G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

January 2019

INSIDE THIS ISSUE

Editor's Note:
We've changed the title of this newsletter to ***Lab Compliance Advisor***, to better reflect our focus on the diagnostic lab industry. It was formerly known as *G2 Compliance Advisor*. ***Lab Compliance Advisor*** continues to provide you with practical "how-to" help to comply with the latest laws, rules and regulations that affect your diagnostic lab.

www.G2Intelligence.com

Upcoming Events

Lab Leadership Summits

Billing & Collections Summit 2019: *Improve Your Lab's Billing & Collections Procedures & Increase Your Cash Flow and Revenue*

March 28, 2019, Orlando, FL
www.lableadershipsummits.com

Compliance Perspectives: PAMA Pitfalls & Survival Strategies

PAMA's deep Medicare reimbursement cuts have had a devastating impact on the lab industry. Recent CMS changes in the 2019 Final Rule should provide a degree of pricing relief but not until 2021. In the meantime, after last year's 10% cut, labs are bracing for an additional 10% cut in 2019. *Bottom Line:* Labs need plans to deal with both the long-term and short-term effects of PAMA.

Continued on page 2

Compliance Alert: New Private-Pay Opioid Law Puts All Drug Addiction & Rehab Labs at Risk of Federal Prosecution

Recent federal legislation addressing the opioid crisis may have unintended consequences on the lab industry. The idea was to allow the feds to prosecute a certain kind of abuse banned by the Anti-Kickback Statute (AKS) even when it doesn't involve a government health program. The new prosecution authority was intended to apply just to private-pay arrangements involving drug addiction treatment and rehabilitation services. But because of the way it was drafted, the new federal prosecutorial power applies to all private-pay arrangements.

What Happened

On Oct. 24, 2018, the President signed the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* (the "SUPPORT Act") consolidating several different opioid-related bills. One of those bills, the *Eliminating Kickbacks in Recovery Act of 2018* (EKRA), EKRA creates criminal penalties for "patient brokering," i.e., an arrangement where a third party enrolls an addicted patient into a private health insurance plan and then arranges for that patient to enter a treatment facility or sober home in exchange for a kickback payment. The sober home or treatment facility then bills the insurance company for treatment services, which often are of substandard quality or never provided at all.

Because the AKS covers just government programs like Medicare and Medicaid, it can't be used to prosecute brokering ar-

Continued on page 8

PAMA Pitfalls & Survival Strategies, *from page 1*

The 4 Big Problems with PAMA

Labs welcomed the PAMA concept of basing Medicare reimbursement on market rates for tests. The problem has been with CMS's implementation.

1. "Applicable Laboratories" Definition

The first problem is the agency's too-narrow definition of "applicable laboratories" that excludes the majority higher priced hospital outreach labs in calculating market rates for lab tests. Although the recent decision to include some hospital outreach lab representation in the 2019 market data collection round helps, industry experts say it's merely an initial step to achieving the true market-based pricing system envisioned in the PAMA law. In the meantime, the downstream pricing effects of the new reporting policy won't be felt until 2021.

2. The Data Collection

Another problem is with the actual data collection. Labs, both big and small, had issues submitting accurate data because they didn't have sound financial systems in place, says **Lâle White**, a nationally recognized expert in medical financial management and compliance and CEO of the leading consulting firm XIFIN. The result was wide disparity in reported prices, e.g., reported reimbursement of $.01 by one lab for the same test a different lab reported receiving $999,999 in payment.

3. The Data Weighing

Adding to these problems, according to White, is that data collection isn't weighted appropriately to reflect the actual market and variance in reimbursement rates among them. Specifically, the relatively highest charging segments, hospital and physician office labs, are severely underrepresented in the collected data:

- *Independent labs* represent only 50% of the CLFS volume but 90% of the collected data; *result:* they were overrepresented in the data by 40%;
- *Hospital labs* represent 27% of the CLFS volume but only 1% of the data collected; *result:* they were underrepresented in the data by 26%;
- *Physician's office labs* are 23% of the CLFS volume but only 7.5% of the data; *result:* they were 15.5% underrepresented in the data.

The next data collection from January to June 2019 is supposed to include more hospital labs. The problem, says White, is that many of these hospital outreach labs aren't ready to provide the data and have no financial systems in place to produce it.

