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Reimbursement Trends: 8 Molecular Assays Score Big Coverage Wins from Medicare, Private Insurers

Molecular labs continue to gain ground with insurers. This summer, 8 more genetic assays received positive coverage decisions—4 from Medicare and 4 from private insurers. The winners included Genomic Health, CareDx, Myriad Genetics, Castle Biosciences, Interpace Diagnostics and NanoString Technologies. Here's a rundown of the key details.

The Medicare Approvals

Four of the approvals came from Medicare via the finalization of Local Coverage Determinations (LCDs) issued by principal contractor Palmetto GBA this spring. All of the determinations take effect Oct. 9.

1. Oncotype DX for Intermediate-Risk Prostate Cancer

Test: Genomic Health's Oncotype DX Genomic Prostate Score (GPS) for assessing the current state and future risk of prostate cancer.

Coverage: GPS, which is currently covered for clinically-low risk men, will also be covered for patients with favorable intermediate-risk prostate cancer under National Comprehensive Cancer Network (NCCN) guidelines. Conditions:

Continued on page 2

Case of the Month: Court Says Labs Must Verify Medical Necessity of Tests that Physicians Order

More often than not, when a lab gets busted for falsely billing Medicare, medical necessity—or the lack thereof—is the reason. While the lab must certify that billed tests are medically necessary, ultimate responsibility for ascertaining whether particular tests meet Medicare medical responsibility standards for the ordering physician bears. However, a new federal court case challenges that common understanding by requiring labs to *independently verify* the medical necessity of ordered tests. Here's a look at the case and why it's so potentially troubling for labs.

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- Testing must be performed by physicians enrolled in a Palmetto MolDX-approved Certification and Training Registry program; and
- Physicians must monitor patients for disease progression and report cases of metastasis or prostate cancer deaths in patients who were deemed low risk by the assay.

Context: The positive coverage decision expands the number of Medicare beneficiaries eligible for the test from 50,000 to 80,000. In January 2017, Palmetto approved Myriad Genetics' Prolaris, which measures the aggressiveness of prostate cancer by analyzing 31 cell cycle progression genes, for men with favorable intermediate risk of prostate cancer under NCCN criteria. (See, LIR Jan. 6, 2017)

2. AlloSure for Kidney Transplant Rejection Risks

Test: CareDx's AlloSure targeted next-generation sequencing (NGS) test for quantifying donor-derived cell-free DNA in kidney transplant recipients.

Coverage: AlloSure covered for measuring the probability of allograft rejection in kidney transplant recipients for whom there is a clinical suspicion of rejection at least two weeks post-transplant. Conditions:

- Patients must be over 18; and
- Before ordering, physicians must assess patients for probability of active renal allograft rejection.

Context: Medicare contractor Noridian has also issued but not yet finalized a positive LCD for AlloSure, which the company claims is the only non-invasive test that uses donor derived cell-free DNA as a biomarker to identify probability of active rejection and directly measure allograft injury. "Noridian typically follows Palmetto's lead relatively quickly (but can take months in some cases)," according to a CareDx source.

3. DecisionDx-UM for Uveal Melanoma Prognosis

Test: DecisionDx-UM, Castle Biosciences' test for assessing metastatic risk of uveal melanoma.

Coverage: Test covered for newly diagnosed uveal melanoma patients and to guide surveillance and referral to medical oncology.

Context: Castle announced that Aetna has also decided to cover the test. In addition, the test is covered by 14 Blue Cross Blue Shield plans in California, Florida, New Jersey, North Carolina, Michigan, Massachusetts, Washington, Oregon, Alabama, Arizona, Louisiana, Utah, Idaho and Alaska—58 million total recipients.

4. EndoPredict Test to Help Breast Cancer Patients Avoid Chemotherapy

Test: Myriad Genetics's EndoPredict, which uses a 12-gene molecular assessment score combined with tumor size, nodal status and other features to determine if it is medically safe for clinically low-risk breast cancer patients to skip chemo.

