G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 36th Year of Publication

Vol. 15, Iss. 10, May 28, 2015

INSIDE THIS ISSUE

www.G2Intelligence.com

Assistant Attorney General Says Criminal Division Fraud-Fighting Efforts Include Labs

Laboratory services are on the list of targets for the Medicare Fraud Strike Force, according to Assistant Attorney General for the Criminal Division of the Department of Justice, Leslie R. Caldwell, who addressed the American Bar Association's 25th Annual National Institute on Health Care Fraud (May 14, 2015). Caldwell highlighted the Criminal Division's health care fraud fighting efforts over the past 25 years, current strategies and future objectives. "Stamping out Medicare fraud and holding those who commit this fraud accountable are core missions of the Criminal Division and the Justice Department."

Past successes

Caldwell contrasted early enforcement efforts, which relied on Centers for Medicare and Medicaid Services to refer cases to the Department of Justice, with current efforts in which the Medicare Fraud Strike Force's "intensive health care fraud enforcement efforts" target billing issues most often subject to fraud. The Strike Force's achievements since its start in 2007 are significant. As Caldwell noted:

- 2,100 defendants charged (relating to $6.5 billion in Medicare billings) since 2007;
- In the most recent fiscal year, 353 defendants charged (relating to $830 million in Medicare billings), 304 guilty pleas and 41 convictions;

Continued on page 2

CCLA Loses Challenge of Pharmacogenomic LCD

The California Clinical Laboratory Association (CCLA) has lost a recent challenge to a local coverage determination (LCD) involving genetic testing. CCLA claimed that Medicare Administrative Contractors (MACs) "are issuing LCDs that amount to blanket and inappropriate denials of Medicare coverage for certain clinical testing services." It had also challenged LCD development processes in general and argued it's unconstitutional for MACs to issue LCDs.

The U.S. Department of Health and Human Services successfully sought to have the complaint dismissed. That complaint arose out of the denial

Continued on page 7

Assistant Attorney General Says Criminal Division Fraud-Fighting Efforts Include Labs, *from page 1*

- In May 2014, the seventh "takedown" of a nationwide operation, with 90 individual physicians, nurses and other professionals charged (linked to $260 million in Medicare billings)

New fraud-fighting methods

Advances in data collection and usage are helping the Strike Force achieve its success according to Caldwell. "The Strike Force is a model of 21st Century data-driven policing." Strike Force now uses nearly real-time billing data from CMS to "bring cases more quickly" and "identify emerging fraud schemes and new types of Medicare fraud" or existing fraudulent conduct that is expanding geographically. Caldwell asserted that such efforts have led to reduced health care fraud activity by "hundreds of millions of dollars." She also advised that the Division is using "traditional investigative techniques" including undercover officers, wires, bugs, hidden cameras, and GPS tracking. Strike Force is also pursuing high-level individuals including physicians and executives as well as multi-district cases, she noted.

"A company should not expect to receive cooperation credit for just producing documents in response to a grand jury subpoena. To the contrary, compliance with lawful process is a legal requirement, not voluntary cooperation."

— Leslie R. Caldwell, Assistant Attorney General for the Criminal Division of the Department of Justice

Future enforcement

Noting that "Medicare Fraud remains a serious drain on our health care system" and the $3 billion in fraudulent Medicare billings recouped by the Department of Justice in 2014, Caldwell turned to discussion of future enforcement efforts, specifically highlighting laboratory services. "Strike Force is looking at emerging fraud trends, and we are seeing those in areas including Medicare Part D, laboratory services, hospital-based services and hospice care. These are the latest frontiers in Medicare fraud. … [W]e are working hard to identify those engaged in these new schemes and to bring them to justice."

Discussing prosecution of corporate entities, Caldwell explained the value of corporate cooperation, indicating that principles the government has applied in the financial sector are "equally applicable" to health care. Entities seeking to benefit from alleged cooperation must "conduct a thorough internal investigation and turn over all available evidence of wrongdoing to our prosecutors in a timely and complete way" and identify culpable individuals, even if evidence points toward high level executives. "A company should not expect to receive cooperation credit for just producing documents in response to a grand jury subpoena," explained Caldwell. "To the contrary, compliance with lawful process is a legal requirement, not voluntary cooperation."

