of the False Claims Act (FCA)¹³ in significant ways, including:

- ❖ Eliminating the presentment requirement and requiring only a nexus to the government. Under FERA, the definition of “claim” was revised to include any request or demand made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the government’s behalf or to advance a government program or interest and the government provides or reimburses any portion of the money or property. Significantly, the act does not define either of the key phrases “used on the government’s behalf” or “to advance a government program or interest.”
- ❖ Incorporating a materiality requirement that adopts the weaker standard. With respect to FCA liability for submission of false records or statements, FERA now specifies that the false record or statement must be material to the government’s payment decision and defines “materiality” as having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.
- ❖ Expansion of the “reverse false claim” provision to expressly include retention of an overpayment. FERA imposes FCA liability for knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay the government. “Obligation” is defined broadly to include an established duty, whether or not fixed, arising from certain relationships, statutes, regulations, or the retention of an overpayment.
- ❖ Authorizing government intervention complaints to relate back to the date of the original complaint. FERA provides a statute of limitations extension in qui tam cases where the government intervenes or amends the relator’s complaint, so long as the government claim arises out of the conduct, transactions, or oc-

¹² Pub.L. No. 111-21, 123 Stat. 1616 (2009).

¹³ 31 USC § 3729-3733.

currences set forth, or attempted to be set forth, in the relator's complaint. Given the delay already inherent in government investigations, this amendment dramatically affects a defendant's ability to defend itself for business conduct dating back many years.

What Enactment Would Mean for Health Care Providers

If S. 1959, or the provisions thereof, become law, providers face greater potential exposure to the penalties imposed by the anti-kickback statute (AKS), the False Claims Act, and the health care fraud statute. The Health Care Fraud Enforcement Act would both authorize the "bootstrapping" of AKS violations into false claims and also make a violation or conspiracy to violate the AKS a federal health care offense, thereby subjecting those convicted of violating the AKS to sentencing under the federal sentencing guidelines, the trebling of damages together with \$5,500 to \$11,000 per claim fines, and possible exclusion from all federal health care programs.

The possibility of more severe penalties under the FCA and federal sentencing guidelines combined with the potential lowering of the AKS intent requirement proposed in other legislation¹⁴ means that it will be imperative for providers to review their financial relationships with potential referral sources to try to align these relationships as closely as possible with a safe harbor or statutory exception.

The HHS Office of Inspector General (OIG) has identified arrangements involving clinical laboratory services, such as waiver of charges to managed care patients in exchange for non-managed care business,¹⁵ certain arrangements for discounted pathology services provided to physicians,¹⁶ and certain discount arrangements between clinical laboratories and skilled nursing facilities as potentially suspect.¹⁷ Providers of clinical laboratory services should be especially cautious with respect to the practices flagged by OIG and should ensure that their compliance program adheres to the recommendations of the OIG in its Compliance Program Guidance for Clinical Laboratories.¹⁸

S. 1959 would also increase provider risk under the health care fraud statute. As outlined above, S. 1959 would lower the intent requirement necessary to establish a violation of the health care fraud statute and also increase the penalties for persons convicted under this statute. This administration has already increased the number of defendants charged with health care offenses, and with the health care fraud statute setting forth a broad prohibition against committing any scheme to defraud any state, federal, or private health plan, these amendments could have far-reaching implications for all health care providers.

In this heightened enforcement climate, health care providers are likely to face increased government scrutiny. Therefore, it is critical that providers continually review, adapt, and audit their compliance programs and their policies governing financial relationships and monitor their financial arrangements with referral sources to ensure they are compliant with the law if they want to adequately address the issues identified by these enforcement efforts.

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¹⁴ Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (as passed by the Senate, Dec. 24, 2009).

¹⁵ OIG Special Fraud Alert, Arrangements for the Provision of Clinical Laboratory Services, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

¹⁶ OIG Adv. Op. No. 99-13 (issued Nov. 30, 1999, posted Dec. 7, 1999).

¹⁷ OIG Letter, Discount Arrangements Between Clinical Laboratories and SNFs (Sept. 22, 1999).

¹⁸ 63 Fed. Reg. 45,076 (Aug. 24, 1998).

Proposed Federal Budget, from page 1

Total obligations for the Health Care Fraud and Abuse Control Account (HCFAC) anti-fraud programs would be \$1.7 billion for 2011, a number referenced by Sebelius Jan. 28 at the National Health Care Fraud Summit (*see related story, pp. 5-8*).

