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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Can The Next PAMA Survey Be Stopped?

There's no way to prevent the third year of scheduled 10% rate cuts for most high-volume lab tests on the Medicare CLFS in 2020. So the American Clinical Laboratory Assn. (ACLA) and its biggest members have put on a full-court press to try to delay the second PAMA survey of private-payer rates. Strategies include a lawsuit, which was initially filed in December 2017, but may take another year before being resolved.

In addition, ACLA is lobbying to round up support for The LAB Act (H.R. 3584), which would delay and revamp the reporting process for the second PAMA survey. The bill was introduced in June by Rep. Scott Peters (D-CA) and has gained bipartisan support from 74 members of Congress. Meanwhile, a counterpart Senate bill (S. 3049) was introduced by Sen. Richard Burr (R-NC) and Sen. Sherrod Brown (D-OH) on December 13.

But the chances of passing The LAB Act into law are slim, CMS seems unwilling to bargain and the upcoming PAMA data reporting period (January 1 – March 31, 2020) is approaching fast. On pages 4-6, *Laboratory Economics* details 10 factors that will influence the pricing data that CMS will use to set CLFS rates for 2021-2023.

Non-Reporting Hospital Outreach Labs At Risk Of Huge PAMA Penalties

If your hospital outreach lab collected more than $12,500 in Medicare CLFS payments between January 1 and June 30, 2019, then you are very likely required under PAMA law to report your private-payers rates to CMS. That's the simple truth and there's no way around it. It means that thousands of hospital outreach labs must go through the difficult and expensive process of identifying their non-patient test volumes and associated payment rates for dozens of private insurance contracts, or face the potential for millions of dollars of penalties. The same goes for non-reporting independent labs and POLs.

CMS did not direct OIG to enforce penalties on non-reporting labs for the first PAMA survey, and so far, CMS has not given any explicit warnings that it plans to do so for the current second PAMA survey. However, some healthcare attorneys think that another low turnout of reporting labs may compel CMS to enforce the law.

For a full analysis of the reporting obligations of hospital outreach labs, see page 2.

Contents

Nearly All Hospital Outreach Labs Must Report PAMA Pricing Data!

A year ago, CMS finalized a rule that requires nearly every single hospital with a lab outreach business to report its private-payer pricing data under PAMA (see *Laboratory Economics*, November 2018). The data collection period covered January-June 2019, and labs are to report their pricing data to CMS during the first quarter of 2020.

Despite several recent CMS bulletins and conference calls aimed at clarifying which labs must report, many hospitals are still confused about their reporting obligation. This is unfortunate because widespread hospital lab outreach reporting could potentially stabilize the Medicare Clinical Lab Fee Schedule (CLFS) in 2021-2023, following three straight years (2018-2020) of 10% PAMA cuts.

Under the new policy, if a hospital outreach laboratory bills Medicare Part B for testing performed on non-hospital patients under the hospital's NPI, the determination of required reporting status for the outreach laboratory is based on its Medicare revenues attributed specifically to Form CMS-1450 14x Type of Bill (TOB). The 14x TOB is used by hospitals to bill for laboratory services provided to non-hospital patients.

Hospital outreach labs are required to collect and report their private-payer payment data if:

1) The majority of their Medicare revenues from 14x TOB billings come from the CLFS and/or Physician Fee Schedule (PFS).

   The majority of Medicare revenues threshold equation is: If Medicare CLFS revenues (based on 14x TOB) + Medicare PFS revenues (based on 14x TOB) is >50% of total Medicare revenues (based on 14x TOB), then the laboratory meets the majority of Medicare revenues threshold and must report.

   However, this requirement is irrelevant and confusing because Medicare revenues for hospital outreach labs billed on 14x TOB are entirely derived from the CLFS and/or PFS. In other words, the revenues from the CLFS and PFS services included in the numerator are the same as the total Medicare revenues included in the denominator. Consequently, all hospital outreach labs will meet the "majority of revenue" requirement.

2) The second requirement is for the hospital outreach lab to have collected at least $12,500 in Medicare CLFS revenues billed on 14x TOB during the data collection period (January-June 2019). All but the smallest hospital outreach labs will meet this threshold.

Which private payment data must hospital outreach labs report?
Hospital outreach labs must report the private payer rate for each test provided to non-hospital patients for which final payment has been made during the data collection period. Private payers include all private health insurance plans (Aetna, BCBS, Cigna, et al.) plus all Medicare Advantage and Medicaid managed care plans.