In discussing the criminal division's collaboration with the Civil Division on parallel prosecutions, Caldwell noted that prosecutors consider the severity and pervasiveness of the alleged activity and the culpability of individuals, among other factors, when deciding whether to bring criminal prosecution. Finally, Caldwell highlighted the growing dangers of cyber breaches and asked organizations to cooperate with the Division in fighting back against cyber criminals. She also pointed out the Division has provided guidance to help avoid and mitigate the risk of data breaches.

Takeaway: Fraud enforcement in the laboratory sector doesn't appear to be abating any time soon as the Department of Justice names laboratory services as a focus of its efforts. G2

Proposed Legislation Aids Personalized Medicine Agenda

H.R. 6, the 21st Century Cures Act, has been presented to the House of Representatives by the Energy & Commerce Committee. "The nonpartisan legislation will help to modernize and personalize health care, encourage greater innovation, support research, and streamline the system to deliver better, faster cures to more patients," according to the Committee's announcement of its unanimous vote (51-0) approving the proposed legislation. The stated purpose for the bill is "[t]o accelerate the discovery, development, and delivery of 21st century cures, and for other purposes." One of the legislation's authors, Committee Chairman Fred Upton, declared in the announcement: "Americans deserve a system second to none. We can and must do better. The time for 21st Century Cures is now."

Sections of the bill promote a global pediatric clinical study network, sharing NIH-funded research data, use of patient experience data in the drug development process, antibiotic development, precision medicine, improved medical device regulation, and vaccines. The bill also addresses improvements to the Local Coverage Determination process.

The bill calls for $10 million in funding for the council in each year from 2016 to 2023.

Section 3081 requires MACs make local coverage determinations available on their websites and Medicare's website 45 days before the effective date and include: the entire determination, when and where it was made public, links to the proposal and comments received regarding same, "summary of evidence that was considered" when developing the determination and sources for the evidence, and "an explanation of the rationale that supports such determination." The College of American Pathologists criticized this provision of the proposed legislation for not going far enough and has proposed even further access—calling for "open, public, and on the record" advisory committee meetings and "upfront disclosure of evidence by MACs when drafting LCDs," according to the May 19, 2015 issue of CAP's *Statline*.

Another section of interest to laboratories (Section 2228) requires that HHS produce within 12 months of the bill's enactment draft guidance revising section V "Demonstrating Insignificant Risk of an Erroneous Result—'Accuracy'" in the January 30, 2008 Guidance titled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices." The draft guidance must also advise about the "appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy." The proposal requires that guidance be finalized by HHS no later than 12 months after the comment period ends for the guidance.

Not surprisingly given the proposal's title, provisions promote development of precision medicine. Section 1141 establishes a Council for 21st Century Cures, charged with "accelerat[ing] the discovery, development, and delivery in the United States of innovative cures, treatments, and preventive measures for patients." The bill calls for $10 million in funding for the council in each year from 2016 to 2023. Section 2041 adds a new Subchapter J—Precision Medicine to the Federal Food, Drug, and Cosmetic Act, which calls for "guidance to assist sponsors in the development of a precision drug or biological product." The guidance would, among other things, ad-

Physicians Sentenced for Diagnostic Testing Schemes

Yet another physician has been sentenced in connection with the Biodiagnostic Laboratory Services LLC (Parsippany, NJ) case. Franklin Dana Fortunato of Montville, NJ was sentenced to 14 months in prison with a year supervised release and a $75,000 fine and $635,000 forfeiture. He previously had admitted accepting bribes in exchange for referral of blood specimens and pleaded guilty to violating the federal Travel Act and filing a false tax return. The government alleged Fortunato received more than $100,000 in bribes through sham lease and service agreements—in some months receiving more than $5,000 in payments. Fortunato admitted he didn't declare the bribes as income. The government also said he didn't report $540,000 gained from patient co-pays and other payments from other health care providers and failed to pay $160,000 in taxes for the undeclared income. So far, 38 individuals—including 26 physicians—have pleaded guilty in cases involving Biodiagnostic Laboratory Services.

