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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

LABS GET EXTRA 60 DAYS TO REPORT PAMA DATA; CALL FOR ONE-YEAR DELAY FOR NEW RATES

The Centers for Medicare and Medicaid Services (CMS) said March 30 that it would "exercise enforcement discretion" until May 30, 2017, on data reporting required under the Clinical Laboratory Fee Schedule (CLFS) repricing initiative. Essentially, this gives applicable labs an extra 60 days to submit their private-payer test volume and payment information. Meanwhile lab trade groups, including the National Independent Lab Assn. and American Clinical Lab Assn., are lobbying CMS to delay the start date for the new CLFS rates, currently scheduled to take effect Jan. 1, 2018, by one year.

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QUEST, LABCORP SUED FOR ALLEGEDLY OVERCHARGING PATIENTS

Quest Diagnostics and LabCorp are each being sued for allegedly billing self-paying patients as much as 10 times more for lab tests compared with their rates for private insurers and Medicare. "The lab companies have two fee schedules – they charge market prices to people with insurance and grossly exaggerated fees to people without insurance," according to Robert Finkel, plaintiffs' attorney with the law firm Wolf Popper LLP (New York City), which is seeking class action certification.

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BCBS OF NORTH CAROLINA ROLLS OUT LAB BENEFIT MANAGEMENT PROGRAM

Effective March 1, 2017, Blue Cross and Blue Shield of North Carolina handed over management of its independent lab network to Avalon Healthcare Solutions (Tampa, FL), a lab benefit management company owned by a group of venture capital firms. Avalon's game plan looks a lot like what LabCorp's BeaconLBS is doing with United Healthcare in Florida (and trying to do in Texas). Avalon will receive payments from BCBSNC that guarantee savings to BCBSNC compared with what the insurer had previously spent on independent lab services. Avalon will keep whatever is left over after it pays claims from its new smaller network of contracted labs.

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LABS GET EXTRA 60 DAYS TO REPORT PAMA DATA (*cont'd from p. 1*)

"Industry feedback suggests that many reporting entities will not be able to submit a complete set of applicable information to CMS by the March 31, 2017, deadline, and that such entities require additional time to review collected data, address any issues identified during such review, and compile the data into CMS's required reporting format," said the agency in an announcement posted on its website March 30.

The 60-day enforcement discretion period is the maximum amount of time CMS can permit to still have sufficient time to calculate the CLFS payment rates scheduled to go into effect on January 1, 2018, according to CMS.

Carol Blackford, Director of CMS' Hospital and Ambulatory Policy Group, said during the annual meeting of the American Clinical Laboratory Association (ACLA) on March 23 that CMS was aware that some clinical labs were having difficulty submitting their test volume and payment information through the agency's portal.

"The overall volume of data reported is lower than we had anticipated," said Blackford. "The problems have to do with formatting or because labs are submitting data for codes not on the list."

ACLA President Julie Khani tells *Laboratory Economics* that she hopes the 60-day extension will give labs sufficient time to certify and submit large volumes of data. The extension will also give CMS additional time to resolve issues with the reporting portal.

Lab Groups Seek 1-Year Delay for New Rates

The data collection issues, combined with ongoing concern over the definition of "applicable laboratory" for reporting purposes, has led a coalition of lab groups to ask for a one-year delay in implementation of the new Medicare lab payment system.

In a March 24 letter to Health and Human Services Secretary Tom Price, 10 lab groups—including ACLA, the National Independent Laboratory Association and the American Association for Clinical Chemistry—said that many labs are still struggling with data collection and reporting. The groups expressed concern that CMS's data collection system is not yet functioning at adequate capacity, as many operational problems from the 2016 test phase appear unresolved and are hampering laboratory data submissions.

Beyond operational data issues, the regulatory definition for "applicable laboratory" must be reassessed and redefined, the groups argue, noting that the HHS Office of Inspector General has estimated that only about 5% of clinical laboratories will report data, with an estimated complete exclusion of hospital laboratories.

"The exclusion of an entire laboratory sector, particularly hospitals operating large outreach laboratories, negatively affects the integrity of rate calculations under PAMA," according to the lab groups.