4. The Pricing Formula

It's not all CMS's fault. Part of the problem is how the PAMA legislation is written, specifically its basing of "market price" on weighted "median" rather than weighted average of data collected. Industry groups have called for a "weighted average" formula that considers every price at the volume of tests performed at that price for all submitters. This is extremely important, says

LCA

Glenn S. Demby, Executive Editor
Elayne Demby, Contributing Editor
Paula Santonocito, Contributing Editor
Lori Solomon, Contributing Editor
Catherine Jones, Contributing Editor and Social Media Manager
Barbara Manning Grimm, Managing Editor
David van der Gulik, Layout & Design
Myra Langsam, Business Development
Michael Sherman, Director of Marketing
Jim Pearmain, General Manager
Pete Stowe, Managing Partner
Mark T. Ziebarth, Publisher

Lab Compliance Advisor
(ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

White, because if the total number of hospital labs had submitted data, the market pricing calculated at a weighted *average* (rather than median) could have yielded a CLFS *increase* of 3.8% increase in the last round. Thus, broadening the "applicable laboratories" definition won't solve all the problems as long as rate-setting continues to be based on weighted median prices.

Private payers are relying on the lower Medicare/Medicaid rates to ratchet down the fees in renewal contracts by an average of 20-30%.

Impact: Artificially Deflated Prices

The immediate impact of these problems is a significant—and unfair—reduction in reimbursements for diagnostic tests. Because reductions are capped at 10%, labs saw a 10% reduction in Medicare and Medicaid reimbursements last year. Going forward the top 75 tests will see a 30% overall reduction by 2020.

White notes that these cuts are significantly more than the original estimates. OIG originally estimated that reductions in lab payments would generate $390 million in Medicare savings in the 2018, the first year of PAMA. But during 2018, OIG revised that estimate to $670 million!

In the long term, a lab that gets 31% of revenue from Medicare and Medicaid can expect to lose 5.33% of total revenue annually, says White. Harder hit will be rural and nursing home labs that receive 50% of their revenues from Medicare and Medicaid, which can expect a 9.44% cut in revenues cut, enough to erode their entire profit margin.

The Private Sector Ripple Effects

These numbers don't do justice to the total losses because they don't account for how Medicare/Medicaid price erosion is also driving down lab test reimbursements in the private sector. Private payers are relying on the lower Medicare/Medicaid rates to ratchet down the fees in renewal contracts by an average of 20-30%, White explains. She estimates the impact of this slow erosion at 3%, a percentage that will grow in 2019 when prices apply to the full year.

The Consequences

How will this hemorrhaging of revenues affect labs and the diagnostics market in the long-term?

Staff cuts. Labs began reducing staff to make up for reimbursement cuts last year, notes White, and suggests more and deeper cuts are likely to occur going forward.

Lab specialization. In the past, clinical labs believed they needed comprehensive menus of tests, says White. But that will no longer be feasible. Instead, more labs will specialize in test types such as diabetes, cancer, genetic, pain, and cardiovascular.

Shuttering of labs. There will be a decline in rural and nursing home labs that receive much of their revenues from Medicare and Medicaid, says White, with the business likely shifting to community hospital labs with higher routine testing margins and deep connections to the community.

Consolidation. Freestanding and physician labs will face even greater pressures to consolidate. Meanwhile, hospitals will pay greater attention to

Continued on page 4

their labs to ensure they operate with greater efficiency to leverage diagnostic services and reduce overall cost of care in hospital while improving outcomes.

Growth in reference labs. As labs pare down their in-house testing menus and weed out tests that don't support the volume necessary for cost-effective operation, reference labs that perform higher level and value tests will pick up the slack and experience growth, White predicts.

Takeaway: 3 Survival Strategies

According to White, there are three strategies labs can implement to not only survive but prosper under PAMA and beyond:

1. Private Payer Contract Negotiation Strategies

Unless and until the PAMA CLFS reflects market reality, labs need to focus on eliminating contracts tied to the Medicare fee schedule. One option that seems to have proven successful for some labs is to negotiate a market rate by CPT code for a subset of codes most important to the lab. To implement this strategy, you'll need to evaluate your costs in run tests, review reimbursement by CPT code and identify outliers that need renegotiation. To prevail in the subsequent negotiation, come to the table armed with a good understanding of your current cost structure, both direct and indirect, by CPT code so you can demonstrate acceptable reimbursement level for each test.

2. Product Strategies

On the product side, consider diversifying your testing menu to add high level, high value tests with reimbursement levels that support the cost structure and expanding specialty testing capabilities. And regardless of menu options, it will be imperative to expand your cost reduction efforts.