In a separate matter, the owner of another New Jersey diagnostic testing facility, Vijay Patel, was sentenced to 12 months in prison for submitting Medicare claims for diagnostic testing services that a cardiologist had performed. As we reported in the January 12, 2015 issue of *National Intelligence Report*, Patel pleaded guilty to one count of health care fraud. The U.S. Attorney explained the cardiologist performing the services was subject to pre-payment review and avoided such review when Patel submitted the claims as if his diagnostic testing facility had performed the services. The government said Patel kept part of the payment received and remitted the rest to the cardiologist.

Takeaway: The number of physicians charged and sentenced for involvement in alleged lab test referral and other testing schemes continues to rise. G2

dress "development of companion diagnostics in the context of a drug development program."

With regard to new devices, Section 2226 amends the Federal Food, Drug and Cosmetic Act to provide that panels determining device classification must have "adequate expertise" to evaluate the device technology and the disease or condition it treats or diagnoses. The applicants making a premarket submission can make recommendations about the expertise needed on the panel. The bill defines adequate expertise to require a panel have at least two voting members "with a specialty or other expertise clinically relevant to the device under review" and "at least one voting member who is knowledgeable about the technology of the device."

The proposed legislation also provides significant attention to sharing of data and interoperability. One section requires NIH grant recipients to share their scientific data gained from NIH-funded research unless subject to confidentiality, privacy or intellectual property rights. Another amends the HITECH Act to "allow the use and disclosure of protected health information by a covered entity for research purposes, including studies whose purpose is to obtain generalizable knowledge, to be treated as the use and disclosure of such information for health care operations" as defined in Section 164.501 of the regulations. It will also allow researchers to remotely access health information if "appropriate security and privacy safeguards are maintained by the covered entity and the researcher" and the researcher doesn't keep a copy of the information. Another section (Section 3001) sets criteria for interoperability: secure transfer, access to all of a patient's available data that is authorized for use, and no information blocking. HHS' National Coordinator of the Office of the National Coordinator for Health Information Technology is charged with issuing guidance with regard to these requirements. HHS will also contract with American National Standards Institute-accredited entities to devise recommendations for interoperability standards. HHS must report to Congress by July 1, 2017 about the initial standards adopted, strategies for achieving interoperability" and barriers to achieving same and a timeline for achieving "widespread interoperability and by December 31, 2019, must report whether the goal was achieved.

Takeaway: Proposed legislation addresses issues of interest to laboratories as it aims to advance personalized medicine. G2

Fraud Case Involves Claims to Private, Not Just Federal, Payers

A fraud case against a dermatologist for billing public and private health care benefit programs should attract attention of laboratories and all health care providers. First, it is noteworthy according to Robert E. Mazer, health care attorney for Ober Kaler in Maryland, that the charges were brought under a criminal statute that applies to both government and private payers, unlike so many other cases that focus solely on claims to Medicare, Medicaid or other federal programs. Another notable item is how the court addressed evidence the government wanted to introduce to prove the dermatologists' intent and guilt.

Facts of the case

A dermatologist was charged with 1) performing Mohs surgery on patients he diagnosed with skin cancer when they didn't have cancer; 2) billing for wound closures as if he performed or supervised them when he had unlicensed medical assistants perform the closures; 3) billing for preparation of and analysis of skin pathology slides when he actually paid outside contractors to perform the service. He paid the contractors $15 per slide and billed $300-$450 to payers for that service. The government sought to introduce evidence regarding those specific prices that the dermatologist paid to contractors and billed to payers but the dermatologist argued that would be "unfairly prejudicial" particularly because what he billed was not what he would receive from payers. The government also sought to provide evidence of the dermatologists' conduct after he became aware he was under investigation, to prove intent and motive. The dermatologist argued this was unfairly prejudicial and was evidence of "subsequent remedial measures" which Federal Evidence Rules prohibit.

Liability for Claims to Private Payers

This case involves a criminal prosecution alleging fraud in billing claims to both public and private payers. In this case, the government brought criminal charges under Section 18 U.S.C. 1347. That statute was enacted as part of HIPAA and makes it a crime to "knowingly and willfully execute[], or attempt[] to execute, a scheme or artifice—

1. to defraud any health care benefit program; or
2. to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services."