NIR

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Coverage: EndoPredict covered only for postmenopausal women diagnosed with early-stage estrogen-receptor (ER) positive, HER2-negative breast cancer who either:

- Are lymph node-negative; or
- Have up to 3 positive nodes and are being considered for adjuvant endocrine therapy.

Context: Two other breast cancer prediction molecular assays on the market have received favorable Medicare coverage determinations from Noridian:

- Oncotype DX Breast from Genomic Health, Inc.; and
- Prosigna from Nanostring Technologies.

The Private Insurance Approval

Two of the tests receiving Medicare approval described above also got the thumbs-up from private insurers, including:

5. Aetna's approval of Castle Biosciences' DecisionDx-UM for uveal melanoma assessment; and

6. Anthem's positive coverage decision for Myriad Genetics' EndoPredict breast cancer recurrence test.

Other tests gaining private insurer approval included:

7. Prosigna for Predicting Risks of Breast Cancer Recurrence

On Sept. 5, NanoString Technologies announced that Anthem had issued a positive coverage decision for the company's Prosigna assay, which provides a risk category and number score relecting a breast cancer patient's 10-year recurrence risks. Prosigna is now covered by every national commercial insurance plan in the U.S., along with a majority of regional plans, according to the company. "We now estimate that over 95 percent of U.S. patients that are indicated for Prosigna are covered."

8. ThyGenX Test for Thyroid Cancer

On July 27, Interpace Diagnostics announced Cigna will cover its ThyGenX molecular thyroid NGS test for identifying more than 100 genetic alterations associated with papillary and follicular thyroid carcinomas. In addition to Cigna's roughly 15 million member, 260 million patients already have access to the test via Medicare, Aetna and UnitedHealthcare.

Takeaway: While positive, the recent spate of positive coverage rulings shouldn't lull anyone into a false sense of security. Coverage for newfangled molecular assays remains piecemeal and frustratingly slow to attain—especially from Medicare.

Aetna Nixes Natera's NIPT Test for Average-Risk Pregnancies…

Not all of the recent coverage news has been positive. In July, Aetna dealt Natera a body blow by cutting the firm's NIPT Panorama assay for average-risk pregnancies out of its newly revised noninvasive prenatal testing policy. Although Aetna will continue to cover NIPT for high-risk pregnancies, the carrier claims that its application to average-risk pregnancies remains investigational and unproven.

…While Guardant Awaits Final Word on Medicare Coverage for Guardant360

Meanwhile, Guardant Health received a preliminary coverage determination from Palmetto this spring for its Guardant360 lung cancer liquid biopsy is still waiting for the Medicare contractor to finalize the LCD. Coverage would be limited to patients with advanced non-small cell lung cancer, i.e., stage IIIB or higher, and be subjects that vary depending on stage of treatment. The LCD rules out coverage of Guardant360 for repeat testing for therapeutic monitoring and assessment of germline variants.

LDTs: TRICARE Beneficiaries Get At Least 3 More Years of Access

Some of the labs that participate in TRICARE got some good news when the Department of Defense announced that it has extended the so called Approved Laboratory Developed Tests (LDTs) Demonstration Project for three more years.

TRICARE & LDTs

TRICARE, the federal health care program for members of the military and their families, normally covers only tests that the FDA has approved as safe and effective. That policy effectively bars LDTs which, despite offering great promise, are still not proven enough to meet the FDA's stringent approval requirements.

But in June 2014, TRICARE launched a pilot project designed to provide the program's 9.4 million beneficiaries limited access to LDTs. The Defense Health Agency (DHA) Evaluation of Non-United States Food and Drug Administration pilot was slated to last three years and expire this June. But on June 20, 2017, the DHA announced that it has extended the pilot through 2020.

