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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

CALIFORNIA IPA NOT OBLIGATED TO PAY FOR OUT-OF-NETWORK LAB TESTS

A California Appeals Court has determined that Angeles-IPA (Monterey Park, CA) is not responsible for paying for lab tests that its physicians order from out-of-network labs. Unilab Corp. (owned by Quest Diagnostics) had sued Angeles-IPA seeking payment of $174,000 for tests it performed after it lost its contract with Angeles-IPA at the end of November 2009. The case may set a dangerous precedent that emboldens payers seeking to deny payment for out-of-network lab test claims. *Continued on page 5.*

FAST-GROWING MDx TESTING MARKET STILL SUFFERING FROM HIGH CLAIM DENIALS

More specific CPT codes and increased scrutiny of claims resulted in an average 41% of molecular diagnostic test claims being denied by Medicare Part B contractors in 2014, according to an exclusive analysis of the latest available Part B data by *Laboratory Economics*. That was a small improvement from the average 42.6% denied MDx test claims in 2013, but still towers above the average 5% to 10% denial rate for routine lab tests. But despite high denial rates, Part B spending on MDx tests is skyrocketing.
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EFFORTS TO DERAIL UHC's BEACONLBS PILOT MAY NOT MAKE IT THROUGH FLORIDA LEGISLATURE

Legislation to derail United Healthcare's requirement that healthcare providers use Beacon Laboratory Benefit Solutions (BeaconLBS) to get pre-authorization for certain lab tests is moving ahead in the Florida Senate but appears doomed in the House, where there is no similar bill or advocate. The "Right Medicine Right Time Act" (CS/SB 1084) was approved unanimously by the state Senate Health Policy Committee February 1 and is now pending in the Appropriations Committee.
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Efforts to Derail UHC's BeaconLBS Pilot (*cont'd from p. 1*)

The measure requires a managed care plan, insurer or HMO to establish a process by which a prescribing physician may request an override of certain restrictions in certain circumstances, providing the circumstances under which an override must be granted, and defining the term "fail-first protocol."

Importantly for clinical laboratories, the measure also prohibits an HMO from requiring that a health care provider use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decision-making related to the use of such services.

UnitedHealthcare in October 2014 launched a pilot program requiring Florida health care providers to use BeaconLBS, a lab benefit management program, when ordering 79 high-volume lab tests. The program began as a pilot, but UHC officials have expressed interest in expanding the program to other states (*Laboratory Economics*, May 2015, p. 3). The program currently applies to UnitedHealthcare's 430,000 fully insured commercial members.

The bill has wide support from state physician associations, including the Florida Medical Assn. and the Florida Society of Pathologists.

Florida physicians have long complained that BeaconLBS, which is a subsidiary of LabCorp, interferes with their ability to order the appropriate tests for their patients. Associations representing health care providers have expressed concern about the negative impact the electronic decision support program will have on the quality of and access to care for patients. Many healthcare providers have also complained that the BeaconLBS Web-based support tools are difficult to use and don't work with their electronic health record systems.

A number of Florida laboratories have also said that the United Healthcare pilot essentially locks them out, allowing LabCorp to determine which labs are in network and how much they should get paid for testing.

Jeff Scott

Jeff Scott, general counsel for the Florida Medical Association and the author of the BeaconLBS provision in the SB 1084, tells *Laboratory Economics* that the bill is expected to be approved by the Senate, but there is no comparable legislation in the House prohibiting insurers from using laboratory benefit management programs to limit provider ordering of tests.

"The session ends March 11, and anything can happen in the last few weeks, so we are keeping our options open," he says. "If it doesn't work this year, we'll try again next year."

Scott says that he has heard from many providers who find the BeaconLBS program time consuming and difficult to use and that some have simply refused to use it. United Healthcare reportedly has begun denying payment to physicians who don't use the laboratory benefit management program, he adds.

Meanwhile, a report from Florida's Office of Insurance Regulation says restricting the use of laboratory benefit management programs could cause HMO medical costs to increase and that would result in higher negotiated premiums for the state's Medicaid program (Florida Department of Management Services, Senate Bill 1084 Fiscal Analysis, Jan. 14, 2016).