3. Master the Data

Above all, labs need to take charge of their own data. In 21st century medicine, data is the key to survival, not just for labs but all providers and payers, White explains. For now, the minimum requirement is sound pricing data for PAMA reporting and controlling costs to offset reimbursement cuts.

But in the long-term, there's so much more at stake. Because diagnostic data drives so many aspects of care, labs are at the very hub of the health care system. All of this adds up to incredible strategic opportunity. Labs have (or could put themselves in the position to have) all the data the other stakeholders need. Thus, for example, using the data your lab generates to link test ordering to outcomes would give you a major strategic advantage in working with physicians and patients; by linking test utilization to treatment costs, you could become a major asset to payers. The recipe for success:

- Recognizing the data opportunity;
- Mapping out a plan to take advantage of it, including the necessary improvements to current data collection, analysis and reporting capabilities; and
- Securing the buy-in of the organizational leaders who provide the investment resources needed to bring the plan to fruition.

OIG Monthly Work Plan Review: December 2018

This month, there were four new Work Plan items, two of which may have implications for at least some labs.

1. States' Compliance with FFS and MCO Provider Enrollment Requirements

Issue: Provider enrollment is a key program integrity tool to protect Medicaid from fraudulent and abusive providers. The 21st Century Cures Act (the Cures Act) requires States to enroll all Medicaid providers, both those in Medicaid fee-for-service (FFS) and managed care organizations (MCOs).

OIG Action: An OIG study, mandated by the Cures Act, will survey State Medicaid agencies about their enrollment of FFS and managed care providers and implementation of required provider enrollment screening activities.

2. Assessing Inpatient Hospital Billing for Medicaid Beneficiaries

Issue: In 2016, hospitals billed Medicare $114 billion for inpatient hospital stays, accounting for 17% of all Medicare payments. The Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) have identified problems with upcoding in hospital billing: the practice of mis- or over-coding to increase payment.

OIG Action: OIG will conduct a two-part study to assess inpatient hospital billing. The first part will analyze Medicare claims data to provide landscape information about hospital billing. OIG will determine how inpatient hospital billing has changed over time and describe how inpatient billing varied among hospitals. It will then use the results of this analysis to target certain hospitals or codes for a medical review to determine the extent to which the hospitals billed incorrect codes.

By the Numbers: DOJ Recovers Billions in FY 2018

Year after year, the False Claims Act (FCA) remains the federal government's most valuable fraud enforcement tool. Although recovery amounts have declined slightly in the past two years, FCA recoveries are still in the billions. As usual, this past year the healthcare industry was responsible for the bulk of the money. Here are the key numbers from the year in FCA recoveries as reported by the U.S. Department of Justice (DOJ) on Dec. 21.

- **$2.8 billion:** Total FCA recoveries in FY 2018;
- **$2.5 billion:** Total recoveries against healthcare providers in FY 2018 (not including state Medicaid);
- **$37.8 billion:** Total FCA recoveries between 2009-2018;
- **$3.7 billion:** Average annual FCA recoveries for three-year period 2016-2018;
- **$22.7 billion:** Total FCA recoveries from healthcare providers between 2009-2018;

- **$2.3 billion:** Average annual FCA recoveries from healthcare providers between 2009-2018;
- **645:** Total *qui tam* (whistleblower) lawsuits filed in FY 2018, an average of 12.4 cases per week;
- **$2.1 billion:** Total recoveries in *qui tam* lawsuits in FY 2018;
- **$301 million:** Total recoveries paid to whistleblowers in FY 2018.

Top 5 FCA Healthcare Recoveries

The five largest recoveries in the healthcare industry for 2018 were:

1. **AmerisourceBergen Corporation and a number of its subsidiaries:** $625 million to resolve allegations that they sought to circumvent important safeguards intended to preserve the integrity of the nation's drug supply and profit from the repackaging of certain drugs supplied to cancer-stricken patients.
2. **HealthCare Partners Holdings LLC (HCP), doing business as DaVita Medical Holdings LLC:** $270 million to resolve its liability for providing inaccurate information that caused Medicare Advantage Organizations (MAOs) to receive inflated Medicare payments.
3. **Health Management Associations (HMA):** $216 million to resolve civil allegations that it billed government healthcare programs for more costly inpatient services that should have been billed as observation or out-patient services, paid illegal remuneration to physicians in return for patient referrals to HMA hospitals, and inflated claims for emergency department facility fees.
4. **United Therapeutics Corporation:** $210 million to resolve allegations that it used a foundation as an illegal conduit to pay the co-pay obligations of thousands of Medicare patients taking its PAH drug.
5. **William Beaumont Hospital:** $84.5 million to resolve allegations of improper relationships with eight referring physicians intended to induce patient referrals.