How the Pilot Works

Under the pilot, a panel of clinical and lab experts from the different military services known as the Laboratory Joint Working Group prioritizes tests for review based on published evidence of medical effectiveness. The Group forwards its recommendations to the DHA director for final approval for TRICARE use. According to the Military Health System, 100 LDTs have so far received the green light, including tests for cancer risk, diagnosis and treatment; pharmacogenetic testing; and diagnosis of genetic syndromes and inherited cardiovascular conditions.

LDTs approved for use by TRICARE are still subject to limitations. Beneficiaries must get pre-authorization and providers must submit a letter of attestation listing the test name, CPT code and indication that the beneficiary meets the coverage criteria requirements.

Takeaway: The extension of the DHA's LDT demonstration project has the potential to further expand LDT test coverage among TRICARE beneficiaries.

Kickbacks: Does OIG Green Light of Free Product Replacements Open Door for Lab Freebies?

The OIG's aversion to offering freebies of any kind to referral sources is longstanding and well known. So the Aug. 25, 2017 Advisory Opinion clearing the way for a provider to replace spoiled products for free is a bit of an eyebrow raiser. And while the arrangement involves a pharmaceutical company rather than a lab, the reasoning of the Advisory Opinion may apply equally to lab arrangements involving free products or services.

Offering free replacements to referral sources is the kind of remuneration that could trigger kickback liability, notes the OIG.

THE PROPOSED ARRANGEMENT

A pharmaceutical company manufactures biologics prone to spoilage when exposed to sunlight, temperature changes and other sensitive environmental conditions. In addition to providing detailed storage and handling instructions, the manufacturer wants to replace products free of charge if they spoil or become unusable after physicians, clinics and hospitals purchase them.

THE QUESTION

Does the proposed arrangement violate the anti-kickback laws?

THE OIG's RESPONSE

No.

THE OIG'S REASONING

Offering free replacements to referral sources is the kind of remuneration that could trigger kickback liability, notes the OIG. There is a safe harbor for written warranties that allows for replacing defective or substandard products. But the proposed arrangement wouldn't qualify because the biologics would be replaced due to spoilage rather than for being defective or substandard.

However, the OIG continues, the proposed arrangement would be okay even without a safe harbor because it poses low risk of fraud and abuse. The Advisory Opinion cites four things about the arrangement that make it so low-risk:

1. Free Replacements Not Tied to Referrals

First, free replacement of the spoiled products is restricted to specific unintentional and unplanned circumstances unconnected to money and which serve the purpose of patient safety and quality of care. The availability of a free replacement reduces the risk of a customer's administering a potentially spoiled product to avoid financial loss, the OIG explains.

2. Low Risk of Overutilization

The proposed arrangement poses little risk of increased costs or overutilization since it covers only the products that customers already bought and intended to use.

3. Low Volume

The proposed arrangement would cover only individual claims of spoiled products, not large losses. And the only remedy would be replacement of the same product that the customer had intended to use but for spoilage.

4. The Insurance Analogy

Finally, the OIG noted that the proposed arrangement would bear be something like an insurance policy, the cost of which the manufacturer would bundle into the price of the products.

Takeaway: The same reasoning and factors underlying it could be applied equally to free services provided by labs to physicians, clinics, hospitals and other referral sources.

Enforcement Trends: Private Sector Playing a Bigger Role in Lab Fraud Crackdown

Laboratories have been on the receiving end of health care fraud allegations for decades. But while the risk of prosecution and litigation haven't changed, the dynamics have. Although federal prosecutors and private whistleblowers continue to supply most of the impetus, they have been joined by a new and powerful ally: the private sector.

Foundation's investors have now filed a class action lawsuit in Massachusetts federal court claiming that the officers knew all along that the representations about Medicare coverage of the tumor tests were false.