Which payment data is non-reportable by hospital outreach labs?
Payment information for registered hospital outpatients and admitted hospital inpatients is not reportable. Hospital outreach labs should only report payment information for their non-hospital patients.

In addition, hospital outreach labs should only report private-payer rates made for specific lab test CPT codes; bundled payment data is not reportable. This means that if a laboratory bills individual lab test codes and the payer bundles the individual lab test codes into a single payment amount, the payer's bundled payment amount is not considered reportable information. Estimated private-payer rates and volumes are not allowed.

Top Hospital-Based Outreach Labs by Medicare CLFS Payments

The vast majority of hospital laboratory outreach programs uses its hospital's NPI and finance department for billing and is now required to report their private-payer data to CMS under PAMA. The table below lists the top 25 hospital-based labs based on their Medicare CLFS payments for outreach lab testing in calendar-year 2018. Medicare CLFS payments typically represent roughly 20% to 30% of total revenue generated by hospital-based outreach labs.

Top 25 Hospital-Based Outreach Labs by Medicare CLFS Payments for 2018

Hospital Name	*Location*	*Total Staffed Beds*	*Medicare CLFS Payments*
New York-Presbyterian Hosp./Weill Cornell Medical Ctr.	New York, NY	2,650	$15,773,274
Northwestern Medicine Central DuPage Hospital	Winfield, IL	395	$14,520,912
Carolinas Medical Center	Charlotte, NC	1,257	$10,679,658
Northwestern Memorial Hospital	Chicago, IL	912	$8,632,640
The Cleveland Clinic	Cleveland, OH	1,285	$8,541,300
Beaumont Hospital	Royal Oak, MI	1,089	$8,446,990
Ascension Saint John Hospital and Medical Center	Detroit, MI	609	$7,925,706
Sentara Norfolk General Hospital	Norfolk, VA	527	$7,496,160
Cedars-Sinai Medical Center	Los Angeles, CA	880	$6,754,941
Memorial Hermann - Texas Medical Center	Houston, TX	1,022	$6,714,963
Baystate Medical Center	Springfield, MA	724	$6,383,088
Evanston Hospital	Evanston, IL	751	$6,345,324
Sparrow Hospital	Lansing, MI	632	$5,731,623
Sarasota Memorial Hospital	Sarasota, FL	766	$5,535,144
Saint Luke's Hospital of Kansas City	Kansas City, KS	460	$5,297,150
Lancaster General Hospital	Lancaster, PA	596	$5,296,860
AdventHealth (Florida Hospital)	Orlando, FL	2,826	$5,182,002
Multicare Tacoma General Hospital	Tacoma, WA	380	$5,139,828
Huntsville Hospital	Huntsville, AL	879	$5,124,712
Willis-Knight Medical Center	Shreveport, LA	799	$5,078,529
Strong Memorial Hospital	Rochester, NY	830	$4,967,136
Morristown Medical Center	Morristown, NJ	693	$4,943,799
Abbott Northwestern	Minneapolis, MN	686	$4,895,913
Beaumont Hospital Dearborn	Dearborn, MI	567	$4,877,586
NYU Langone Medical Center Tisch Hospital	New York, NY	1,127	$4,826,500

Source: *Laboratory Economics* from CMS and American Hospital Directory

10 Factors That Will Influence The Second PAMA Pricing Survey

Starting January 1, independent labs, POLs and hospital outreach labs will begin reporting their private-payer rates to CMS, which will use this information to set the Medicare CLFS rates for 2021-2023.

The first PAMA survey was based on private-payer data collected by independent labs and POLs from January-June 2016. The second PAMA survey adds hospital outreach labs and covers data collected from January-June 2019.

CMS will use the private-payer pricing data submitted by labs to calculate "weighted median rates" for each lab test billing code on the CLFS. The new rates will take effect in 2021-2023 subject to price cuts of no more than 15% per year per lab test code (up from a 10% per year max cut for 2018-2020).

Predicting what the new rates will be for 2021-2023 is difficult because there are so many unknown variables. Below we have listed 10 factors that will influence the second PAMA pricing survey.