Current Implementation Timeline

January 2016–June 2016:	Data collection period.
January 2017–March 2017:	Data reporting period (extended until the end of May).
May 2017:	Publication of Federal Register notice announcing annual public meeting and Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel Meeting.
July 2017:	Annual public meeting and CDLT Panel Meeting.
August 2017:	End of public comment period for pricing method recommendations.
September 2017:	Posting of preliminary rates and aggregate-level data for public comment.
October 2017:	Public comment period closes.
November 2017:	Posting of final payment amounts for the CY 2018 CLFS.
January 1, 2018:	New rates become effective.

QUEST, LABCORP SUED FOR ALLEGEDLY OVERCHARGING (*cont'd from p. 1*)

The lawsuits claim that when an insurance plan denies coverage for lab tests performed by Quest or LabCorp, the lab companies directly bill the patient at excessive list prices (or "rack rates") that bear no relationship to fair market value rates, resulting in bills that can exceed $1,000. To make matters worse, Wolf Popper says that both Quest and LabCorp turn unpaid invoices over to collection agencies if individuals do not pay the alleged excessive charges.

Nearly all labs balance-bill patients significantly higher rates for out-of-network services, but lawyers have targeted Quest Diagnostics and LabCorp because they have the deepest pockets.

Wolf Popper's lawsuit against Quest provides several specific examples of alleged overcharging. For example, Lawrence D. Catti was billed $218.48 by Quest for a Homocysteine test (CPT code 83090), conducted on January 7, 2017. Mr. Catti's insurer (Aetna) denied coverage on grounds that it considered the test "experimental or investigational." If Aetna had accepted coverage, it would have reimbursed Quest $15.02 and Mr. Catti would have had no copay. However, because Aetna denied coverage, Quest billed Mr. Catti the full $218.48—approximately 14.5 times the fair market value rate negotiated between Aetna and Quest, according to the lawsuit.

In its lawsuit against LabCorp, Wolf Popper cites plaintiff Holden Sheriff who was charged $2,988 for a series of eighteen tests performed on November 22, 2016. Ms. Sheriff's insurer (Cigna) denied coverage of three tests (CPT codes 81240, 81291, 81241), which were genetic tests not sought by Ms. Sheriff or her referring doctor. Nonetheless, LabCorp billed Ms. Sheriff the aggregate rack rate of $1,043.79 for the three uncovered tests, according to the lawsuit.

In both cases, Wolf Popper is requesting class action certification and seeking to recoup alleged overpayments by consumers and punitive damages.

A LabCorp spokeswoman says, "We believe our billing and pricing practices are lawful and we intend to vigorously defend this lawsuit."

Comparison of Quest and LabCorp "Rack Rates" Versus Medicare CLFS

Code	Description	LabCorp's Rack Rate	Quest's Rack Rate	2017 CLFS Max Amount
80053	Metabolic Panel	$46.00	$84.22	$14.49
81003	Urinalysis	$31.00	NA	$3.08
81291	MTHFR Genetic Test	NA	$328.85	$59.88
82306	Vitamin D; 25 Hydroxy	$273.00	$150.00	$40.61
82378	CEA	NA	$158.49	$26.01
82652	Vitamin D; 1, 25 Dihydroxy	$616.00	NA	$52.81
83036	Hemoglobin A1c	$66.00	$70.40	$13.32
85025	CBC	$31.00	$40.56	$10.66
87340	Hepatitis B Test	$74.00	NA	$14.17
87624	HPV High-Risk Test	NA	$125.84	$48.14
82105	Alpha-Fetoprotein (AFP)	NA	$152.58	$23.01
87340	Hepatitis B Surface Antigen	$87.00	NA	$14.17

Source: Wolf Popper and CMS for 2017 CLFS rates

Quest did not respond to a request for comment.

The lawsuit against Quest was filed in US District Court for the District of New Jersey (case# 2:17-cv-01590), while the lawsuit against LabCorp was filed in US District Court for the Middle District of North Carolina (case # 1:17-cv-193).

Increased Patient Responsibility for Paying Healthcare Costs

The Wolf Popper lawsuits come at a time when more and more workers are being steered into high-deductible health plans that make them responsible for paying the first $1,000 or $2,000 of their healthcare expenses. Last year, 29% of all workers with employer-sponsored health insurance were enrolled in a high-deductible plan (defined as $1,000 or greater annual deductible for single coverage/$2,000 or greater for family coverage), according to the Kaiser Family Foundation/ Health Research & Education Trust 2016 Employer Health Benefits Survey.