QUEST DIAGNOSTICS REPORTS FULL-YEAR 2015 RESULTS

Quest Diagnostics (Madison, NJ) reported net income of $709 million for full-year 2015, up from $556 million in 2014. Quest's reported revenue increased by 1% to $7.493 billion in 2015. Quest anticipates revenue growth in the range of 1.5% to 2.5% for 2016. On January 28, the company held a conference call with analysts and investors to discuss its year-end results. Here's a summary of some key topics:

Growth Areas

Quest's gene-based and esoteric testing business grew by approximately 5% to $1.8 billion in 2015. Quest cited several specific fast-growing areas, including BRCA testing, prescription drug monitoring, non-invasive prenatal testing ("QNatal Advanced") and infectious disease testing (HIV and HCV).

Among its weakest areas was anatomic pathology, where revenue fell by 2.6% to $631 million in 2015. Quest also cited continued weakness in Pap testing. Quest's Pap testing volume has declined to less than 10 million since peaking at approximately 14 million in 2009.

Acquisitions

Quest purchased MemorialCare Health System's laboratory outreach business in an all-cash transaction valued at $35 million in August. In addition, Quest recently agreed to buy Hartford HealthCare's outreach business (Clinical Laboratory Partners). Quest says it's working on detailed integration plans and expects the deal to close later in the first quarter of 2016. Quest also recently signed a deal to manage the inpatient labs for seven Barnabas Health hospitals in northern New Jersey.

Florida Medicaid Pricing Lawsuit

Laboratory Economics asked Quest to comment on a qui tam Medicaid pricing lawsuit that Florida Attorney General Pam Bondi is pursuing against Quest and LabCorp. Here are Quest's comments:

> The crux of the lawsuit, filed by a competitor, is a dispute about what the phrase "usual and customary charge" in the Florida Medicaid statute means. Our understanding of that phrase is consistent with how the Agency for Healthcare Administration, which administers Florida Medicaid, has used the term as well as industry custom and practice.
>
> The proposed legislation [see *LE*, February 2016, p. 1] would definitively clarify the meaning of the phrase, rather than leave the issue to be decided by a single circuit court in Florida in a way that could subject providers to further ambiguity about how to conduct themselves going forward. The Florida Attorney General has acknowledged that the interpretation of the phrase "usual and customary charge" should be guided by legislative intent, as reflected in the text of the statute, and therefore it is entirely appropriate that the state legislature express its intent in order to ensure providers have clear guidance.
>
> The situation in Florida is unlike other recent state qui tam Medicaid-billing cases involving Quest, all of which were brought by the same competitor [Hunter Labs and Chris Riedel] and have since been resolved. Quest settled a case in California

that involved a statute very different from Florida's statute. Other state cases were settled for nominal amounts after Quest obtained favorable rulings.

The lawsuit (case #2007-CA-003549) has survived efforts to dismiss by Quest and LabCorp and is currently in the discovery phase. The suit contends that Quest and LabCorp defrauded Florida by charging Medicaid more than their usual and customary charges for lab tests, which the suit defines as any amount the companies accepted as payment from any other third-party payer.

Quest Diagnostics Financial Summary ($ millions)

	2015	2014	% Change
Revenue by product			
Gene-based and esoteric	$1,754	$1,676	4.7%
Anatomic pathology	631	648	-2.6%
Routine	4,580	4,549	0.7%
Drugs of abuse	NA	NA	NA
Other*	528	562	-6.0%
Total revenue	7,493	7,435	0.8%
Operating cash flow	810	938	-13.6%
Capital expenditures	263	308	-14.6%
Free cash flow	547	630	-13.2%
Pretax income	1,126	849	32.6%
Net income	709	556	27.5%
Diluted EPS	4.87	3.81	27.8%
Total debt	3,651	3,742	-2.4%
Cash & securities	133	192	-30.7%
Shareholders' equity	4,713	4,330	8.8%
Bad debt %	4.0%	4.0%	0.0%
Days sales outstanding	47	48	-2.1%
Employees	44,000	45,000	-2.2%
Est'd number of requisitions	158.0	156.4	1.1%
Est'd revenue per requisition	43.6	43.5	0.1%

*Other revenue includes clinical trials testing, information technology services and testing services for life insurance companies
Source: Quest Diagnostics and requisition estimates from *Laboratory Economics*

CALIFORNIA IPA NOT OBLIGATED TO PAY (*cont'd from p. 1*)

A Synopsis of the Case

Angeles-IPA is an independent physician association with 400 physicians covering southern California. Angeles-IPA had contracted with Quest (dba Unilab) to be the in-network laboratory for the IPA's managed care patients. The IPA terminated its contract with Quest effective November 30, 2009, and then told its physicians to send all lab tests to a different contracted lab, AMA Laboratory (Monrovia, CA). [Note: In 2012, LabCorp became the new contracted lab provider for Angeles-IPA.]