1. **Leftover cuts from first PAMA pricing survey.** The first PAMA pricing survey resulted in median rates for most high-volume lab test codes that were 37% below the pre-PAMA 2017 rates. However, the 10% max cut per year for 2018-2020 means that the full reduction has not yet been absorbed (see summary table on page 6). For example, the lipid panel (CPT 80061) had been reimbursed by Medicare at $18.37 in 2017. The first PAMA survey calculated a median rate of $11.23 (a 39% cut). In 2018, the max 10% cut lowered the lipid panel rate to $16.53. In 2019, another 10% reduction lowered the rate to $14.88. In 2020, a third 10% cut will lower it to $13.39. So there is still another 16% cut needed to get to the final median rate of $11.23. Of course, this may be changed depending on the results from the second PAMA pricing survey.

2. **Hospital outreach labs are now required to report.** *Laboratory Economics* estimates that there are well over 3,000 hospital outreach labs that are now required to report their private-payer rates to CMS. However, only a limited number of hospital outreach labs are expected to actually comply with their reporting obligation. Many hospitals still do not understand that they are required to report, while others do not have the information systems in place needed to collect and report their non-patient private-payer rates.

3. **CMS has excluded the highest-priced hospital lab data.** Hospital outreach labs are required to report only pricing data for their non-hospital patients. Hospital outpatient lab tests, which have by far the highest private-payer reimbursement rates, are excluded from PAMA reporting.

4. **Bundled claim payments are excluded.** A significant portion of non-hospital patient lab tests are paid in a bundled amount at the claim level. Claim level payments that do not identify specific payment rates per lab test code are excluded from PAMA reporting. Reporting estimated payment rates is not permissible. This will reduce the amount of pricing data reported by hospital outreach labs.

5. **LabCorp and Quest Diagnostics have gotten bigger.** Pricing information from LabCorp and Quest dominated the first PAMA pricing survey—accounting for some 60% of the data used by CMS to calculate median private-payer rates. Over the past three years, both labs have grown by acquisition. Since the initial survey covering first-half 2016, LabCorp has acquired PAML, Mount Sinai outreach lab, Sequenom, et al., while Quest has acquired PeaceHealth Labs, Med Fusion, Shiel Medical Lab, Cleveland HeartLab, et al. Payer contracts held by these acquired labs have been transitioned to the lower fee schedules held by the two national labs. This means that pricing data from LabCorp and Quest may comprise an even larger portion of the overall data supplied to CMS in the second PAMA pricing survey.

6. **LabCorp and Quest Diagnostics will report more in-network rates.** Effective January 1, 2019, LabCorp secured an in-network contract with Aetna, while Quest moved in-network with UnitedHealthcare. This coincided with the start of the second PAMA data collection period. During the first PAMA survey (January-June 2016), Quest and LabCorp had been out-of-network and presumably receive higher rates. They'll each be reporting lower in-network rates for their respective new in-network contracts for the second PAMA survey.

7. **Reduced private-payer rates to independent clinical labs.** Back in 2016-2017, both LabCorp and Quest Diagnostics had the foresight to lock down nearly all of their private insurance contracts at pre-PAMA rates for multi-year contract lengths. This has helped them limit the fallout from PAMA to mostly just their Medicare and Medicaid fee-for-service revenues.

   But most independent clinical labs were unable to lock in pre-PAMA rates for their private insurance contracts. Consequently, private payers have taken advantage of expiring lab contracts to begin mirroring the PAMA pricing cuts. Data from the billing firm XIFIN Inc. indicates that starting in early 2018, Aetna, Cigna, the Blues, and UnitedHealthcare began demanding 20% to 25% off of the 2018 Medicare fee schedule (which had already been cut by 10%) for lab contract renewals. Furthermore, Multiplan, which negotiates contracts for multiple insurance carriers, cut rates in some regions by as much as 50%.

   Similarly, financial reports for OPKO's BioReference Labs and Enzo Biochem's clinic lab division show intense pricing pressure from private payers in 2018-2019. As a result, these labs and other smaller independent labs will likely be reporting lower private payer rates for the second PAMA survey.

8. **The growth of Medicare Advantage.** Enrollment in Medicare Advantage (MA) plans increased to 22.75 million (representing 37% of all Medicare recipients) in 2019, up from 18.39 million (32% share) in 2016. When private health insurers contract with CMS to offer an MA plan, they receive monthly capitated payments for enrollees, which must cover all Part A and Part B benefits (except hospice). If they can stay under budget, the insurer will profit. If not, they lose money. This gives MA plans a strong incentive to squeeze rates paid to providers, including labs. MA plans were the quickest to use the initial PAMA rate cuts as justification to lower their lab rates. The increase in MA enrollment combined with their lowered rates will negatively influence the second PAMA survey.