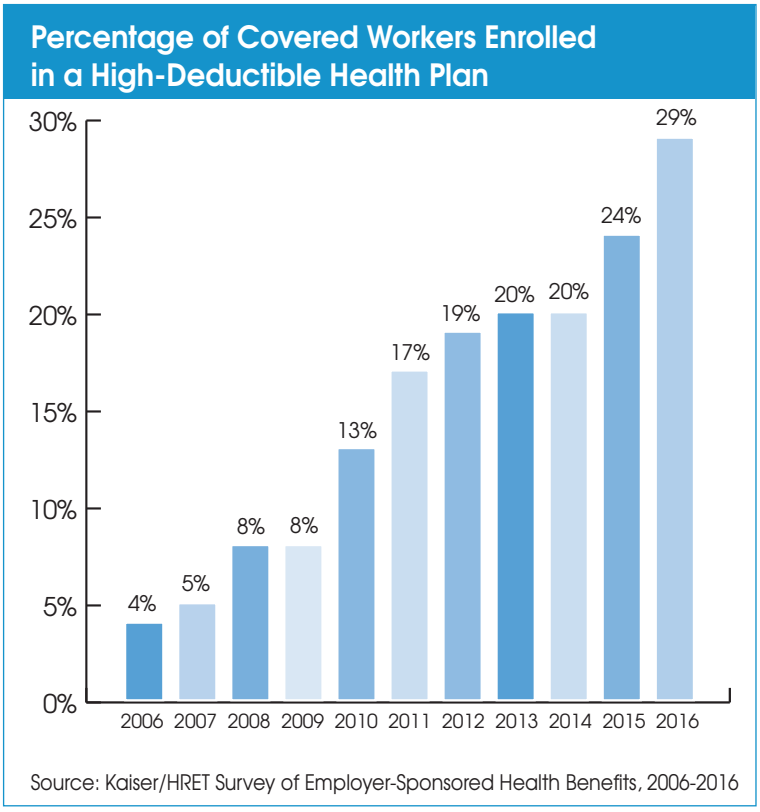
Increased Scrutiny of Lab Test Claims and More Denials

The lawsuits also provide anecdotal evidence of the increased scrutiny that Aetna, Cigna, BCBS plans, and other insurers are giving to lab test claims in their effort to weed out non-covered tests and deny payment. In particular, these insurers seem to be increasingly denying claims for Vitamin D tests, allergy panels, add-on STD tests with Pap screenings, and various genetic tests.

State Lawmakers Taking Aim at Surprise Medical Bills

In related news, some states, including California, Florida and New York, have enacted legislation designed to limit the amount that non-participating (out-of-network) providers can bill patients.

The law in Florida (HB 221: effective July 1, 2016), for example, protects patients who receive care at an in-network health facility, but are unknowingly treated by an out-of-network provider. The law prohibits out-of-network practitioners, including surgeons, anesthesiologists and pathologists, from balance-billing patients.



And more states have similar "surprise bill" legislation in the works.

For example, in Oklahoma (House Bill 2216) has passed the House and is now pending in the Senate. HB 2216 would require in-network hospitals to notify patients if certain providers, including pathologists, are out of their network, disclose whether the provider will practice balance billing and present a good-faith estimate of out-of-network charges. The bill states that hospitals must provide patients the above information 14 days before they receive scheduled, nonemergency services. If it passes Oklahoma's Senate, the bill would take effect Nov. 1.

AURORA DIAGNOSTICS REPORTS $29M LOSS FOR 2016

Aurora Diagnostics (Palm Beach Gardens, FL) reported a net loss of $29.1 million for 2016 versus a net loss of $83.4 million in 2015; revenue increased 7.7% to $284 million. Excluding the benefit of acquisitions, Aurora's revenue increased 0.6% in 2016. The company processed 2.1 million accessions in 2016 (up 2.2%), while average revenue per accession was $130 (up 4%).

As of Dec. 31, 2016, Aurora reported cash holdings of $18.5 million and total debt of $397.1 million, which requires interest payments of more than $40 million per year.