Adding Strike Forces

The requested discretionary spending would allocate \$90 million, up from \$30 million in FY 2010, to the Department of Justice for its health care fraud and abuse efforts. This investment would go toward funding additional HHS-DOJ Medicare Fraud Strike Forces, which currently operate in seven cities but would expand to 20 cities in FY 2011 due to the increased funding.

The strike forces have been in operation since 2007 and were enhanced by the creation last year of the joint HHS-DOJ Health Care Fraud Prevention and Enforcement Action Team (HEAT) task force.

According to the HHS budget in brief, \$94 million in discretionary funding, up from \$30 million in FY 2010, would be set aside for the fraud and abuse activities of the HHS Office of Inspector General, with a remaining \$376 million, up from \$251 million in FY 2010, going to program integrity activities covering Medicare, Medicare Advantage, the Medicare prescription drug program, Medicaid, and the Children's Health Insurance Program (CHIP).

The increased funding would generate \$25 billion in Medicare and Medicaid savings over the next 10 years, HHS said in its briefing on the budget, \$15 billion as the result of seven program integrity proposals included in the budget and \$10 billion as the result of discretionary investment.

Seven Budget Proposals

The seven proposals include:

- ❖ modifying medical review limitations;
- ❖ establishing a Centers for Medicare and Medicaid Services-Internal Revenue Service collaboration to identify providers who have not filed federal income tax returns;
- ❖ extrapolating Medicare Advantage sample error rates for all plan payments;
- ❖ tracking drug utilizers and providers to cut down on overutilization;
- ❖ consolidating medical review;
- ❖ consolidating Medicare provider enrollment activity; and
- ❖ expanding Medicare revocations. 🏛️

Former Michigan Clinic Owner Sentenced in Medicare Fraud Scheme

The former owner and manager of a Detroit-area clinic was sentenced Feb. 4 to 63 months in prison for her role in a \$2.3 million Medicare fraud conspiracy, the Department of Justice said (*United States v. Briceno*, S.D. Fla., No. 09-20748).

Dulce Briceno, a Florida resident, pleaded guilty Oct. 9, 2009, to taking part in the scheme, which involved billing Medicare for services and medications that were never provided or medically unnecessary. Her case was transferred to the U.S. District Court for the Southern District of Florida from the Eastern District of Michigan.

Briceno, who was ordered to pay \$1.8 million in restitution, told the government she had agreed to manage the clinic, X-Press Center in Livonia, Mich., in exchange for a percentage of the profits generated. DOJ said she admitted “routinely” billing Medicare for services not provided and said the clinic purchased only “a small fraction” of medications billed to the program.

Medicare Beneficiaries Recruited

Medicare beneficiaries were recruited to come to the clinic and sign documents indicating they had received the services, and were paid kickbacks in return, the government said. The kickbacks were in the form of cash and prescriptions for narcotic drugs. Between September 2006 and March 2007, the center submitted about \$2.3 million in fraudulent claims, for which Medicare paid approximately \$1.8 million, according to the government.

The case was prosecuted by senior trial attorney John K. Neal and trial attorney Benjamin D. Singer of the fraud section of the DOJ criminal division. The case, brought as part of the government’s Medicare Fraud Strike Force, was investigated by the Federal Bureau of Investigation and Department of Health and Human Services Office of Inspector General.

The Obama administration is seeking additional funding for the strike force, which it plans to expand to 20 cities from the current seven. Since beginning operations in March 2007, strike force operations have resulted in the indictments of more than 500 people who have collectively billed Medicare for more than \$1 billion, DOJ said. 🏛️

Diagnostic Testing Facility Denied Reimbursement Over Improper Documentation of Necessity

A federal district court in California sustained a final decision by the health and human services secretary that an independent diagnostic testing facility (IDTF) was not entitled to Medicare reimbursement because it failed to include required documentation of medical necessity in its claims (*KGV Easy Leasing Corp. v. Sebelius*, C.D. Cal., No. 2:08-cv-06281-DSF-RZ, 1/29/10).

The U.S. District Court for the Central District of California held Jan. 29 that KGV Easy Leasing Corp. never presented medical records, witness testimony, or signed declarations from physicians named on the order forms attesting to the accuracy of the information allegedly contained on the forms. In addition, the court found, KGV never submitted any other form of evidence that verified the information on its order forms or that established medical necessity.

Under 42 U.S.C. §1395l(e) and 42 C.F.R. §424.5(a)(6), Medicare payment cannot be made unless the party seeking payment furnishes the HHS secretary with the information required to substantiate medical necessity.

Problems Not Addressed

The court found that KGV knew at least by the time of the Medicare Part B carrier’s redeterminations that its preprinted forms did not meet the documentation requirements for reimbursement.