9. **The new drug testing codes will get hammered.** New codes for definitive drug testing (G0480-G0483) were introduced by CMS in 2016. These codes rank among Medicare's highest lab test volumes and expenditures (see table page 6). They were exempt from the first PAMA survey and instead got a tiny 2.7% Medicare rate cut. However, they are subject to the second PAMA survey and significant rate cuts should be expected.

10. **No real threat of penalties for scofflaws.** Collecting and reporting private-payer data to CMS is a costly and time-consuming exercise for labs. Failure to report data as required by PAMA subjects labs to fines of up to $10,000 per day for each omission or misrepresentation. These penalties could easily run up to several million dollars for even a small non-compliant lab. Only 1,942 labs reported their pricing data to CMS in the first survey out of an estimated total of more than 13,000 labs that were required to do so. However, despite the low participation, CMS did not direct OIG to investigate or penalize the scofflaws. Even more labs, including hospital outreach labs, are required to report in the second PAMA survey. A simple statement by CMS indicating its intent to enforce the law and impose penalties on non-reporting labs would go a long way toward raising survey participation. But CMS has not done this and appears to be giving non-reporting labs another free pass.

Hangover Cuts From First PAMA Survey Must Be Absorbed In 2021

Three straight years of 10% annual rate cuts (2018-2020) will not fully bring many high-volume lab tests down to the median CLFS rates set by the initial PAMA survey, according to an analysis by *Laboratory Economics*. For example, after three years of the max 10% annual rate reduction, the comprehensive metabolic panel (CPT 80053) would still require another 14% cut in order to reach the median rate determined by the first PAMA survey. In addition, several high-volume drug testing codes (G0480-G0483) were never repriced in the first PAMA survey because they were newly introduced codes without accurate private-payer pricing data. The bottom line is that Medicare rates for most high-volume CLFS tests are starting out in a hole that will either be raised or lowered by the second PAMA survey that will determine rates for 2021-2023.

Top 25 Lab Tests Based On 2018 Medicare Part B Spending

CPT Code	Description	2018 Allowed Charges	2020 CLFS Rate (with 10% cap)	First PAMA Survey Median Rate	PAMA Overhang
80053	Comprehensive metabolic panel	$376,167,159	$10.56	$9.08	-14%
G0483	Drug test, definitive, 22+ classes	318,659,111	246.92	NA	NA
80061	Lipid panel	316,798,860	13.39	11.23	-16%
84443	Thyroid stimulating hormone (TSH)	314,040,900	16.80	14.87	-11%
85025	Complete blood cell count	282,848,218	7.77	6.88	-11%
82306	Vitamin D	235,244,806	29.60	26.37	-11%
80307	Testing for presence of drug	227,961,585	62.14	62.14	0%
83036	Hemoglobin A1C level	178,428,197	9.71	8.50	-12%
81528	DNA-based colorectal cancer screening	170,684,377	508.87	508.87	0%
G0482	Drug test, definitive, 15-21 classes	160,942,030	198.74	NA	NA
81479	Unlisted molecular pathology procedure	135,670,753	NA	NA	NA
81408	Molecular pathology procedure, Level 9	123,156,681	2,000.00	2,000.00	0%
G0480	Drug test, definitive, 1-7 classes	105,798,068	114.43	NA	NA
G0481	Drug test, definitive, 8-14 classes	97,417,178	156.59	NA	NA
81519	Breast cancer gene expression	78,474,014	3,873.00	3,873.00	0%
83970	Parathyroid hormone	77,108,520	41.28	36.76	-11%
80048	Basic metabolic panel	74,709,698	8.46	8.06	-5%
82607	Vitamin B-12	74,570,038	15.08	13.43	-11%
84153	Total PSA	74,238,666	18.39	16.38	-11%
84439	Thyroxine measurement	58,250,989	9.02	8.03	-11%
87086	Urine culture/colony count	51,404,406	8.07	7.19	-11%
81162	BRCA 1&2 gene analysis	50,896,967	1,824.88	1,615.81	-11%
87798	Infectious agent detection by DNA or RNA	50,206,286	35.09	29.83	-15%
85610	Prothrombin time	48,672,346	4.29	4.29	0%
82728	Ferritin (blood protein) level	$47,696,393	$13.63	$12.13	-11%

Source: *Laboratory Economics* from CMS and Medicare Part B carrier files

Labs In Quandary Over EKRA's Ban On Commission-Based Lab Sales

It's been more than one year since the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) became law as part of broader legislation (The SUPPORT Act) intended to address the national opioid crisis. EKRA is an all-payer anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or any type of laboratory.