Plans to Refinance Debt

Aurora says that it has reached a non-binding agreement with the owners of $200 million of senior notes (CUSIP: 051620AB8, 10.75%, maturity 1/15/2018). Under the agreement, the owners will be issued new notes with their maturity extended by two years to January 15, 2020. In addition, the note holders will be given penny warrants to purchase up to a 15% equity stake in Aurora. The exchange offer is expected to close by May 30, 2017.

Aurora also has $197 million of debt outstanding under a senior secured credit facility from the private investment firm Cerberus Business Finance, LLC. This debt, which is secured by essentially all of Aurora's assets, must be repaid in October 2017 if the company is unable to extend the maturity of its $200 million of senior notes.

Aurora Diagnostics Financial Summary ($000)

	2016	2015	% Change
Total revenue	$284,039	$263,744	7.7%
Operating cash flow	6,976	2,330	199.4%
Capital expenditures	2,417	2,279	6.1%
Free cash flow	4,559	51	NA
Interest expense	41,945	40,980	2.4%
Net loss	-29,143	-83,435	NA
Total debt*	397,100	389,300	2.0%
Shareholders' Equity	-219,786	-190,783	NA
Total number of requisitions	2,121,000	2,076,000	2.2%
Avg. revenue per requisition	$130	$125	4.0%

*Excludes up to $17.7 million of contingent consideration owed to acquired pathology practices

Source: Aurora Diagnostics

AURORA BUYS RHODE ISLAND-BASED PATHOLOGY GROUP

Meanwhile, during March 2017, Aurora says it acquired 100% of the equity of University Pathologists, a hospital-based pathology practice based in Warwick, Rhode Island. Aurora paid $11.4 million cash for University Pathologists, including its technical lab, University Pathologists Diagnostics. In addition, Aurora issued contingent notes payable annually over three years up to a total of $2 million.

University Pathologists provides hospital-based professional anatomic pathology services to eight hospitals and operates a technical lab in Fall River, MA that serves physician practices in Connecticut, Massachusetts and Rhode Island. The group employs 25 pathologists and six pathologist assistants that process more than 100,000 surgical cases and 60,000 cytology specimens annually.

With this acquisition, Aurora Diagnostics now operates 27 pathology lab practices and employs more than 180 pathologists that serve roughly 13,000 referring physicians and act as medical directors for 109 hospitals throughout the U.S.

PUBLICLY-TRADED LABS GREW 4% IN 2016

On a combined basis, 19 publicly-traded labs grew their revenue by 4% to $18.2 billion in 2016 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Excluding Quest Diagnostics and LabCorp, 17 smaller publicly-traded labs grew by 9.2% last year (after adjusting for acquisitions).

Revenue growth was fastest at two genetic-testing lab companies: Invitae Corp. (up 199%) and Exact Sciences (up 152%).

Acquisition-adjusted revenue for LabCorp was up 3.9% last year, while Quest Diagnostics' revenue was up 1.7%. The third largest U.S. lab company, Opko/Bio-Reference Labs, had estimated revenue growth of 9.2%.

Revenue Growth at 19 Publicly-Traded Lab Companies ($000)

Company	Revenue 2016	Revenue 2015	Reported Change	Pro Forma Change*
Quest Diagnostics	7,515,000	7,493,000	0.3%	1.7%
LabCorp Diagnostics[1]	6,593,900	6,199,300	6.4%	3.9%
Opko/Bio-Reference	1,012,129	927,252	9.2%	9.2%
Myriad Genetics[2]	753,800	723,100	4.2%	4.2%
Sonic Healthcare USA[3]	713,950	700,400	1.9%	1.9%
Genomic Health	327,868	287,458	14.1%	14.1%
Aurora Diagnostics	284,039	263,744	7.7%	2.2%
Miraca Life Sciences USA[4]	261,300	257,700	1.4%	1.4%
NeoGenomics	244,083	99,802	144.6%	10.0%
Foundation Medicine	116,865	93,203	25.4%	25.4%
Exact Sciences	99,376	39,437	152.0%	152.0%
Enzo Clinical Labs[5]	70,915	63,414	11.8%	11.8%
Veracyte	65,085	49,503	31.5%	31.5%
Psychemedics	38,980	26,975	44.5%	44.5%
CareDx	29,600	27,881	6.2%	6.2%
Cancer Genetics Inc.	27,049	18,040	49.9%	8.0%
Invitae Corp.	25,048	8,378	199.0%	199.0%
Combimatrix	12,869	10,088	27.6%	27.6%
Rosetta Genomics	9,234	8,268	11.7%	11.7%
Total, 19 companies	$18,201,090	$17,296,943	5.2%	4.0%
Total, 17 companies (excluding Quest and LabCorp)	$4,092,190	$3,604,643	13.5%	9.2%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