Three more levels of administration review, including the Medicare Appeals Council, the administrative law judge, and the qualified independent contractor, agreed with the carrier’s determination, but KGV never addressed the problems cited by the reviews, the court found.

“KGV might have presented medical records, witness testimony, or submitted signed declarations from the various physicians named on the order forms attesting to the accuracy of the information allegedly contained on those forms,” Judge Dale S. Fischer wrote. “KGV chose to do none of those things.”

KGV billed Medicare for providing IDTF services to Medicare beneficiaries between Sept. 1, 2005, and Feb. 28, 2006, submitting 386 claims. When the carrier denied KGV’s claims, the testing facility submitted eight requests for ALJ hearings.

The ALJ consolidated the hearing requests into one proceeding and employed an independent statistician to create a statistically valid random sampling of the claims. The ALJ concluded that KGV was not entitled to Medicare payment for any of the 386 claims after extrapolating the results of the 15 sampled claims.

Claims Denial Affirmed

The Medicare Appeals Council affirmed the ALJ’s decision denying the claims, which constituted the HHS secretary’s final decision, and KGV then filed the action in court.

KGV submitted copies of its preprinted physician order forms, but the court found a number of deficiencies and determined that the forms did not conform to the requirements of 42 C.F.R. §410.33(d), which requires both that the tests be ordered by the Medicare beneficiary’s treating physician and that the tests be used “in the management of the beneficiary’s specific medical problem.”

The court found that the order forms only identified the physician who referred the beneficiary for the test and that none of the documentation KGV provided established that the referring physician named on the order form was the beneficiary’s treating physician.

Further, the court found that the only information regarding a beneficiary’s clinical picture came from the preprinted order form from which a referring physician must select preprinted symptoms and possible diagnoses. This did not conform to the requirements of the local coverage determination because it provided insufficient clinical information about the beneficiary, the court found.

Waiver Provision Cited

Nevertheless, the court found that if services are not medically necessary, Medicare payment may still be made in accordance with a “waiver” provision.

The waiver, contained in Section 1879 of the Social Security Act, states that Medicare payment may be made if neither the beneficiary nor the provider knew or reasonably could have been expected to know that such services would be excluded from Medicare coverage.

As a Medicare supplier, KGV was charged both with knowledge of the regulations and with the understanding that Medicare would not provide reimbursement for services that are not demonstrably medically necessary and otherwise properly documented.

The court determined that because the medical documentation requirements for IDTFs are contained in federal regulations that took effect on Jan. 1, 1998, more than seven years before the earliest of the claims in question, KGV was not entitled to a waiver. The court concluded that the HHS secretary’s final decision was without legal error and was supported by substantial evidence. Accordingly, the court upheld the secretary’s decision. 🏛️

NEW ANTI-FRAUD BILL INTRODUCED: An anti-fraud bill introduced Jan. 28 by Sen. Chuck Grassley (R-Iowa) incorporates numerous provisions from the Senate's health care reform bill (H.R. 3590), including enhanced screening for providers who want to participate in federal health care programs, as well as improved coordination among the various federal agencies given the task of fighting health care fraud. "This bill brings together common sense, bipartisan initiatives to fight fraud, waste and abuse in taxpayer-sponsored health care programs, which all face serious budgetary challenges," Grassley, ranking member on the Finance Committee, said in a statement announcing the bill, known as the Strengthening Program Integrity and Accountability in Health Care Act (S. 2964). No committee hearings have been scheduled as yet.

NATIONAL PRACTITIONER DATA BANK RULE ANNOUNCED: The Department of Health and Human Services Jan. 27 released the final rule governing the National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, which includes new sections requiring due process procedures from various reporting agencies. The final rule, from the Health Resources and Services Administration, appeared in the Jan. 28 *Federal Register* and goes into effect March 1. It includes a series of revisions designed to clarify the functions of the data bank, including modifying several definitions to include due process mechanisms. The final rule also expands the number of entities that are required to report adverse information to the National Practitioner Data Bank, including private accreditation organizations and peer review organizations.

HOSPITAL EXEC PLEADS GUILTY TO KICKBACKS: The former chief financial officer of a Southern California hospital agreed Feb. 9 to plead guilty to paying kickbacks to recruiters who delivered homeless patients to the facility for unnecessary services for which the hospital then billed Medicare and Medicaid, the U.S. attorney in Los Angeles announced (*United States v. Rubio*, C.D. Cal., No. CR 10-00123 UA). The plea agreement by Vincent Rubio, who served as chief financial officer at Tustin Hospital and Medical Center from 2003 to 2007, marks the fifth individual to be charged in the ongoing "skid row" health fraud investigation. 🏛️

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