The language in EKRA is broadly written. Most concerning for labs is EKRA's ban on volume-based commission payments made to either W-2 employees or 1099 contractors. The ban applies to sales reps at all types of laboratories (toxicology, molecular, routine clinical, anatomic pathology, et al.). EKRA has labs in a quandary. Should they take the major step of restructuring their sales force to comply with EKRA, or wait for a potential change in the law?


Danielle Sloane

For an update and further insight into EKRA, *Laboratory Economics* recently spoke with Danielle Sloane, healthcare attorney at Bass Berry Sims (Nashville, TN).

Has there been any additional OIG guidance, clarification, or changes to the EKRA law banning volume-based commissions for lab sales reps since it was passed late last year?
No. Nothing yet, though I understand there are some laboratory organizations, including ACLA, working toward legislative clarification.

Do you anticipate any near-term changes (within 6 months) that would narrow the scope of EKRA?
I do think it is likely that the law may be clarified, ideally to permit anything that is permitted by the federal Anti-Kickback Statute, which clearly allows labs to pay volume-based commissions to their W-2 sales rep employees.

However, although ideal, it seems a bit less likely that EKRA will be carved back to only apply to toxicology or to permit commission-based sales arrangements between labs and independent contractors. Unfortunately, a number of recent laboratory enforcement actions in the genetic testing space involving independent contractor commission-based sales arrangements have highlighted that aggressive marketing goes beyond just toxicology. [See LE, October 2019, p. 11 and this issue, pages 9 & 10.]

Is the EKRA law subject to whistleblower lawsuits?
Probably not. There is no private right of action under EKRA. However, it could be used as the basis for a False Claims Act whistleblower suit, but only with respect to government claims and for behavior that is not already prohibited by the Anti-kickback Statute.

Outside of the lab industry, are there any other similar laws that have been passed targeting volume-based commissions for other types of healthcare services? Or is the EKRA law targeting labs unique?
Yes, independent contractor commission-based sales arrangements have always been within the purview of, and carried risk under, the federal Anti-Kickback Statute.

With respect to W-2 employees, there are not many similar laws except at the state law level. For example, Texas has an EKRA-like state law focused on sales commissions in the addiction treatment space.

In addition, there are a variety of state fee-splitting laws, some of which are specifically focused on labs and prohibit sharing fees with referral sources. However, in most states these provisions have

not been interpreted to prohibit commission-based sales arrangements for employees or independent contractors.

Most labs have not yet changed their sales rep compensation structure to comply with EKRA on the hope that this law will be narrowed. What are the risks involved with not complying with EKRA? All laboratories should understand that commission-based sales arrangements are prohibited by EKRA. EKRA is a criminal statute, and the penalties are potentially significant – up to a $200,000 fine, up to 10 years imprisonment, or both, per occurrence.

However, given that there has been no enforcement, no guidance issued by the DOJ or the DHHS, and only minimal commentary from these agencies in public presentations (e.g., noting EKRA as a potential enforcement option for the DOJ to reach beyond federal healthcare programs), the risk of enforcement right now seems relatively low for most laboratories with strong compliance programs and infrastructure that are not engaging in questionable behavior.

It seems likely that the DOJ will, at least initially, aim to use EKRA to get at egregious behavior, such that the risk of enforcement against a laboratory is likely proportional to the likelihood of bad acts by their sales team or others. For those choosing to take a wait and see approach, it may be wise to structure its sales arrangements to comply with an Anti-kickback safe harbor and/or ensure its compliance program has sufficient checks and balances in place to prevent, and quickly catch, any questionable sales tactics. At the very least, EKRA heightens the need for a good compliance infrastructure at your laboratory.

EKRA-Compliant Sales Rep Compensation Models

The EKRA law has made it a crime for any laboratory to pay a volume-based commission payment to a member of its sales force (both W-2 and 1099 employees). The big question now is, will any labs change their compensation practices and risk losing their most productive sales reps? It is the understanding of Peter Francis, who has 46 years of lab sales and management experience and operates his own sales training firm, Clinical Laboratory Sales Training LLC (Woodstock, MD), that none of the major commercial labs have restructured their sales force compensation plans to comply with EKRA, and only a handful of smaller labs have made changes to their policies. Below Francis outlines a few alternative compensation structures that would comply with EKRA.