Securities Fraud Lawsuits by Corporate Shareholders

One of the most common manifestations of private sector enforcement is securities fraud lawsuits against labs by their own shareholders. *The pattern:* Investors charge the lab with making misleading statements and omissions about business to inflate stock value. Later, when the truth is revealed, stock prices plunge and investors are left holding the bag.

A recent example is the class action lawsuit against Foundation Medicine Inc. Established in 2009, Foundation is a molecular diagnostics company known for its next-generation sequencing-based cancer assays including FoundationOne for solid tumors and FoundationACT for circulating tumors. At up to $7,200 per test, Foundation is heavily reliant on major insurance coverage. So when the Cambridge, Mass.-based company made statements suggesting imminent Medicare coverage of the tumor tests, its common stock took off.

But in July 2015, after nearly 18 months of optimism, the bubble burst. The company disclosed that the expected Medicare approval wouldn't be forthcoming any time soon and slashed its financial guidance for the year. The immediate response was a 24% ($7 per share) stock decline. More bad coverage news and deeper guidance cuts in caused further stock losses in November.

Foundation's investors have now filed a class action lawsuit in Massachusetts federal court claiming that the officers knew all along that the representations about Medicare coverage of the tumor tests were false. From now through Sept. 26, the trial lawyers are looking for investors who bought Foundation stock during the affected period (February 2014 to November 2015) to participate in the suit, including those willing to serve as the lead plaintiff.

Consumer Fraud Lawsuits for Overbilling

Consumer lawsuits represent another form of private sector enforcement action against labs. Perhaps the most notable examples are the current patient suits charging Quest and LabCorp with overbilling lab tests. Separate federal court complaints, each of which may become a class action, in New Jersey (vs. Quest) and North Carolina (vs. LabCorp) contend that the labs billed "fees far in excess of the market rates negotiated at arm's length with third party payers such as insurance companies." According to one of the plaintiffs' lawyers, the patients "had no agreement with the respective labs,

and when their insurance companies did not pay their claims, the labs unilaterally charged them excessive, nonmarket-based rates."

The Quest lawsuit cites the example of a couple who were each billed $328.85 for an MTHFR genetic test done in November 2013. Aetna denied coverage, saying the tests were "experimental or investigational." If Aetna *had* paid for the tests, Quest would have received much less than the $328.85 it billed the patients, the complaint alleges.

The plaintiff's attorney in the LabCorp case cites the example of a patient who was charged $616 for a vitamin D test. Horizon BlueCross Blue Shield refused to pay for the test. But it did pay LabCorp for the six other tests the patient received. Payment amount: $63.65, or just 17 percent of the aggregate rack rate of $370. LabCorp then billed the patient for the vitamin D test at the full rack rate of $616, the attorney claims.

Other Notable Securities Fraud Cases Against Labs

While it may be the most recent, Foundation is hardly the only lab to be sued by its shareholders for securities fraud. Others include:

Theranos: In November 2016, investors filed a series of class action lawsuits alleging that the privately held blood testing firm and its CEO made false claims about its relatively bloodless finger-prick technology to inflate the value of its securities. "Thousands of investors were spoon-fed continuous lies touting the company's 'world-changing' technology that would 'revolutionize' the industry," according to an attorney representing one group of plaintiffs. In April 2017, a California federal judge refused to dismiss the case against Theranos.

Alere: In October 2016, shareholders sued Alere and its officers for making misstatements and omissions about the company's sales in Latin America, Africa and China and overall financial condition to inflate share value and attract acquisition suitors ahead of announcing its $5.8 billion merger deal with Abbott in February 2016. When the truth about the company's finances came to light in the spring, share prices plunged and Abbott tried to pull out of the deal before eventually agreeing to go through with the acquisition at a reduced price.

NantHealth: A series of March 2017 securities fraud class action suit by shareholders accuse the California-based precision medicine company of making misleading statements about a $12 million contract with the University of Utah and overstating the number of reported test orders to inflate share value ahead of the company's initial public offering.