The case could set a precedent whereby payers simply refuse to pay for lab tests performed by non-contracted labs.

However, after Angeles-IPA terminated its contract with Quest, some Angeles-IPA physicians mistakenly placed Angeles patient specimens and requisition forms into Quest's pickup boxes rather than the boxes for the newly contracted in-network lab. Quest picked up these specimens, performed the tests ordered on the paper Quest-requisition forms, and sent the results to the ordering physician. When Quest billed for these tests, it only then discovered that they were for Angeles-IPA patients. Angeles-IPA refused to pay the $174,000 billed by Quest for these tests and took the position that Quest should recover the test costs from the ordering physicians.

Quest contended that an implied contract arises when an Angeles-IPA physician obtains the patient's specimen, fills out a Quest requisition from, and places the specimen and requisition form inside a Quest pickup box. Quest argued that through the course of this conduct, Angeles-IPA implicitly authorizes Quest to perform the test ordered because the physician is an authorized agent of Angeles-IPA.

Throw the Specimen Away

Quest suggested that Angeles-IPA had a financial incentive to ignore the leakage of lab tests to Quest. "The court need look no further than Angeles' own President, Founder, Shareholder and contracted physician, Dr. Azurin, who ordered dozens of tests from Quest after the contract terminated, which remain unpaid," argued Quest.

Angeles-IPA took the position that Quest can recover the costs of the misdirected tests by billing the ordering physicians—but Quest is unlikely to bill its referring physicians.

At his deposition, Azurin was presented with a hypothetical situation in which a specimen is sent to a non-contracted lab, which does the work and reports the results to the ordering physician. When asked if he thought the lab should be paid for its work, Azurin answered, "No, because in the first place they should not have…performed the test…They should have thrown the specimen away." Quest referred to Azurin's testimony as shocking and said a laboratory has an ethical and moral obligation to perform tests in a timely manner.

Unable to Control Leakage to Non-Contracted Labs

Executives at SynerMed (Monterey Park, CA), the claims administrator for Angeles-IPA, stated that the misdirection of specimens to non-contracted laboratories ("leakage") is an industry-wide problem, and that Angeles-IPA had tried several strategies to try to limit it. One was to cap-deduct the contracted laboratory for the tests that were misdirected to the out-of-network laboratory. But that strategy was rejected when LabCorp, the contracted laboratory for Angeles, objected. Another

involved progressive discipline: for a first violation, the physician received a warning and follow-up education; for a second, a stern warning was issued; and for a third, the cap-deduction was imposed against the physician who misdirected the specimens. But at some point, that strategy also was abandoned, and Angeles ceased paying Quest for the misdirected tests.

Appeals Court Affirms Decision in Favor of Angeles-IPA

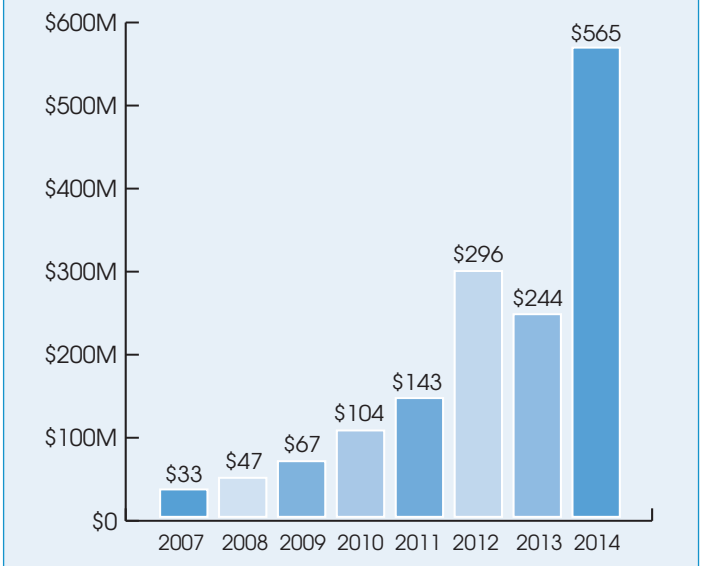
A trial court had granted summary adjudication for Angeles-IPA. And on January 13, 2016, an appeals court affirmed the judgment and said that Quest had not identified a statute or regulation that requires an IPA to pay an out-of-network laboratory where there is no contractual obligation to do so. "Given that the relationship between Angeles and its physicians was that of independent contractors, the physicians' misdirection of specimens, which was neither caused nor ratified by Angeles, did not create an implied agreement that Angeles would pay for the post-contract tests," according to the decision from California Court of Appeal. The Appeals Court found that because Quest had no contract with Angeles, which had no prior knowledge that specimens had been sent to Quest, there is no money owed.