Peter Francis

For bona fide W-2 sales rep employees:

1. Salary plus variable compensation based on the number of sales calls made that included a face-to-face discussion [with documented contact name(s)] during a calendar month.
2. Salary plus variable compensation tied to the number of activated new accounts (irrespective of specimen volume or revenue) within a specified timeframe.
3. Salary plus an annual bonus tied to a customer satisfaction survey (with the survey rating goals discussed with the sales rep beforehand).
4. Temporarily switching sales reps to a fixed salary based on their historic productivity—reverting back to traditional commissions if and when EKRA is amended.

Francis notes that EKRA-compliant relationships with 1099 sales rep contractors are trickier and more risk-prone, because it remains difficult to oversee their activities. At a minimum, he suggests that labs sign 1099 sales reps to one-year written contracts under which they are paid a fixed monthly or bi-weekly fee for providing a specified schedule of services.

Boston Heart Pays $27 Million To Settle Kickback Allegations

Boston Heart Diagnostics (Framingham, MA), which specializes in advanced lipid testing, has agreed to pay $26.7 million to settle False Claims Act allegations, the U.S. Department of Justice recently announced.

The DOJ alleged that Boston Heart coordinated with independent marketers to boost patient referrals for small Texas hospitals. The independent marketers "set up companies known as management service organizations, to make payments to referring physicians that were disguised as investment returns but were actually based on, and offered in exchange for, the physicians' referrals," according to the DOJ. As a result, physicians allegedly referred patients to the hospitals for tests performed by Boston Heart, which were then billed to Medicare and Medicaid.

In addition, DOJ said that Boston Heart conspired with the hospitals to submit claims for outpatient lab tests for patients who were not hospital outpatients, in order to receive higher reimbursement rates.

The settlement also resolves allegations that Boston Heart paid processing and handling fees, waived patient copays and deductibles, and provided physician practices with free in-office dieticians in exchange for lab test referrals.

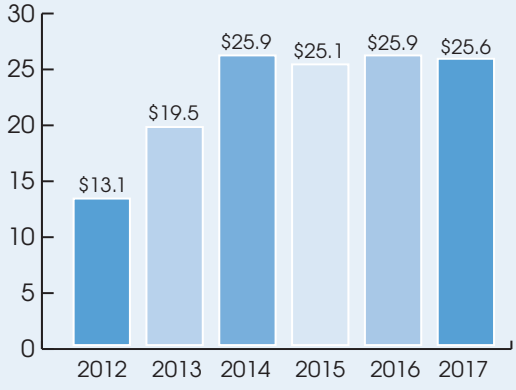
Whistleblowers Chris Riedel and Claudia Bradshaw will receive $4.36 million of the settlement, according to the DOJ.

Riedel was a board member at Boston Heart from 2007 until the company was acquired by Bain Capital in late 2010. He filed his original whistleblower suit against Boston Heart in 2012. Riedel is also the whistleblower who famously sued LabCorp and Quest Diagnostics for allegedly overcharging California's Medi-Cal program for lab tests (see LE, September 2019). Riedel's whistleblower share is approximately $4.27 million.

Bradshaw is a registered nurse who worked at Boston Heart from January 2014 to January 2017. In her position as clinical specialist, Bradshaw supported Boston Heart's sales reps and provided clinical consults to physician clients on interpretation and treatment related to the company's lipid tests. Bradshaw's whistleblower share is approximately $95,000.

In addition to the $26.7 million settlement, Boston Heart is required to pay $1.4 million to the whistleblowers' law firm Cotchett, Pitre and McCarthy LLP (Burlingame, CA).

Boston Heart Medicare Part B Payments ($ millions)



Source: CMS

Boston Heart is now a subsidiary of Luxembourg-based Eurofins Scientific. Eurofins acquired Boston Heart in early 2015 for $140 million plus earn-outs of up to $60 million based on reaching certain milestones.

"We are pleased to put behind us legacy issues relating to qui tam lawsuits dating in some respects as far back as 2012," said Patrick Noland, Boston Heart President since April 2017. "Boston Heart is a very different organization today compared to what it was then and up to two and a half years ago."

Boston Heart received total Medicare Part B payments of more than $135 million between 2012 and 2017, according to data from CMS.