Consumers—Misrepresentation

Consumers have also sued labs for misrepresenting their products. Once more, Theranos has been in the eye of the storm. Those same bloated statements by the company about the capabilities of its finger-pricking technology cited in the shareholders' lawsuits spurred consumers to bring a class action lawsuit in Arizona.

But this time, the strategy didn't work. In June 2017, a federal judge tossed out most of the claims against Theranos. For one thing, there was no proof that the consumers ever actually used the product. Thus, for example, at least three consumers said that multiple vials of blood were drawn. The problem with that contention is that vials aren't part of the finger-pricking technology.

Note: The private consumer fraud case should not be confused for the consumer fraud case brought by Arizona that Theranos settled with the State Attorney General in April. (For more on the case, see Theranos Announces Settlement Agreements with CMS and Arizona Attorney General, NIR, April 26, 2017.)

Creditors

The massive Health Diagnostics Laboratory, Inc. (HDL) case spawned a new form of private sector action against lab fraud: creditor lawsuits against bankrupt labs. In

Perhaps the biggest private sector threat to labs that cheat are private insurers seeking to recover falsely billed lab services.

April 2015, HDL agreed to pay $47 million to settle False Claims Act claims involving alleged kickbacks and medically unnecessary testing. The DOJ accused HDL (and another lab called Singulex) of inducing physicians to refer to them for blood testing, including medically unnecessary large multi-assay panels, by paying them sham specimen processing and handling fees of between $10 to $17 per referral and routinely waiving copayments and deductibles. The government also contended that the labs had an illegal sales contract with a marketing firm named Blue Wave.

In June 2015, roughly two months after the settlement, HDL filed for Chapter 11. But bankruptcy would not bring closure. HDL's creditors sued HDL and Blue Wave for $600 million. The creditors also targeted the physicians who accepted kickbacks for referring patients to HDL.

Private Insurers

Perhaps the biggest private sector threat to labs that cheat are private insurers seeking to recover falsely billed lab services. Cigna's $84 million lawsuit against HDL is a notable example, as is the current case by UnitedHealthcare against Dallas-based Next Health LLC and its genetic lab testing subsidiaries for allegedly fraudulent billing of over $100 million in services generated by illegal kickbacks for physician referrals.

Takeaway: While most labs are honest, lab fraud is still big business. And so is recovering the money paid out as a result of fraud. For decades, the government and private whistleblowers have cornered the market in fraud recovery. But now the private sector has gotten into the act, including private insurers, investors, consumers and even bankruptcy creditors.

New Laboratory IT Systems Transfer Standard Brings True Interoperability Closer to Reality

The vision of true interoperability of electronic health care information has moved one step closer to reality with the release of a new information technology (IT) standard. Called LIVD, the standard maps *in vitro* diagnostic (IVD) test results directly to the Logical Observation Identifiers Names and Codes (LOINC) code set for identifying lab procedures and results.

In other words, LIVD enables the automated transfer of test results directly to laboratory information systems and electronic health records without transmitting plain text or non-machine-readable PDF reports. Previously, there was no unique relationship between LOINC codes and individual tests.

The Standard at a Glance

The standard, released by the IVD Industry Connectivity Consortium in collaboration with Integrating the Healthcare Enterprise's (IHE's) Pathology and Laboratory Medicine domain, the Regenstrief Center for Biomedical Informatics, the CDC and the FDA, builds on findings from the NIH's 2016

workshops on Promoting Semantic Interoperability of Laboratory Data. The LIVD specification adopts interoperability, as defined by the Office of the National Coordinator for Health IT's Interoperability Roadmap.

The LIVD specification outlines an IVD industry-defined format to facilitate the publication and exchange of LOINC codes for vendor IVD test results. "This effort will accelerate the inclusion of universal LOINC codes in laboratory reports to clinicians and health care systems because it will eliminate the additional laboratory effort now needed to figure out the right LOINC code for each laboratory test," notes Clem J. McDonald, M.D., director of the NIH's Lister Hill National Center for Biomedical Communications in a statement. "The increasing use of universal LOINC codes in laboratory reports will unleash the same wave of efficiency and quality improvements as bar codes did for grocers and retailers."

