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HIGHLIGHTS

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Pathway Genomics Settles False Claims Case

Pathway Genomics ended 2015 by settling a whistleblower suit with the federal government for $4.03 million.

The San Diego-based Pathway and the U.S. Attorney's Office announced the settlement on Dec. 30, typically among the slowest news days of the year. It involves not only the federal government, but 29 states and the District of Columbia.

The agreement settles allegations that Pathway violated federal anti-kickback laws by paying physicians as much as $20 for each saliva sample of a patient it remitted for genetic testing pertaining to medication sensitivity. According to the U.S. Attorney, some physicians received more than $13,000 worth of these payments, and many physicians did not use Pathway's laboratory services prior to receiving such payments. Pathway billed federal health care programs such as Medicare and TRICARE for the tests performed. It no longer pays any fees for physicians to submit tests.

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Palmetto Issues New Codes For BRCA, "Hotspot" Testing

Medicare fiscal intermediary Palmetto GBA quietly released new payment guidelines last month for several molecular tests under its MolDx program.

Palmetto issued new codes related to BRCA testing, tied to 146 specific genes. It approved 26 CPT codes for 40 separate BRCA tests for what it called "limited payment." They include tests being performed by Roche, Veracyte, CardioDX and other well-known labs. It assigned the same code, 81162, for tests being performed by Ambry Genetics, LabCorp, Myriad Genetics and Quest Diagnostics. The effective date for the Myriad test was in 2006, while the others had an effective date in 2014. That reflects the rise of competition for BRCA testing services after a 2013 U.S. Supreme Court decision that a patent could not be held on a single gene, invalidating the patent and monopoly Myriad had on BRCA testing.

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Palmetto Issues New Codes For BRCA, "Hotspot" Testing, *from page 1*

Ten other labs were also assigned the unlisted CPT code 81479. They include Foundation Medicine's Foundation One test, Agendia's MammaPrint, and variants on the BRCA test offered by LabCorp and Myriad. Altogether, Myriad has been assigned five different codes for its BRCA variants. The assignment of so many codes at once may help mute some of the grumbling from molecular labs that the MolDX program has been slow to create straightforward payment pathways for their tests.

Another significant change by Palmetto was a determination that so-called next-generation sequencing "hotspot" tumor panels (between five and 50 genes being assayed) should be billed differently than sequencing panels, which include more than 50 genes. Palmetto issued three new codes for testing: 81445 (for a solid tumor of five to 50 genes); 81450 for the same testing for hematologic tumors, and 81455 for any tumor assay involving more than 50 genes.

"This may be a relief to some labs, because two of these codes were given very low list prices by CMS through the 2015 gapfill method," wrote Bruce Quinn, M.D., a senior director at FaegreBD Consulting, on his blog. Those codes, 81445 and 81450, will begin paying at around $700 apiece beginning on Jan. 1 of this year.

Palmetto also issued a hotspot code for BRCA testing, 88145. That was assigned to just one assay, the CANCER26 test performed by the Medical University of South Carolina.

However, Palmetto has still left unresolved billing for comprehensive genomic profiles (CGPs). "Because CGP includes SNVs, small and large insertions and deletions, CNVs, and rearrangements, CPT codes 81445, 81450, and 81455 do NOT describe a CGP service," Palmetto posted on its website. "Therefore, to report a CGP service, test providers should use CPT code 81479 - Unlisted molecular pathology procedure."

Takeaway: Palmetto has issued a large number of molecular testing codes that become effective in the new year. G2

Congressional Members Lobby CMS on PAMA Regulations

Forty-four members of House of Representatives last month asked the Centers for Medicare & Medicaid Services (CMS) to make significant changes in how the Protecting Access to Medicare Act (PAMA) regulations would be implemented in the coming year—changes that echo demands being made by the laboratory sector as a whole.

CMS issued proposed regulations for the implementation of PAMA in the second half of last year, and the laboratory sector vigorously lobbied to make significant changes in the final regulations. The Dec. 16 letter to acting CMS Administrator Andy Slavitt presumably will keep up the pressure on the agency to relent.