FAST-GROWING MDx TESTING MARKET (*cont'd from p. 1*)

The introduction of new codes and reimbursement rates caused Part B spending (i.e., allowed charges) on MDx tests to drop by 17% in 2013. However, the market more than doubled to an all-time high of $565 million in 2014.

Among the fastest-growing MDx test codes in 2014 was CPT 81479 (unlisted molecular pathology procedure) which jumped from $4.2 million in allowed charges in 2013 to $68.7 million in 2014. The growth in Part B spending on CPT 81479 occurred despite a stunning 88.8% denial rate for this code in 2014. Assuming all Part B claims for CPT 81479 had been paid (zero denials), then the Medicare program would have spent $563 million on this single code in 2014. Lab companies billing Medicare most frequently for CPT 81479 include Genoptix Inc., Ambry Genetics Corp. and Bostwick Laboratories, according to Part B provider utilization data.

Medicare Part B Spending on Molecular Tests ($ millions)



Source: CMS (for 2007-2012 sum of allowed charges for CPT codes 83890-83914, 88381 and 88384-88386; for 2013-2014 sum of allowed charges for CPT codes 81200-81407, 81479, 88381 and G0452)

"Many payers are automatically rejecting any claim with CPT 81479. For claims with multiple codes, including at least one CPT 81479, the whole claim is being held for manual review," notes Rina Wolf, Vice President at XIFIN Inc. (San Diego).

Wolf says payers, both Medicare and private insurers, are holding MDx test claims and demanding documentation showing medical necessity for testing and how it will contribute to physician treatment decisions. "Some molecular labs have grown so frustrated that they have stopped billing Medicare, knowing there is little chance they will get paid."

"More payers are requiring preauthorization for the newer molecular test codes," adds Deb Larson, Executive Vice President at the billing management firm TELCOR Inc. (Lincoln, NE). "They want medical records and patient test results from previously ordered tests," says Larson. She notes that while routine clinical labs typically get their claims paid within 15 to 60 days, molecular labs are often still actively working with payers to get one-year-old claims paid.

"A lot of molecular testing businesses are running out of money and it's become difficult to raise money from outside investors," adds Wolf. "There are some brilliant lab scientists and entrepreneurs out there that have underestimated the cost of studies and the number of years it can take to convince payers to reimburse for even the most wonderful new test."

The need for real-time billing data is critical for molecular labs. They need to know who's paying claims and how much and who's not paying, so their reimbursement specialists can prioritize which payers to focus on," according to Larson. "It's a hard business to be in right now."