Pittsburgh Lab Owner To Plead Guilty In Medicare Kickback Scheme

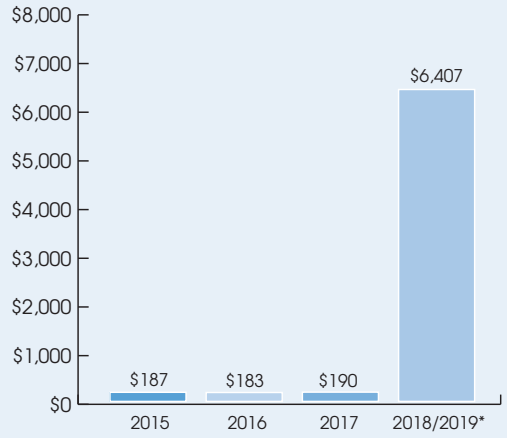
Ravitej Reddy, age 52, is expected to plead guilty to federal charges that he conspired with out-of-state marketing companies to pay kickbacks in exchange for Medicare patient specimens, the *Pittsburgh Post-Gazette* reported on December 10.

Reddy owns two CLIA-certified labs: Personalized Genetics (dba Personalized Genomics) in Pittsburgh and Med Health Services Management in Monroeville, PA.

Reddy paid kickbacks to conspirators at marketing companies in Georgia, Florida, Texas and South Carolina, according to charges filed by the U.S. Attorney's Office for the Western District of Pennsylvania on November 26. The outside marketers collected DNA samples from Medicare beneficiaries using cheek-swab kits sent directly to their homes or obtained at "health fairs" across the United States.

Reddy and the marketers paid kickbacks to a telemedicine company in Florida in exchange for physician orders for expensive genetic testing panels with charges that averaged more than $12,000 per beneficiary. The contracted doctors at the telemedicine company authorized the testing without examining or evaluating the patients, the U.S. attorney's office said.

Average Medicare Payment at Personalized Genomics and Med Health



*From May 2018 – April 2019

Prior to the alleged scam, Reddy's two labs had collected an average of about $190 per Medicare beneficiary for performing primarily routine lab tests

Source: CMS and U.S. Attorney's Office

Furthermore, prosecutors said that neither of Reddy's two labs possessed the lab instruments necessary to perform genetic tests and that nearly all of the actual testing was performed by an outside reference laboratory.

However, prosecutors said that Reddy's two labs billed Medicare more than $127 million between May 2018 and April 2019 for tests performed on 9,365 beneficiaries (>$12,000 per beneficiary). During this period, Reddy's labs received Medicare payments totaling about $60 million (about $6,407 per beneficiary) and he paid outside marketers more than $17 million.

Reddy's plea hearing is scheduled for January 10. He is facing up to 25 years in prison. However, Reddy is expected to plead guilty and is likely cooperating with prosecutors in exchange for a lighter sentence.

Quest Diagnostics Buys Assets of Boston Clinical Laboratory

Quest Diagnostics has acquired certain assets of Boston Clinical Laboratory (BCL-Waltham, MA). BCL is a small routine clinical lab that serves the Boston area. Quest says that it plans to transition BCL's test volume to its regional laboratory in nearby Marlborough, Massachusetts. BCL, which was founded by its President Zahra Sheikhinejad, PhD. in 1999, has estimated annual revenue of roughly $5-$10 million. "Given increasing reimbursement pressures on today's labs, now is the right time for BCL to transition the business," said BCL's Chief Operating Officer Hossein Bayat, PhD. in a statement.

Lab Industry Conference Call Summary

Below *Laboratory Economics* summarizes the highlights from conference calls and shareholder letters released by a few publicly-traded lab companies.

Enzo Biochem: Responds to Hedge Fund

Enzo Biochem (Farmingdale, NY) will hold its 2019 Annual Shareholders Meeting on January 31, 2020. This year's meeting is particularly critical, as hedge fund Harbert Discovery Fund has taken a 12% stake in Enzo and is seeking to replace two board members up for election.

In a December 5 letter to shareholders, Enzo said, "Harbert's track record consists of aggressively targeting highly illiquid, small-cap companies outside of the healthcare sector and, through back-door pressure tactics, forcing these companies to install Harbert-designated appointees to the Board to implement changes designed only to advance Harbert's short-term interests….We can only interpret their behavior as an indication that their true intent in obtaining Board seats is to abandon Enzo's long-term strategy and attempt to drive a fire sale of the company at depressed valuations."