Beyond the Numbers

The DOJ FY 2018 FCA report is noteworthy not just for the numbers but the enforcement trends it cites, including:

Aggressive Government and Taxpayer Watchdog: U.S. Health and Human Services Assistant Attorney General Jody Hunt noted that the "deceptive and fraudulent practices directed at the U.S. government and American taxpayer" will not be tolerated, indicating that DOJ has placed "a high priority on rooting out and pursuing those who cheat government for their own gain."

Executive & Individual Accountability: As in the past, the DOJ has continued to go after individuals. Of the individuals the DOJ cited as being held personally liable for alleged false claims in 2018, several involved laboratory testing, including:

- Three individuals who were found to have paid physicians illegal remuneration disguised as "handling fees" of between $10 and $17 for each patient they referred to two blood testing labs: Health Diagnostic Laboratory (HDL) of Richmond, Virginia, and Singulex Inc. of Alameda, California, resulting in a $114 million settlement;
- Dr. Michael Frey, a pain management specialist and one of two principal owners of Advanced Pain Management Specialists P.A. in Fort Myers, Florida, who agreed to pay $2.8 million to resolve allegations that he violated the FCA in a number of ways, including receiving illegal kickbacks and by ordering medically unnecessary lab tests.

False Claims Act Recoveries in *Qui Tam* Cases against Healthcare Providers Since 2009 (In billions of dollars)

Year	*Qui Tam* Recovery against Healthcare Providers	Total Recovery against Healthcare Providers
2009	$1.398	$1.636
2010	$1.972	$2.519
2011	$2.271	$2.449
2012	$2.548	$3.105
2013	$2.673	$2.734
2014	$2.344	$2.432
2015	$1.966	$2.127
2016	$2.627	$2.724
2017	$2.151	$2.184
2018	$1.945	$2.513
Total	**$21.895**	**$24.423**

Source: U.S. Department of Justice

Takeaway: The DOJ's reporting of FY 2018 fraud recoveries show that large scale and individual enforcement efforts continue—and that laboratory testing remains a target for enforcement agencies.

New Private-Pay Opioid Law, From Page 1

rangements involving patients with commercial or private-pay insurance. EKRA was intended to close that gap. Specifically, EKRA makes it a federal crime, carrying a fine of up to $200,000 and/or imprisonment for up to 10 years, to knowingly and willfully:

- Solicit or receive any remuneration for referring a patient to a recovery home, clinical treatment facility or lab; or
- Pay or offer any remuneration either to induce such a referral or in exchange for an individual using the services of a recovery home, clinical treatment facility or lab.

The Law of Unintended Consequences

Letting the feds prosecute kickbacks involving private payers is a big departure and, arguably, an encroachment on the prosecutorial powers of the states which have their own kickback laws. So, the EKRA exception was supposed to be a narrow measure to deal with the opioid crisis. The problem is that EKRA's language is so broad that it permits prosecution of any lab or non-hospital provider who provides addiction treatment or recovery services, even if the referral in question does *not* involve addiction treatment and recovery services.

EKRA Exceptions

The EKRA ban is subject to exceptions, including for:

- Certain disclosed discounts under a health care benefit program;
- Certain payments to bona fide employees and independent contractors (although there are several provisos to this rule and it doesn't mirror a similar exception in AKS);
- Payments for services that meet the AKS safe harbor for personal services and management contracts;
- Certain coinsurance and co-payment waivers and discounts;
- Certain federally qualified health center arrangements that meet the AKS exception; and
- Remuneration made pursuant to certain arrangements that HHS deems necessary.

Is This Some Kind of a Bad Joke?

It appears that this hair-raising consequence was unintended. If so, prosecutors may decline to use their new powers in cases not involving addiction and recovery. Better yet, Congress may go back and amend the statute so that it's more narrowly tailored to addiction treatment or recovery services referrals.

Takeaway: How to Protect Yourself

The problem is that it's unclear when that will happen—or even whether it will happen at all. So, for now at least, if your lab provides these services, you may now be subject to not just state but also federal prosecution for patient brokerage arrangements even if they don't involve addiction treatment and recovery services. The good news is that because such arrangements are currently illegal under state laws, your current arrangements and relationships are probably already compliant. Still, the overlap between the AKS and state kickback laws isn't 100%. *Result:* Unless and until the EKRA rule is modified or neutered by the Justice Department, you need to vet all your current provider relationships and arrangements for patient brokering risks.