Final PAMA rules were initially expected to be issued by CMS late last year, but it has yet to issue them. The agency issued proposed rules in October, and accepted more than 1,000 comments during the public comment period. CMS is legally required to finalize the rules by June 30.

The letter, which was signed by both Republican and Democratic lawmakers—many of whom receive substantial contributions from health care companies and related

political action committees—noted that a "number of laboratories are prohibited from participating in the reporting process. We are deeply concerned that this prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices."

The letter did not provide more specifics about which labs are being excluded, but the laboratory sector has expressed concern to CMS that the exclusion of hospital-based laboratories—which tend to be paid at higher rates than standalone labs—would dramatically ratchet down Medicare reimbursements. Under PAMA, laboratories receiving at least $50,000 annually in payments through the Clinical Laboratory Fee Schedule would have to submit payment data for evaluation.

The House members also asked CMS to expand its definition of an advanced diagnostic laboratory test (ADLT) to include protein biomarkers, which it said had been inexplicably excluded from the proposed regulations. Laboratory lobbies have also asked that protein biomarkers be included. "Protein-based diagnostics are being used to make clinical decisions regarding patient care today, and encouraging further development in this area is crucial," the letter said.

In addition to expressing this concern, the members of Congress also asked for more flexibility regarding the reporting deadlines for data, which under the proposed guidelines could begin as soon as this month. "The proposed timeline presents a significant challenge to the laboratory community as it provides little time to prepare, certify and submit upwards of millions of data points based on a yet-to-be released set of agency requirements," they wrote. The lab sector has also asked that deadlines for gathering and reporting data be set back, possibly into 2017.

"This Dear Colleague letter vigorously illustrates that the proposed timeline for reporting data and pricing will result in skewed data and Medicare rates that do not reflect the market," American Clinical Laboratory Association President Alan Mertz said in a statement. "This strong, bipartisan statement is in alignment with the position of clinical lab community, strongly urging CMS to delay implementation of the PAMA CLFS reforms until improvements can be made, not only to protect access to clinical laboratory services for Medicare beneficiaries, but also to ensure continued diagnostic innovation." The House Members letter is similar to one sent by 19 members of the U.S. Senate.

Takeaway: Members of Congress have been adding their voices to the concerns of the laboratory sector to CMS regarding the proposed PAMA regulations. G2

Research/Applied Project Opportunities from the International School of Biomedical Diagnostics at Arizona State University

The International School of Biomedical Diagnostics (ISBD) at Arizona State University (ASU) recently invited companies in biomedical diagnostics and affiliated fields to partner with ISBD on research projects addressing issues in the diagnostics industry. Industry partners will benefit from projects executed by an inter-disciplinary team of students in ISBD's Biomedical Diagnostics online Master's degree program that have significant value to the company's business. "An ideal project is one which is multi-faceted and requires an inter-disciplinary team to address a challenge or problem the company has but [doesn't] have the resources to do at that time," explains Carl Yamashiro, Associate Research Professor, Biomedical Informatics at ISBD. He indicates some of the past projects have provided competitive intelligence to the host company on industry developments and the status of diagnostics in a particular area—which can, for example, allow the company to determine whether they can and should develop a product that will be competitive in that area. Other potential subjects for research projects include regulatory, bioethics and quality systems issues and challenges. Given the online nature of the degree program, laboratory-based research cannot be considered for these projects.

"By partnering with ISBD and ASU on supporting such projects, you are playing a very significant role in educating future leaders in the diagnostics and allied fields, and possibly identifying future colleagues to help drive the long term success of your company," said the ISBD/ASU announcement inviting research proposals. ISBD's Master's degree program "is designed to provide students a broad perspective of the field with a focus on applied research, technology development, reimbursement and regulation and current perspectives in the biomedical diagnostics field."

Many of the students already have professional experience working in laboratories and bring their own expertise to their projects, notes Yamashiro. Additionally, partnering companies also benefit from the breadth of knowledge available to the students from university faculty, several having more than 20 years experience in the diagnostics industry. While the research program operates within the department of biomedical informatics, the program can draw on expertise in the other schools and colleges within ASU in disciplines such as bioengineering, health economics, regulatory science, law and nursing. "[I]f there's a need for expertise in a particular discipline, … [the research team] can go to a resident expert here at the university that can give them advice," says Yamashiro.