Note that conduct violates the statute if it relates to "any health care benefit program"—not just federal or public programs. And, the penalty can be fines or up to 10 years jail time or both, up to 20 years in jail if "serious bodily injury" results from the fraud or even life imprisonment if death results from the fraud.

Finally, the statute imposes liability even if the person didn't "have actual knowledge of" this statute or a "specific intent to commit a violation" of the statute.

Evidence of Financial Gain and Post Scheme Conduct

The dermatologist was successful in getting the trial court to exclude evidence regarding the prices he paid contractors and charged the government as well as evi-

dence of his conduct after he was aware he had come under government scrutiny. But the government appealed and the fourth circuit court of appeals reversed, saying the evidence should be allowed.

The government intended to use the evidence of conduct that occurred after law enforcement interviewed the dermatologist. It asserted that evidence showed he stopped sending pathology slides to outside contractors, stopped performing the Mohs surgery without a biopsy to support medical necessity, and deleted scheduling records that showed who performed wound closures. The dermatologist claimed the evidence of his conduct after he was interviewed by the government was unfairly prejudicial and also shouldn't be allowed because it demonstrated "remedial measures." The government claimed it demonstrated his "consciousness of guilt" and was needed to rebut any argument that the billings at issue were "isolated mistakes" and to show the government didn't just "cherry pick" certain transactions. The government said the evidence was necessary to prove the entire scheme to defraud.

The court concluded that the law doesn't limit the government to introducing evidence regarding just the specific instances of violations detailed in the complaint. It explained that in large and complex health care fraud cases the government needed "adequate latitude" to show defendant's criminal intent—in other words, knowing and willful conduct.

The court agreed that "evidence of financial gain is particularly probative in a fraud case to establish the defendant's intent to defraud."

The dermatologist's conduct after the law enforcement interview (which the parties referred to as "post-scheme" conduct) was relevant to proving "knowledge and intent to defraud." The court noted he stopped sending pathology slides to the outside contractors after he was interviewed by federal agents but before the agents were aware of this practice. It also explained the fact that he stopped performing the surgeries without biopsies indicated he was aware that doing so was a violation of a standard of care for diagnosing skin cancer. Additionally, the court said the deleted schedules refuted the dermatologist's claim that it was honest mistakes that led to billing for services as if he performed them when non-licensed individuals actually performed the service.

Finally, the court agreed with the government about the relevance of evidence concerning the disparity between the amount the dermatologist charged payers and the amount he paid outside contractors for the preparation of pathology slides. He paid $15 to the contractors for each slide but billed insurers $300-$450 per slide. The dermatologist argued that evidence was unfairly prejudicial and it was irrelevant because payers paid predetermined rates—so, he knew he wouldn't receive the billed amount. But the government claimed the "substantial disparity" showed motivation. The court agreed that "evidence of financial gain is particularly probative in a fraud case to establish the defendant's intent to defraud."

United States v. Bajoghli, No. 14-4798 (4th Cir. May 11, 2015).

Takeaway: Remember that laboratories and other providers can be subject to financial liability and even criminal penalties for alleged fraud, not just for claims to federal health care programs, but also claims to private payers as well! And, actions taken after a laboratory has knowledge it is under investigation may be used against it. G2

CCLA Loses Challenge of Pharmacogenomic LCD, *Continued from bottom of p.1*

of Medicare coverage for pharmacogenomic testing that had been ordered for an 82-year-old registered nurse in Virginia who had multiple chronic conditions. She had suffered allergic reactions to medications prescribed for those conditions so her physician had ordered the pharmacogenomic testing to determine appropriate treatment. The coverage determination giving rise to the dispute was Palmetto LCD L34499 which was the basis for denial of coverage for the pharmacogenomic testing. CCLA claimed that LCD and others threatened access to medically necessary lab services.