Physician-Owned Labs May Be Especially Vulnerable

Last but not least, the new laws create a compliance risk for physician-owned labs that avoided AKS by structuring referrals so that only non-federally and non-state covered patients are referred. Such safeguards may no longer be enough, and you may need to restructure your arrangements to ensure compliance with the new rules. Given the broad scope of EKRA physician-owned labs need to review and potentially restructure their business arrangements to avoid violating the statute.

Case of the Month: Texas Court Strikes Down Obamacare—So, Now What?!

What came as a Christmas gift to many Republicans could be a lump of coal in the stockings of health insurers and the patients they cover. On Dec. 14, a federal judge in Texas did the unthinkable by ruling that the entire *Affordable Care Act* (aka Obamacare), is unconstitutional. While a group of attorneys general from Democratic states is promising to appeal the decision, the new more conservative makeup of the Supreme Court makes ACA's ultimate fate less then certain. Meanwhile, the insurance markets are scrambling to make sense of the situation.

The Controversy over Obamacare's Constitutionality

What makes this new decision especially shocking is that it seemed like the whole Obamacare constitutionality question was settled six years ago in a case called *NFIB v. Sebelius*. According to the U.S. Supreme Court, the mandate coupled with the penalty for not having health insurance constituted a federal tax and thus a lawful exercise of the U.S. Congress's constitutional taxing powers.

But the situation changed when the Republicans took control of Congress and lowered the penalty to $0, effective in 2019. As a result, a group of Republicans decided to bring a new federal lawsuit challenging the law.

The New Case

The plaintiffs in the new case, Texas v. United States, argue that removing the penalty effectively cuts out the taxation character of Obamacare and with it, the basis for finding the law constitutional. And because the individual mandate is not severable from the rest of the law, the entire ACA should be invalidated.

The Federal District Court in Fort Worth agreed with that argument, declaring not just the individual mandate but all of the remaining provisions of the Obamacare law unconstitutional.

What Does It Mean?

The *Texas* ruling is, no doubt, a serious blow to Obamacare. And while the wound may prove fatal, this thing is a long way from over. A group of Democrat attorneys general are planning to appeal the decision all the way to the U.S. Supreme Court, if necessary. And Obamacare will remain in effect pending ultimate resolution of the case.

Even so, there can be no doubt that Obamacare's long-term survival is in serious doubt. Prospects for ultimate court victory appear dim. The problem the Democratic AGs face is that the next rung up the judicial ladder is the Fifth Circuit Court of Appeals, a court known for its conservative tendencies. If the Fifth Circuit does uphold the lower court ruling, another showdown in the U.S. Supreme Court is likely. The good news for the Democrats is the Court's previous positive ruling on Obamacare's constitutionality; the bad news is the change in circumstances, namely the repeal of the penalty, not to mention the new more conservative makeup of the Court.

Future House Speaker, Nancy Pelosi, has vowed that Democrats will "move swiftly to formally intervene in the appeals process to uphold the lifesaving protections for people with pre-existing conditions and reject Republicans' effort to destroy the *Affordable Care Act*."

The Real World Impact

When and if Obamacare is ultimately found unconstitutional, it will have a direct and immediate impact on the features of the law that have driven the health insurance market for much of the last decade, including:

- Protections for people with pre-existing conditions;
- ACA Medicaid expansion;
- The employer health insurance mandate; and
- Insurance for children under 26 who are insured through their parents' plans.

Obamacare nullification would also remove key restrictions on insurers:

- Annual and lifetime coverage limits would once again be permitted;
- Caps on out-of-pocket expenses could be eliminated; and
- Insurers could once again charge more based on age, gender and profession.

Of course, the non-insurance-related aspects of Obamacare would also face a highly uncertain future, including those dealing with:

- Closing of the Medicare drug donut hole;
- Creation of the Center for Medicare and Medicaid Innovation; and
- Restaurant menu labeling.

Deus Ex Machina for Obamacare?

The final chance at saving Obamacare would be in the form of new Congressional legislation. Future House Speaker, **Nancy Pelosi**, has vowed that Democrats will "move swiftly to formally intervene in the appeals process to uphold the lifesaving protections for people with pre-existing conditions and reject Republicans' effort to destroy the *Affordable Care Act*." Of course, control of the House isn't enough. Saving Obamacare will require a bi-partisan effort that involves not just the Republican-controlled Senate but also a President that utterly despises the system adopted under his predecessor.