[1]LabCorp's revenue is for its lab testing business only (excluding clinical trials); [2]Myriad Genetics' revenue is for fiscal year ended June 30, 2016; [3]Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2016 (using constant exchange rate of 1 AUD = 0.75 USD); [4]Miraca's revenue is for U.S. lab business for fiscal year ended March 31, 2016; [5]Enzo's revenue is for lab services only for fiscal year ended July 30, 2016.

Source: *Laboratory Economics* from company reports

SPOTLIGHT INTERVIEW WITH UTMB'S MICHAEL LAPOSATA

Michael Laposata, MD, PhD

The University of Texas Medical Branch (UTMB) in Galveston, Texas, is a full-service academic medical center laboratory that provides lab services to patients of the UTMB Health System, the Texas Department of Criminal Justice and the Federal Bureau of Prisons. The UTMB laboratory performs about 1 million tests per year and employs more than 200 people in the laboratory. *Laboratory Economics* recently spoke with Michael Laposata, MD, PhD, Chairman of the Department of Pathology at UTMB.

Is the UTMB laboratory growing its volume?
We're definitely growing. For one thing, we're part of a network and we're building connections to other University of Texas hospitals and even other Texas hospitals that are not part of the network. We're also bringing other hospitals, such as Angleton Danbury Hospital, into the UTMB enterprise. We also will be collaborating with MD Anderson Cancer Center's newest outpatient facility being built in League City, which is supposed to open by the end of the year (MD Anderson is part of the University of Texas system). And we're growing because more people are moving to Southeast Texas.

Which areas of testing are growing the fastest?
Genetic testing and coagulation testing are growing the fastest in our laboratory.

Where have you achieved your greatest cost savings?
The goal is not only to save money establishing the diagnosis but to improve the outcome of the patient as well. The financial proposition to getting a more accurate and a quicker diagnosis is virtually impossible to calculate, but it is obvious that each expert-driven narrative is a benefit to the patient.

Tell me about your plans to launch an outreach program at UTMB.
The biggest part of any academic medical center doing an outreach program is to provide more than a commercial lab provides. Commercial labs provide test results, but we are hoping to yield a diagnosis with the test results that are generated. Physicians are looking for help. We're already doing coagulation testing for physicians, but we're looking to do more.

Can you describe UTMB's diagnostic management teams and their role in the future?
We have four active diagnostic management teams at UTMB. DMTs can focus on just one disease or on a group of diseases. We review, in real time, all the diagnostic information and synthesize a report that includes a diagnosis. DMTs are focused on the synthesis of all diagnostic information. This is not just looking at slides through the microscope and saying "Here's what I saw." DMTs are about making diagnoses, not giving test results. This information has to be placed in the patient's chart and delivered to clinicians in time for decision-making. DMTs are not common because it requires a complete re-evaluation of what a lab director does.

What do you see as the biggest challenges facing pathology?
There is no future for the person who manages documents, gets the blood in and the numbers out, and only asks questions when posed to him or her. There is a tremendous need for laboratory directors who provide advice to treating doctors desperate for help on test selection—so that costly over- and under-utilization of laboratory tests is prevented; and for expert interpretations in the patient's record for all doctors on the healthcare team to see in real time the meaning of complex lab test results for all complex evaluations, not only ones associated with a question. Doctors in the field—whether MD or PhD—are slow to open the door to this service line which they can provide better than anyone else.

BCBSNC ROLLS OUT LAB BENEFIT MANAGEMENT (*cont'd from p. 1*)

BCBSNC's switch to the Avalon-managed lab network applies to all of BCBSNC's under-65 members, but not its Medicare Advantage plans. All independent labs that file claims reporting POS 81 (place of service: independent lab) must now be contracted with and submit their claims to Avalon in order to be considered "in-network."

Out-of-network claims from non-participating labs will still be submitted directly to, and paid by, BCBSNC. However, BCBSNC drastically cut its out-of-network lab fee schedule in July 2015.