Companies whose research proposals are selected will be asked to provide a mentor to work with a team of 3-4 master's students, spending an average of 1-2 hours per week overseeing progress of the research and providing practical advice. Teams will be conducting projects from March 14 - July 8, 2016. Proposals with a description of the scope of work must be submitted by January 29, 2016, to Carl Yamashiro at carl.yamashiro@asu.edu. For more information, contact Carl by email or call (480) 884-0348.

Inside The Lab Industry

A Review of 2015 and a Preview of 2016 for the Laboratory Sector

The year 2015 was a big one for the laboratory sector. It featured some big deals, big fizzles and all sorts of grappling over pending regulations. Here were some of the year's biggest stories, followed by a preview of significant events that are expected to transact during 2016.

Biggest Story of 2015

For the past several years, Theranos had promised to upend the entire paradigm of the laboratory business. The Silicon Valley startup was offering tests that could be performed with just a few drops of blood, as well as publication of all of its prices, and charges 50 percent of Medicare rates. The company, founded a decade ago by Stanford University dropout Elizabeth Holmes, had contracts to set up draw/test centers with retail giants Walgreens and Safeway, hundreds of millions of dollars in venture capital invested and a $9 billion valuation. It also successfully lobbied Arizona lawmakers to allow direct-to-consumer testing. But the *Wall Street Journal* began poking around into the very secretive way Theranos conducted business and found that it was performing just a handful of tests on its proprietary platform—and relying on other platforms and standard blood draws for the rest.

LabCorp closed its $6.1 billion acquisition of pharma testing firm Covance, and with a single stroke eclipsed Quest Diagnostics as the largest laboratory company in the United States.

Meanwhile, the Theranos platform has come under scrutiny for alleged instability and the FDA has asked the company to stop using its collection system for non-approved tests. Safeway has backed out of its deal, and Walgreen's is taking a closer look at its arrangement.

For the moment, Theranos is in hunker-down mode. However, there have been published reports in the New York Times and elsewhere suggesting that the company's conduct in recent months could wind up hurting other startups in the health care arena. Whether that is the case will likely become more clear in 2016 and beyond.

And, some law firms have announced they will be conducting investigations into Theranos on behalf of its investors—usually a precursor for litigation. The company will be tested in 2016 as much or more than its patients.

Most Significant Transactions of 2015 (Tie)

1. LabCorp closed its $6.1 billion acquisition of pharma testing firm Covance, and with a single stroke eclipsed Quest Diagnostics as the largest laboratory company in the United States. For the first nine months of 2015, LabCorp reported revenue of $6.26 billion. For all of 2014, its revenue was $6.01 billion. Covance's nutritional chemistry business has allowed LabCorp to expand even further into non-traditional lab testing, as it announced in October the acquisi-

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tion of Safe Foods International Holdings, LLC (SFIH) and two affiliates, the International Food Network and the National Food Laboratory. Expect to see both LabCorp and Quest continue to snap up affiliated businesses in their respective bids to diversify, expand and please their ever-demanding shareholders.

2. Just a couple of years ago, Health Diagnostic Laboratory (HDL) reported revenue of about $400 million a year, and it seemed poised to lead a new niche in lab testing for the sake of preventative health. But a 2014 *Wall Street Journal* article about its practice of paying large handling fees to physicians led to a lawsuit by the feds, a slew of litigation involving the company's former employees and advisors, and a rapid downward spiral in sales and reputation. HDL filed for chapter 11 bankruptcy protection in June—just a couple of months after it had paid $49.5 million to the U.S. Justice Department to settle kickback allegations. And just a few months after that, Texas-based True Health Diagnostics—which began operations in only 2014—purchased the assets of HDL for a mere $37.1 million. HDL now operates under the True Health name, and references to the once roaring startup are expected to be few and far between in the coming years.

Republican candidates have threatened to repeal the Affordable Care Act if elected—a strong possibility should Congress remain in GOP hands in 2017.