Denied Claims for High-Volume Molecular Tests in 2014

CPT	Short Description	Submitted Claims	Denied Claims	Percent Denied	Allowed Charges
81226	CYP2D6 genotype	440,311	61,964	14.1%	$170,390,301
81225	CYP2C19 genotype	457,979	86,488	18.9%	$108,292,937
81479	Unlisted molecular pathology procedure	533,897	474,167	88.8%	$68,657,346
81401	Molecular pathology procedure, Level 2	984,693	562,044	57.1%	$47,795,973
81227	CYP2D9 genotype	395,038	185,478	47.0%	$36,629,670
81211	BRCA1,BRCA2 gene analysis	22,188	5,092	22.9%	$34,145,619
81241	Factor V gene analysis	293,483	36,254	12.4%	$21,423,803
81240	Factor II gene analysis	284,223	35,060	12.3%	$16,703,465
81291	MTHFR gene analysis	315,293	75,724	24.0%	$14,255,170
81213	BART Testing	19,964	4,247	21.3%	$9,150,262
81404	Molecular pathology procedure, Level 5	34,139	14,396	42.2%	$4,773,131
81235	EGFR mutation analysis	19,336	6,060	31.3%	$4,396,813
81206	BCR/ABL1	17,643	2,403	13.6%	$3,319,734
81317	PMS2 gene analysis	4,788	853	17.8%	$3,070,155
81270	JAK2 gene analysis	31,748	10,556	33.2%	$2,638,886
81400	Molecular pathology procedure, Level 1	66,960	46,914	70.1%	$2,430,272
G0452	Molecular pathology interpretation	167,406	67,429	40.3%	$1,961,087
81207	BCR/ABL1 translocation analysis	12,087	1,579	13.1%	$1,898,756
81403	Molecular pathology procedure, Level 4	47,152	30,842	65.4%	$1,845,415
81275	KRAS mutation analysis	15,357	6,230	40.6%	$1,797,250
88381	Microdissection	30,228	11,422	37.8%	$1,704,632
81210	BRAF gene analysis	12,064	3,182	26.4%	$1,596,213
81292	MLH1 gene analysis	3,810	1,590	41.7%	$1,429,052
81374	HLA Class I Typing	14,237	3,592	25.2%	$1,049,793
81263	Leukemia/lymphoma B-cell mutation analysis	2,852	586	20.5%	$900,032
81342	T-cell receptor gene rearrangement analysis	3,989	969	24.3%	$803,013
81310	NPM1 gene analysis	4,376	1,036	23.7%	$748,654
81256	Hemochromatosis gene analysis	12,086	4,002	33.1%	$718,453
81298	Hereditary colorectal cancer gene analysis	2,218	669	30.2%	$445,894
81301	Microsatellite instability	1,470	346	23.5%	$441,168
Totals		4,251,015	1,741,174	41.0%	$565,412,949

Source: *Laboratory Economics* from CMS

THE FAR-REACHING INFLUENCE OF PALMETTO'S MOLDX PROGRAM

Since its launch in late 2011, the Molecular Diagnostic Services Program (MolDX) run by Palmetto GBA, a subsidiary of Blue Cross Blue Shield of South Carolina, has denied coverage for more than 1,000 different molecular and genetic tests.

The Palmetto MolDX program determines coverage and reimbursement for all labs submitting MDx test claims to Medicare in the JM region (NC, SC, VA and WV). Its policies are also followed by Noridian which processes Medicare claims in JE (CA, NV and HI) and JF (AK, AZ, ID, MT, ND, OR, SD, UT, WA and WY), as well as by CGS which administers MolDX in J15 (TN and OH). In total, Palmetto's MolDX program decisions apply to more than 13 million Medicare fee-for-service enrollees in 19 states.

Meanwhile, the Protecting Access to Medicare Act of 2014 (PAMA) permits CMS to designate between one to four Medicare Administrative Contractors (MACs) to establish coverage policies and/or process claims for payment for clinical laboratory services nationwide. CMS is reviewing comments on the advantages and disadvantages of such a potential consolidation. If CMS chooses to move forward with MAC consolidation, the most likely candidate would be Palmetto.

HELOMICS SUES FOR MEDICARE COVERAGE

Helomics Corp. (formerly Precision Therapeutics-Pittsburgh, PA) filed a lawsuit against Medicare administrator Novitas Solutions in Pennsylvania federal court in mid-December, seeking to stop Novitas from instituting a non-coverage policy for Helomics' ChemoFx test. The test measures how well different chemotherapies work before they are prescribed to a patient. On average, ChemoFx tests for 10 therapies per tumor, at a total cost of $4,346 per patient, according to a study published in *Gynecologic Oncology* in January 2015.

Novitas had announced that it considers the test experimental and planned to stop reimbursing for ChemoFx effective January 1, 2016. Helomics' lawsuit argued that the non-coverage decision was made with no evidence to back it up and would force the company out of business.

In late January, the court ruled in favor of Novitas and granted its motion to dismiss. However, Novitas has put its non-coverage decision on hold and is currently still reimbursing for ChemoFx.