As of March 23, Avalon had contracted with a total of 19 in-network participating labs, including Quest Diagnostics and AmeriPath, Greensboro Pathology, Pathgroup Labs and Wake Medical Laboratory Consultants. After a lengthy and contentious negotiation, LabCorp also joined the Avalon-managed lab network.

In addition to obtaining rate concessions from its in-network participating labs, Avalon will help manage utilization of high-cost genetic tests.

The situation must be a bit confounding to LabCorp, given that North Carolina is its home state and it invested millions to develop its own lab benefit management company (BeaconLBS), observes *Laboratory Economics*.

Furthermore, LabCorp's BeaconLBS has encountered vocal resistance from pathology and other physician associations in Florida and Texas. But Avalon's launch of similar programs for BCBS of South Carolina (effective Jan. 1, 2016) and now BCBSNC have occurred with little outcry from the lab and pathology communities.

eviCore's Genetic Test Management Expanding at BCBS Plans

Similarly, eviCore healthcare (Bluffton, SC), another private-equity-backed lab benefit management company, has been contracting with a growing number of BCBS plans without controversy. eviCore provides utilization management/preauthorization services for a wide list of high-cost tests, including BRCA gene testing, genetic panels, pharmacogenomics tests and some pathology services.

Within the past 12 months, eviCore has started outpatient genetic test utilization management programs for AmeriHealth (effective July 1, 2016), BCBS of Illinois (Oct. 3, 2016), Highmark BCBS (Aug. 1, 2016) and BCBS of Texas (Oct. 3, 2016).

Laboratory Benefit Management Companies at a Glance

Company	*Owners*	*Clients*
Avalon Healthcare	Francisco Partners, Echo Health Ventures, Mosaic Health, BCBS of South Carolina	BCBS of South Carolina, BCBS of North Carolina
BeaconLBS	LabCorp	United Healthcare (Florida and Texas)
eviCore Healthcare	General Atlantic, TA Associates	AmeriHealth, BCBS of Illinois, BCBS of MT, BCBS of OK, BCBS of Texas, BCBS of WV, Highmark BCBS, and many others

Source: *Laboratory Economics*

OIG ON HUNT FOR LAB VIOLATIONS, FALSE CLAIMS

Despite widespread alerts, guidance and advisory opinions designed to educate clinical laboratories about potential risk areas, the Health and Human Services Office of Inspector General (OIG) continues to uncover cases where labs knowingly or unknowingly violate federal laws.

In fiscal year 2016, the OIG took criminal action against 765 healthcare providers, civil action against 690, and excluded 3,635 providers from participation in federal health programs, according to Karen Glassman, senior counsel with the OIG. Glassman spoke about recent compliance actions at the annual meeting of the American Clinical Laboratory Association, held March 23 in Washington, D.C.

Data mining has allowed the OIG to identify when labs bill multiple claims for urine drug screening when only a single unit may be billed per patient encounter, as well as when labs upcode low to moderate complexity drug screening tests to high complexity, noted Glassman. In recent years, the OIG has reached 10 settlements with labs relating to these types of claims violations totaling more than $8.9 million, including a $1.58 million settlement with Gainesville Pain Management and a $5 million settlement with Medicus Laboratories.

Labs also continue to self-disclose fraudulent activity that they discover themselves, explained Glassman. In May 2016, Regional Medical Laboratory Inc. paid $1.1 million to resolve alleged "pull-through" kickback activity, and in February 2017, Quest Diagnostics paid $1.15 million to resolve alleged Stark and kickback issues.

The most common violations for labs include billing for tests not ordered or performed, miscoding of CPT codes, misrepresentation of diagnosis codes and lack of medical necessity, according to Glassman.

Recent areas of interest include contracts with third-party marketing firms, medically unnecessary genetic testing and sham clinical trials.

- **Contracting with outside marketing firms and sales reps:** Marketing services can be contracted to an outside firm, but the lab is ultimately responsible for submitted claims.
- **Genetic testing:** More specific coding (rather than code stacking) is allowing OIG to data mine to identify labs that may be performing unnecessary tests.
- **In-office phlebotomists:** Labs may employ phlebotomists at physician practices without violating kickback laws provided: 1) the phlebotomist only performs specimen collection and processing services for their lab employer; and 2) they do not perform any free services for the physician practice.
- **Sham clinical studies:** The OIG is on the lookout for the increasing prevalence of "sham clinical studies" used to recruit patients for unnecessary genetic tests. Red flags include studies with no identified parameters and controls, sometimes having an institutional review board (IRB), but they're paid with no real diligence. Other traits include labs or contracted sales reps paying physicians $50-80 to check a box and get patients enrolled in a fake clinical trial.