LIVD complements IHE's Laboratory Analytical Workflow (LAW) profile, which contains rules for exchanging orders and results between IVD devices and health IT systems. Together, LIVD and LAW offer a "plug-and-play" solution.

A Leap of Progress

While some vendor systems began documenting PDF instructions on associating LOINC codes with laboratory information systems, the process was manual and thus a potential source of errors. The new standard allows automatic sending of lab values to the electronic health records and enables units of measure standardization to normalize lab result values.

"The LIVD specification addresses a major pain point for today's clinical laboratory," said Serge Jonnaert, president of the IVD Industry Connectivity Consortium in a statement. "We finally have a true plug-and-play solution to interface IVD instruments to middleware and LIS systems. Clinical laboratories will no longer be subjected to outrageously high fees for custom connectivity implementations."

Moving Forward

It has been reported that Abbott Laboratories, Roche and BioMérieux are among the companies that committed LIVD will be available on product websites for labs to download. The hope is that in the future there will be a central web-based portal to act as a repository of files. But for now, downloadable versions of the LIVD specifications are available voluntarily by manufacturers.

Takeaway: Adoption of the LIVD standard will improve results standardization, plus transmission efficiency and quality by automatically linking IVD test results with lab IT systems.

Court Says Labs Must Verify Medical Necessity of Tests that Physicians Order, *from page 1*

What Happened

The case began as a whistleblower suit filed by former United Healthcare medical director claiming that Boston Heart Diagnostics routinely billed Medicare for tests that were medically unnecessary for certain diagnostic codes. Boston Heart noted that all of the tests were properly ordered by the treating physicians and that it's up to physicians to determine whether those tests were necessary. So it asked the court to toss the complaint without a trial.

What the Court Decided

The D.C. District Court ruled that the medical director had a valid whistleblower claim and deserved the chance to prove it in court. Having billed Medicare for the tests, Boston Heart had an obligation to provide independent verification of their medical necessity, according to the court. The fact that the ordering physicians' medical necessity determination conflicted with the diagnostic codes provided should have raised a red flag and led Boston Heart to make its own inquiry, the court reasoned [*U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*].

The ruling cites a California case (called *Garcia v. Sibelius*) stating that Medicare regulations "place the burden of establishing the medical necessity of diagnostic tests on the entity submitting the claim." But, as attorneys have noted, it's an apples and oranges comparison because unlike in *Groat* where the lab billed for the tests, the ordering physician was the billing entity in the Garcia case.

The Implications

Attorneys have criticized the *Groat* ruling. "The court fails to recognize that treating physicians—who have the most complete picture of an individual patient's needs and medical conditions—are in the best position to make determinations of medical necessity," according to an attorney with the leading law firm Jones Day. "Lab employees, by contrast, often do not even have occasion to interact with the patient in person," the attorney adds. Requiring lab employees to independently evaluate medical necessity would be not only unrealistic but potentially illegal under state licensing rules and practice-of-medicine restrictions.

Practical Impact

Getting physicians to document medical necessity is hard enough. The Groat case is scary because it's saying that labs could no longer simply rely on physicians to verify that ordered tests are medically necessary. They'd also have to do their own independent assessment to ensure those tests are medically necessary for the patient.