2015's Oddest Lab Tidbit

The compelling Netflix documentary series "Making A Murderer" reported that the FBI laboratory in Quantico, Va. rapidly created a diagnostic test to detect the presence of the preservative EDTA in a blood sample. The test was created to counter a claim that evidence in a Wisconsin murder case had been planted by investigators. The EDTA test was used only for this specific case. The results of the test itself may have been inconclusive, according to the documentary, and records show that the FBI lab does not have a CLIA waiver. The defendant in the case—who had previously spent 18 years in prison for a rape until he was exonerated by DNA evidence—was convicted of murder.

2016: Stories To Watch

1. **The Presidential election.** Republican candidates have threatened to repeal the Affordable Care Act if elected—a strong possibility should Congress remain in GOP hands in 2017. This could lead to a dramatic scaling back of enrollees in Medicaid and commercial insurance, and would no doubt hit the bottom lines of many labs hard. Conversely, should a Democrat win the White House, several more states could wind up electing to expand Medicaid eligibility under the ACA. That would create more revenue opportunities for labs.
2. **How PAMA unfolds.** The Protecting Access to Medicare Act of 2014 is intended to bring Medicare reimbursement to laboratories closer in line to what com-

Inside The Lab Industry

Pathway Genomics, HDL, Pharmasan, Millennium Health and other labs have been pressured by the feds in recent months to cough up hefty settlements regarding billing and coding issues.

mercial payers have negotiated in recent years. But the laboratory sector has lobbied on what PAMA's final regulations should look like perhaps as hard as any policy being formulated in Washington. Whether hospital laboratories will be in the mix of reporting their reimbursement and the timeline for implementation remain to be seen. Expect at least the latter to be pushed back by six months, if not longer.

3. **Regulation of laboratory developed tests.** The U.S. Food and Drug Administration wants to regulate laboratory developed tests, claiming that some of the more esoteric assays can put patient safety at risk. The laboratory sector believes that some mild tweaking of CLIA regs should do the trick, claiming that FDA regulation could stifle innovations. Neither side has conceded any ground, and the FDA took the extraordinary step late last year of publishing a list of 20 tests it says are dangerous, and why. Whether or not the agency will get its way will become clearer this year.
4. **Continued regulatory crackdowns by federal agencies.** Pathway Genomics, HDL, Pharmasan, Millennium Health and other labs have been pressured by the feds in recent months to cough up hefty settlements regarding billing and coding issues. Some of the penalties have been quite hefty; in Pathway's case, it recently agreed to pay a penalty representing about a third of annual revenues (see Page 1). The $256 million settlement Millennium agreed to pay last autumn was quickly followed by a bankruptcy filing that essentially led to its creditors swapping some $1.2 billion in debt in lieu of being handed over complete control of the company. Expect to see more settlements and penalties during the coming year—and possibly some surprising admissions of liability from a few labs.
5. **Mergers and acquisitions.** Although sector observers say that consolidation of medium-sized and smaller laboratories has mostly run its course, hospitals continue to see their outreach laboratory business as peripheral. Expect to see more deals in this segment, particularly if hospital labs are excluded from the PAMA-related calculations. Esoteric molecular labs are also growing significantly, and it may be time for some of the stronger players to consolidate and diversify their testing portfolios, picking up some firms that have new tests that show promise. And now that the smoke has cleared over some of the most significant CPT codes linked to pathology payments, expect to see some more pathology practices change hands as well.

Takeaway: The significant events that transpired during 2015 are likely to be topped by the goings-on in the laboratory sector during 2016. G2

Pathway Genomics Settles False Claims Case, *from page 1*

The penalty likely represents a significant chunk of Pathway's annual revenue, which the business survey service Hoover's estimates is currently about $12 million, up from about $5 million in 2012, records show.

"As a result of the improper remuneration paid through this illegal kickback scheme, the company submitted hundreds of false and non-reimbursable claims for payments based on prohibited referrals to Medicaid, Medicare and other government programs."

— Ross Brooks, Attorney

"The defendants allowed greed to corrupt their trusted relationship with their patients and ultimately affect patient care decisions," said Eric S. Birnbaum, the FBI agent in charge of the investigation, in a statement. "[This] settlement should make it abundantly clear that the FBI and our law enforcement partners will not allow kickbacks and bribes to influence patient care decisions."