The lesson for labs, says Glassman, is to constantly identify potential risk areas through internal or external audits, employee reports, management and employee surveys, public data from comparable institutions and public reports of enforcement actions. "Compliance is a team sport," she says, noting that all areas of an organization should be actively involved in ensuring compliance with federal and state laws.

PRESTIGE TO PAY $1M TO SETTLE ALLEGED GENETIC TESTING SCAM

Prestige Healthcare (Louisville, KY) has agreed to pay the United States $995,500 to resolve allegations that it violated the False Claims Act by participating in an alleged scheme to falsely bill Medicare for unnecessary genetic testing.

Prestige operates approximately 70 nursing homes in seven states.

The United States alleged that in 2014, Prestige was approached by an entity known as Genomix, LLC (Newport Beach, CA), which claimed that it could perform genetic testing on Prestige's Medicare residents to determine if they were properly metabolizing their medications. The United States alleged that in 2014 and 2015, Prestige provided Genomix with insurance and personal medical information, as well as access to Prestige patients in nursing homes in several states for purposes of conducting the testing. Genomix conducted the testing by taking cheek swabs of each Prestige patient and then sending the cheek swab to a laboratory for analysis.

The United States alleged that Prestige failed to ensure that physician orders were obtained for the genetic testing prior to its being conducted, and that Prestige physicians were not aware of and did not agree with the medical necessity of the testing.

The failure to obtain physician orders and resident permission for the tests were uncovered by Wisconsin Department of Health state surveyors in 2015, according to the DOJ.

The announced settlement resolved only Prestige's civil liability and did not resolve any liability of Genomix, which is a separate entity headquartered in Southern California. As part of the settlement, Prestige has agreed to cooperate in the United States' ongoing investigation.

PHILIPS DIGITAL PATHOLOGY SYSTEM CLEARED FOR PRIMARY DIAGNOSIS

The FDA has cleared the Philips IntelliSite Pathology Solution (PIPS) for primary diagnostic use. It's the first digital pathology system to be approved for primary cancer diagnosis in the United States.

The FDA evaluated data from a clinical study that involved about 2,000 surgical pathology cases. It was one of the largest studies that directly compared the use of digital pathology to conventional microscopes.

Sixteen pathologists at Cleveland Clinic, University of Virginia, Miraca Life Sciences and Advanced Pathology Associates performed about 16,000 reads of the cases. The results showed that the diagnoses made using PIPS were comparable to those made using the conventional method.

Correction: Medicare Travel Allowance for 2017

Information in the March issue of *Laboratory Economics* provided incorrect information regarding the 2017 Medicare travel allowance for collection of laboratory specimens. The per-mile travel allowance (P9603) for 2017 is $0.99 per mile—this is to be used when the average trip to a patient's home is longer than 20 miles roundtrip. The flat-rate trip basis allowance (P9604), which is used by some Medicare administrative contractors, is $9.85.

REVIEW YOUR PRIVATE-PAYER CONTRACTS NOW, BEFORE IT'S TOO LATE!


Andrew Stimmler

Most high-volume test codes will be reduced by the maximum allowed 10% after CMS resets its Clinical Laboratory Fee Schedule (CLFS) effective Jan. 1, 2018, according to Andrew Stimmler, Founder & Managing Partner at the consulting firm Shipwright Healthcare Group, LLC (Greensboro, NC). Additional cuts are expected in subsequent years as well. The anticipated Medicare cuts have the potential for a rippling effect because most commercial payers base their rates on a percentage of the CLFS.


Steve Stonecypher

Stimmler's comments came during a special *Laboratory Economics* teleconference, *Turbulent Times in the Payer Space for Labs & Pathologists*, on April 13. Stimmler was joined by Steve Stonecypher, Managing Director at Shipwright.