The good news is that Boston Heart has already appealed the ruling. And if the attorneys are right, Boston Heart will win the appeal. Of course, if the attorneys are wrong, labs (at least the ones in the D.C. Circuit where the Groat appeal will be decided) will have a significant new billing burden to contend with.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Lab Charged in Kickback Scheme Fights to Keep Its CLIA License

Case: Next Health is in a legal fight for its life. Earlier this year, the feds indicted two officials of the Dallas lab company for accepting $190,000 in bribes in exchange for allegedly generating $200 million in hospital referrals for overpriced and medically unnecessary drug and genetic tests. In May, CMS inspectors cited Next Health for CLIA testing violations. Claiming that it's the victim of a "premeditated" scheme, Next Health has now asked a federal court for a restraining order to prevent CMS and state agencies from revoking or suspending its CLIA accreditation. Loss of the CLIA license would put Next Health out of business, the suit contends.

Significance: Next Health's legal adversaries aren't limited to the public sector. In February, UnitedHealthcare brought its own lawsuit against the firm in connection with the kickback scheme contending that it ran into the range of $100 million. (See the related article on page 7 for more on private sector suits against labs.)

Marketer Accused of Offering Gift Cards for Urine Samples

Case: Speaking of Next Health, one of the lab's former marketers is dealing with kickback troubles of its own. In an unrelated case, an Austin marketer has been charged with giving soldiers $50 Walmart gift cards for urine and saliva samples. Next Health and other client labs allegedly performed tests on the samples under the guise of a "wellness study" and billed Tricare for reimbursement. The marketer has pleaded not guilty to the charges.

Significance: The case is a reminder that kickbacks and bribes may implicate not only the referral source and testing lab but the sales and marketing personnel involved in making the allegedly illegal business arrangements.

Urinalysis Lab at Center of Opiate 'Pill Mills' Scam

Case: A urinalysis lab with a shady past figures prominently in an equally shady scheme involving TennCare, Tennessee's Medicaid program. According to federal prosecutors, Confirmatrix Labs paid kickbacks to pill mill operators that dispensed medically unnecessary opiates for referring patients to the lab for urine testing patients had to undergo to take the meds. And TennCare was billed for the whole shebang via a series of Confirmatrix shell companies.

Significance: Neither Confirmatrix nor its officials have been charged in the scheme. However, that may be just a matter of time. Confirmatrix's founder has a track record having served three years in federal prison for running a massive music counterfeiting operation. Another red flag is Confirmatrix's abnormally high per-patient costs. One private study named the lab "the biggest outlier" among reviewed firms for Part B payments, noting its $2,406 per-patient billing rate as opposed to the national per-patient average of $751.

Spine Clinic Charged with False Billing of Urine Tests

Case: The feds indicted the co-owner and billing manager of a Louisiana spine and pain management clinic for falsely billing Medicare and private insurers for $4.4 million worth of medically unnecessary services, including $3.9 million in quantitative urinalysis tests. The clinic was planning to open a urinary testing lab and began storing specimens for unnecessary testing once the lab went on line, the indictment claims.

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Labs in Court, *continued from page 11*

Significance: The Louisiana indictees are not alone. More than 400 defendants have been charged with health care fraud as part of the 2017 National Health Care Fraud Takedown spanning 41 federal enforcement districts and 30 State Medicaid Fraud Control Units. (For more on the Takedown, see GCA, July 2017, page 3.)

Genetic Testing Company Linked to Indiana False Billing Prosecution

Case: Now we know why the FBI raided the HQ of Proove Biosciences in Southern California. The genetic testing company is apparently caught up in a Takedown case targeting illegal dispensing of oxycodone and opioids by Physicians Primary Care (PPC) in Indiana. The indictment claims that three individuals affiliated with PPC, including an MD and two nurse practitioners, caused Proove to fraudulently bill for genetic tests administered to PPC patients that were medically unnecessary and never interpreted.

Significance: It's important to note that Proove hasn't been formally charged with any offenses. And in a recent statement, the company's founder and CEO emphasized three key points, including the fact that Proove:

- Received written and signed medical necessity determinations for the tests in question;
- Cut ties with the indicted PPC physician immediately upon learning of the investigation in 2014; and
- Has cooperated with the FBI and U.S. Attorney's office.