NeoGenomics: The Shift Toward NGS and Molecular Testing

"I mentioned that the NGS [next-generation sequencing] and molecular growth rates were in excess of 50% during the quarter and that's a continuation of very strong momentum. NGS is becoming a greater part of our mix, but it's still relatively low. We have a comprehensive menu, and as you know we're offering every discipline. And interestingly, every single test modality increased during the quarter, so that indicates we're taking market share, but I think NGS will over time take some marketshare away from traditional FISH testing, particularly in the solid tumor FISH area. But I think that we expect NGS generally to continue to grow at an outsized pace relative to our other test modalities as far as my eye can see," according to Chairman and CEO Douglas VanOort [Conference Call, October 29].

OPKO Health: The Impact of Employed Physicians

Roughly 60% to 70% of physicians are now employed by either a hospital or a large medical group. "That movement from physicians away from their own practices to being employed has had a significant impact on selling [lab testing service] to physicians. So the decider in a lot of the diagnostic lab industry, where it used to be the individual physician at small groups, is really now more of a C-suite decision," noted Jon Cohen, MD, Executive Chairman of OPKO's BioReference Laboratories [Piper Jaffray Healthcare Conference, December 4].

Sonic Healthcare: More Hospital Partnerships and JVs Expected

"Our pipeline for acquisitions and hospital laboratory opportunities are rich, and we're certainly in the midst of something very exciting in the U.S. market in terms of potential growth….There are sizable opportunities outside of M&A in the area of [Hospital] partnerships and joint ventures," according to Colin Goldschmidt, MD, Chairman and CEO of Sonic Healthcare [Conference Call, August 26, 2019].

Exact Sciences: More In-Network Coverage

Exact's Cologuard test is currently covered for 96% of its core estimated total addressable population, men and women between the ages of 50 and 85 at average risk of colon cancer, according to Chairman and CEO Kevin Conroy [Conference Call, October 29]. This compares with 57% in-network coverage back in early 2016 (during the first PAMA data collection survey period).

Lab Stocks Up 27% Year To Date

Twenty lab stocks have risen by an unweighted average of 27% year to date through December 13. In comparison, the S&P 500 Index is up 26% so far this year. The top-performing lab stock thus far in 2019 is Natera, which has soared 162%, followed by Veracyte, up 127%, and NeoGenomics, up 110%. Shares of LabCorp are up 32%, while Quest Diagnostics is up 26%.

Company (ticker)	Stock Price 12/13/19	Stock Price 12/31/18	2019 Price Change	Enterprise Value ($ millions)	Enterp Value/ EBITDA	Enterp Value/Annual Revenue
LabCorp (LH)	$166.59	$126.36	32%	$23,520	12.4	2.1
Quest Diagnostics (DGX)	105.20	83.27	26%	18,440	12.1	2.4
Sonic Healthcare (SHL.AX)	28.93	22.11	31%	16,090	16.4	2.6
Exact Sciences (EXAS)	87.20	63.10	38%	10,770	NA	14.9
Guardant Health (GH)	75.90	37.59	102%	6,330	NA	34.4
Natera (NTRA)	36.58	13.96	162%	2,750	NA	9.6
NeoGenomics (NEO)	26.42	12.61	110%	2,740	55.7	7.2
Genomic Health (GHDX)*	63.44	64.41	-2%	2,160	31.9	4.9
Myriad Genetics (MYGN)	25.58	29.07	-12%	2,020	27.3	2.4
Invitae (NVTA)	17.16	11.06	55%	1,490	NA	7.6
Opko Health (OPK)	1.56	3.01	-48%	1,270	NA	1.4
Veracyte (VCYT)	28.51	12.58	127%	1,210	NA	10.4
CareDx (CDNA)	21.75	25.14	-13%	886	NA	7.7
Castle Biosciences (CSTL)	29.50	16.00	84%	432	43.9	9.5
Exagen (XGN)	17.97	14.00	28%	168	NA	4.2
Enzo Biochem (ENZ)	2.62	2.78	-6%	97	NA	1.2
Psychemedics (PMD)	9.10	15.87	-43%	50	6.5	1.3
Interpace Diagnostics (IDXG)	0.45	0.80	-44%	43	NA	1.7
Cancer Genetics Inc. (CGIX)	6.06	7.20	-16%	15	NA	0.5
Biocept (BIOC)	0.26	0.86	-69%	3	NA	0.6
Unweighted Averages			27%	$90,483	25.8	6.3

*Genomic Health was acquired by Exact Sciences on November 8, 2019. Source: *Laboratory Economics* and Capital IQ

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