However, while the Republicans are unlikely to rescue Obamacare, they may be willing to work alongside the Democrats to forge a new system to replace and even improve it. Of course, that would require the kind of bi-partisan effort the likes of which this country hasn't seen in over two decades.

Labs IN COURT

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

Molecular Lab Vigorously Denies But Pays $1.8 Million to Settle Fraud Charges

Case: The feds claim that Molecular Testing Labs, a toxicology and genetics lab in Washington State, paid local labs in exchange for Medicare and Tricare referrals; it then turned what had been an *Anti-Kickback Statute* offense into a *False Claims Act* violation by billing for the tests it provided as a result of those ill-gotten referrals. While unshakably insistent on its innocence, the lab recognized that discretion is the better part of valor and agreed to pay out up to $1.8 million to settle.

Significance: While credible, Molecular's vigorous denial of wrongdoing is a potent reminder of the tough choice providers face when charged with fraud violations: invest a fortune in time, effort and legal fees to resist or pay a substantial settlement amount to make the situation go away. Citing the hundreds of thousands it had already racked up, a written statement from Molecular's chief compliance officer said that, like many health care providers do, it entered into the settlement so it could "stop spending our valuable resources on the case.

North Carolina Hospital Settles Self-Disclosed Kickback Claims for $2.2+ Million

Case: Rex Hospital, Inc., dba UNC Rex Healthcare, agreed to shell out $2,277,762 for kickbacks violations stemming from its deal to lease a doctor from a community hospital to provide cardiology services. In addition to paying the community hospital a market-based fee for the lease, the OIG contends Rex paid kickbacks by also paying the physician's salary and bonuses for the cardiology services provided, reimbursements that should have been made by the community hospital.

Significance: The price of the settlement appears relatively high, especially when you consider that Rex self-disclosed to the OIG.

Owner of MD Practices Settles Fraud Charges for $3.07 Million

Case: Individual physicians implicated in frauds committed by the practices and clinics they own is this month's predominant theme. Leading off is the MD owner of a pair of medical practices in Delaware and Maryland doing business as Got-A-Doc Walk-In for alleged false billing of Medicare and Medicaid for lab services, including services:

- Not medically necessary;
- Not performed by an eligible provider;
- Not provided at all; and
- Not properly documented.

Significance: As part of the settlement, the doctor has agreed to surrender his medical licenses. And the doctor's misery is just beginning insofar as the settlement covers only the civil charges and not his potential criminal liability stemming from the scheme.

Pain Clinic Co-Owner Pleads Guilty to Drug Testing Kickback Charges

Case: The Louisiana physician received $336,000 in kickbacks from a drug testing lab representing a percentage of the reimbursement proceeds generated via the referrals of Medicare patients' urine samples for testing over a two-year period. He'll be sentenced in March.

Significance: The other physician co-owner of Louisiana Spine & Sports LLC was indicted last year for his part in an alleged $4.4 million false billing scheme involving medically unnecessary quantitative urinalysis tests and billing for minor surgical procedures performed on days before or after patient visits.

Continued on page 12

Chicago Doctor Indicted for Approving Medically Unnecessary In-Home Tests

Case: Working out of a Chicago-based clinic, a doctor allegedly prescribed and authorized ultrasounds, and percutaneous allergen and nerve transmission tests for Medicare patients even though he knew the in-home tests weren't medically necessary. During the course of the four-year scheme, he approved the tests after they had been completed, the indictment contends. He now faces six fraud charges, each of which carries a maximum prison sentence of 10 years.

Significance: The details of the alleged scheme are particularly slimy—albeit not necessarily true. According to the indictment, the doctor attempted to cover his tracks by submitting fraudulent bills from multiple entities. Then, once the entities received payment from Medicare, they sent him a check representing a percentage of the proceeds as his share for the business.

10x Genomics Ordered to Pay $23.9 Million for Infringing Bio-Rad's Patents

Case: The Federal District Court jury found that 10x willfully infringed three genetic analysis technology patents that Bio-Rad licensed from the University of Chicago on an exclusive basis. Specifically, the jury concluded that all single-cell and linked-read genomics products sold by 10x, including GemCode Long Read, Chromium Genome/Exome and Chromium Single Cell 3 willfully infringed the patented technology.

Significance: The court case is just one front in the IP war between the firms. 10x has filed a complaint with the International Trade Commission accusing Bio-Rad of illegally importing microfluidic systems violating its own patents into the US for sale. 10x also issued a statement expressing its strong disagreement with the court verdict and its intention to appeal.