Generally, challenges to LCDs must be brought through the administrative process rather than directly to court but there are exceptions allowing individual Medicare recipients like the nurse to bring a challenge in court, including if the constitutionality of a provision is the only legal issue, and no facts are disputed. The court determined that the nurse on whose case the claims were based didn't have an injury the court could address. That's because she wasn't obligated to pay for the services after Medicare coverage was denied—instead, the laboratory providing the service bore the cost because it didn't provide her with an Advance Beneficiary Notice alerting her to potential Medicare denial. Also, she and her doctor were able to review the test results so she wasn't denied access to services. The court also dismissed the parties' argument there was potential for future injury, noting that it was speculative that the pharmacogenomic testing would be ordered again and that the laboratory would issue an ABN in that future instance, rendering the patient responsible for the cost of the testing.

CCLA, representing laboratories who would be similarly denied payment under the coverage decision, couldn't bring the claim either the court said, because they first had to appeal the coverage denial through the administrative Medicare claims review process and had no statutory right to circumvent that appeal process.

The court rejected claims a statutory right was violated because it said the nurse's ability under the statutory exception to challenge Medicare denials in court, rather than waiting until administrative options were exhausted, was merely an expedited appeal route rather than a substantive statutory right.

California Clinical Laboratory Association v. Secretary of Health and Human Services, Civ. Action No. 14-cv-0673 (KBJ), (DDC May 20, 2015).

Takeaway: Coverage for personalized medicine suffers a blow with CCLA's failed challenge to LCD denying Medicare coverage for pharmacogenomic testing.

Palmetto GBA Issues Proposed Draft LCD for Oncotype DX® Prostate Cancer Assay

Prostate cancer testing has received significant attention lately as the industry seeks to find reliable ways of identifying the appropriate treatment strategy for patients diagnosed with such cancer. A new draft local coverage determination (LCD) proposed by Medicare Administrative Contractor Palmetto GBA notes that "[i]n 2014, nearly 233,000 men in the US will be diagnosed with prostate cancer, which accounts for 14% of all new cancers." The Centers for Disease Control and Prevention (CDC) indicates that prostate cancer is "the most common cancer among American men" and "one of the leading causes of cancer death among men

of all races." The draft LCD recognizes the potential for genetic testing to help get the most appropriate treatment for these patients.

As the CDC notes, some prostate cancers are slow growing and don't cause health problems. Therefore, not all patients diagnosed with prostate cancer require aggressive treatment but it is difficult for treating providers to determine which patients have an aggressive form of the cancer and which do not.

Recognizing this difficulty, Palmetto is proposing a LCD for an assay that measures cancer aggressiveness. The Oncotype DX® Prostate Cancer Assay is described in the LCD as a "prostate biopsy-based 17-gene RT-PCR assay, representing four molecular pathways (androgen signaling, cellular organization, stromal response and proliferation) that provides a biologic measure of cancer aggressiveness." It is "indicated for men who are considered candidates for active surveillance."

The proposal would cover the Oncotype DX® under certain conditions that indicate a patient may be appropriate for observation rather than more aggressive treatment. The comment period ends July 24, 2015.

Specifically, the LCD proposes coverage under the following conditions:

- needle biopsy with localized adenocarcinoma of prostate (no clinical evidence of metastasis or lymph node involvement);
- patient is classified as either very low risk disease or low risk disease (determining factors include Gleason score (from biopsy) and PSA);
- patient's life expectancy is 10-20 years;
- patient is eligible for both conservative and aggressive treatment "and is considering conservative therapy";
- no pelvic radiation or androgen deprivation therapy was provided before patient's biopsy;
- ordering physician must be "certified in the Genomic Health™ Oncotype DX® Prostate Cancer Assay Certification and Training Registry;
- patient must be monitored "for disease progression according to active surveillance guidelines as recorded in NNCN guidelines"; and
- "physician must report the development of metastasis or prostate cancer deaths in patients not treated definitively who were deemed low risk by the assay."

The draft LCD requires Genomic Health™ submit reports to Palmetto GBA every 6 months.

Takeaway: Proposed local coverage determination recognizes advances in prostate cancer diagnosis and aims to improve treatment and save on treatment costs. G2

National Intelligence Report (ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315 • Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Christopher P. Young, Contributing Writer; Stephanie Murg, Managing Director;
Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Michael Sherman, Director of Marketing; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.