The feds were tipped off by a whistleblower, former Pathway sales executive Monique Gipson. She filed a *qui tam* suit against the company in April 2014. Gipson was employed by Pathway for little more than six months.

"As a result of the improper remuneration paid through this illegal kickback scheme, the company submitted hundreds of false and non-reimbursable claims for payments based on prohibited referrals to Medicaid, Medicare and other government programs," said Ross Brooks, one of Gipson's attorneys. Typically, a *qui tam* relator receives 15 percent of the amount of the settlement paid to the feds—about $600,000 in this case.

Pathway issued a statement that was a model of brevity. "Pathway admits no wrongdoing as part of the settlement and is neither an admission of liability or wrongdoing by the Company, nor a concession by the United States that its claims are not well founded. Pathway has fully cooperated with the inquiry and was not required to enter into a corporate integrity agreement. We now consider this matter closed," the bulk of its statement said.

The settlement announcement is the third involving a laboratory entangled in a whistleblower suit since late November.

Wisconsin-based Pharmasan Laboratories and a corporate affiliate agreed to pay $8.5 million to settle allegations that it had submitted food allergy assays to Medicare—which bars coverage for that kind testing—using CPT codes for fluorescent antibody assays and other tests that are actually covered by the program.

That case involved a unique admission that the government could prove certain facts concerning false billing and the company also agreed to engage in an extensive corporate integrity agreement. Pharmasan also took the unusual step of suing the relator in that matter—the company's former insurance billing manager—and securing a judgment against him and his corporation by default.

In the other case, Piedmont Pathology Associates, Inc. and Piedmont Pathology PC in Hickory, N.C., agreed to pay $500,000 to settle false claims charges. A former Piedmont salesperson had sued, claiming the organization had exchanged medical software licenses for patient referrals.

Takeaway: Pathway Genomics' settlement is one of several involving laboratories that were announced in the closing weeks of 2015.

INDUSTRY BUZZ

ACMG Issues Position Statement on Direct-to-Consumer Tests

The American College of Medical Genetics and Genomics (ACMG) has spoken up on the issue of direct-to-consumer testing, issuing semi-formal standards for assays that are marketed directly to the public.

Among the ACMG's recommendations: Labs offering direct-to-consumer testing should have CLIA and other relevant state certifications. There must also be a specific clarity of purpose regarding the assay.

According to the ACMG statement, "the consumer should be fully informed regarding what the test can and cannot say about his or her health. Many direct-to-consumer genetic tests do not give a definitive answer regarding whether an individual will develop a given condition but instead only provide information about the risk or probability of developing a disease."

To that end, labs should make available a genetic counselor or other genetic expert to inform the patient as to whether they should undertake specific tests. The patient should also "be apprised of the potential for receiving results that can neither confirm nor rule out the possibility of disease or unexpected results that are unrelated to the specific reasons for testing, as well as the implications of genetic test results for family members."

Loosening of federal regulations in recent years has allowed labs to market many tests directly to patients without the supervision of a physician. Although uptake has been relatively slow, labs such as Theranos and Sonora Quest Laboratories have begun offering tests directly to patients at retail clinics in Walgreen's and Safeway stores. Other large labs, such as PAML in Washington State, have begun offering direct-to-consumer testing to younger patient populations.

Along with ensuring the patients are fully informed regarding the tests they are undertaking, ACMG also recommended that labs ensure their privacy and inform them of what will be done with their genetic samples once testing is complete, and whether the results may have impact on the type of medical care they may need to receive in the future, and whether it could preclude them obtaining disability, life or other forms of insurance.

Takeaway: The ACMG is taking a strong position on how laboratories regulate direct-to-consumer tests. G2

References

American Clinical Laboratory Association
202-637-9466

American College of Medical Genetics and Genomics
301-718-9603

FaegreBD Consulting
202-312-7440

Food and Drug Administration
888-463-6332

LabCorp
336-229-1127

Palmetto GBA
803-735-1034

Pathway Genomics
858-450-6600

Quest Diagnostics
800-222-0446

True Health Diagnostics
972-987-1390

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