Many commercial payer contracts are linked directly to the CLFS and automatically adjust January 1 each year, while some plans load new fee schedules on June 30 or September 30. Blues plans are typically reset as a percentage of the CLFS every 3-5 years, observed Stonecypher.

Therefore, Stonecypher said it's imperative that clinical labs immediately identify which of their contracts are linked to changes to the CLFS, and renegotiate them to a fixed year [e.g., 2016 or 2017 rates]. "If you wait until after the new lower CLFS rates are released, it may be too late. There will be a flood of labs scrambling to do the same thing," noted Stonecypher.

Stonecypher reminded listeners that the CLFS rate adjustments will also affect many pathology groups and labs because Medicare rates for Pap testing (including HPV, chlamydia, gonorrhea, et al.) and routine cancer marker rates (e.g., Total PSA, CEA, CA 15-3, CA 125, et al.) are on the CLFS and will be included in the pricing adjustment.

The Spread of Laboratory Benefit Managers

Given the explosion in new genetic and molecular tests, it's an all-consuming proposition for a health plan's medical affairs teams to review and keep up to date on all the related clinical utility studies and guidelines (e.g. ACMG, ACOG, AUA, etc.), noted Stimmler. "So for most health plans, the choice is this: hire additional medical affairs personnel to immerse themselves full-time in this…or outsource to an LBM? And many are choosing the latter."

Is the lower reimbursement worth the added volume you might get as a BeaconLBS Laboratory of Choice? "It would all depend on the individual lab themselves. BeaconLBS is obviously promoting its labs of choice over participating labs, specifically in where you are listed when a physician orders on the drop-down menu. But I'm not sure if the lower price pays off. It depends on how sticky your clients are," answered Stonecypher. [See separate article on LBMs on page 1.]

Value-Based Reimbursement

The move to value-based reimbursement will mean some form of capitation, according to Stonecypher. "For example, the lab benefit management models are really just a twist on capitation. Taking the lab spend and believing they can do a better job managing that spend, either through utilization control and/or reducing out-of-network leakage. I think there are already capped models out there today, besides the West Coast. I've come across them in Colorado, Arizona, Florida and Texas. I think it can be a standard cap, or a cap with a risk pool for the most sick, almost like a reinsurer or similar to how the Medicare Advantage plans have shared savings."

LAB STOCKS UP 23% YTD

Sixteen lab stocks have risen by an unweighted average of 23% year to date through April 13. In comparison, the S&P 500 Index is up 6%. The top-performing lab stocks so far this year are Cancer Genetics, up 159%; Foundation Medicine, up 82%; and Exact Sciences, up 74%. At the two largest public labs, LabCorp is up 11% and Quest Diagnostics is up 6%.

Company (ticker)	Stock Price 4/13/17	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	3.50	1.35	159%	66	NA	2.5	2.6
CombiMatrix (CBMX)	4.55	2.65	72%	13	NA	1.0	1.9
Enzo Biochem (ENZ)	7.95	6.94	15%	368	11.7	3.5	4.2
Exact Sciences (EXAS)	23.27	13.36	74%	2,570	NA	25.9	7.7
Foundation Medicine (FMI)	32.30	17.70	82%	1,140	NA	9.8	6.9
Genomic Health (GHDX)	30.66	29.39	4%	1,040	NA	3.2	6.6
Invitae (NVTA)	10.48	7.94	32%	443	NA	17.7	4.4
LabCorp (LH)	142.10	128.38	11%	14,560	20.2	1.5	2.7
Myriad Genetics (MYGN)	18.15	16.67	9%	1,240	20.5	1.7	1.7
NeoGenomics (NEO)	7.74	8.57	-10%	610	NA	2.5	3.7
Opko Health (OPK)	7.62	9.30	-18%	4,250	NA	3.5	2.0
Psychemedics (PMD)	19.90	24.99	-20%	109	16.8	2.8	7.0
Quest Diagnostics (DGX)	97.25	91.90	6%	13,340	21.6	1.8	2.9
Rosetta Genomics (ROSG)	2.71	5.04	-46%	6	NA	0.7	0.7
Sonic Healthcare (SHL.AX)	21.57	21.40	1%	9,040	19.6	1.8	2.4
Veracyte (VCYT)	8.16	7.74	5%	276	NA	4.2	4.6
Unweighted Averages			23%		18.4	5.3	3.9

Source: Capital IQ

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