EXACT SCIENCES SUES HUMANA FOR UNPAID CLAIMS

Exact Sciences (Madison, WI) has sued Humana for its refusal to pay for the company's Cologuard test for colon cancer. The lawsuit, filed in a federal court in Kentucky on February 1, alleges that Humana has illegally refused to pay more than $800,000 worth of claims for 4,664 Cologuard tests that Exact has performed for Humana members since October 2014.

The lawsuit centers on statutes in some states, including Kentucky, that require insurers to cover costs for all colorectal cancer screening tests recommended by the American Cancer Society. The Cologuard test was included in those guidelines in 2014, which means that Humana should cover the test, according to Exact Sciences.

Exact says that Humana has wrongly denied coverage for its claims on various grounds, including that Cologuard is "experimental or investigational" and that Exact failed to secure preauthorization before performing its tests. Humana has not yet filed a response to Exact's lawsuit.

LAB PACs TARGET HOUSE ENERGY & COMMERCE COMMITTEE MEMBERS

Political action committees (PACs) representing major lab organizations are targeting their biggest donations thus far in the 2016 election cycle to members of congress who are part of the House Energy and Commerce Committee. The House Energy and Commerce Committee is currently weighing FDA's proposal to takeover regulation of laboratory-developed tests (LDTs), a move that is strongly opposed by the entire lab industry.

ACLA, CAP, LabCorp and Quest Diagnostics have so far given the most to Rep. Fred Upton (R-MI) and Rep. Michael Burgess, MD (R-TX). Upton and Burgess have each received a total of $17,500 from the four lab organizations, according to data from the Center for Responsive Politics (as of January 31, 2016).

Upton is Chairman of the House Energy and Commerce Committee. He is also an Ob/Gyn physician and Vice Chair of the Health Subcommittee that has held hearings on LDTs. Upton is opposed to FDA regulation of LDTs and has instead called for continued CLIA oversight with some adjustments.

Other Energy and Commerce Committee members that have received sizable donations from the four lab PACs include Rep. Joe Pitts (R-PA), $9,000, and Rep. Marsha Blackburn (R-TN), $6,000.

Meanwhile, Sen. Orrin Hatch (R-UT) has so far received a total of $11,500. Hatch is Chairman of the Senate Finance Committee, which oversees Medicare finances. Hatch also recently sent a letter to CMS urging the agency to include hospital labs and also delay the starting date for labs to report their private payment rates for the PAMA repricing initiative (see *LE*, February 2016, p. 1).

Top Recipients of Lab PAC Donations thus far in 2016* Election Cycle

Politician	Committee Assignments	ACLA	CAP	LabCorp	Quest	Total
Rep. Fred Upton (R-MI)	Energy & Commerce, Chairman	$5,000	$2,500	$5,000	$5,000	$17,500
Rep. Michael Burgess (R-TX)	Energy & Commerce	7,500	0	5,000	5,000	17,500
Sen. Orrin Hatch (R-UT)	Finance, Chairman	2,000	5,000	2,500	2,000	11,500
Sen. Richard Burr (R-NC)	Finance	5,000	0	5,000	0	10,000
Rep. Joe Pitts (R-PA)	Energy & Commerce	2,500	3,000	2,500	1,000	9,000
Rep. Marsha Blackburn (R-TN)	Budget, Energy & Commerce	0	3,500	2,500	0	6,000
Sen. Rob Portman (R-OH)	Budget, Finance	0	5,000	0	0	5,000
Rep. Vernon Buchanan (R-FL)	Ways and Means	0	3,500	0	0	3,500
Rep. Jackie Speier (D-CA)	Oversight and Govt. Reform	0	2,700	0	0	2,700

*As of January 31, 2016
Source: Center for Responsive Politics

LABS STILL WAITING FOR FINAL RULE ON PAMA TEST REPRICING

With the Centers for Medicare and Medicaid Services (CMS) running months behind schedule in releasing its final rule implementing changes to how Medicare pays for lab tests under the Clinical Laboratory Fee Schedule (CLFS), experts say it is unlikely the new payment system will go into effect on Jan. 1, 2017, as mandated by the Protecting Access to Medicare Act (PAMA).

Under PAMA, the agency was supposed to have issued a final rule by June 30, 2015, a deadline CMS missed. A proposed rule was released Sept. 25, 2015. Since then, the agency has received over 1,300 comments expressing concern about the proposal and its impact on reimbursement of lab tests. Final comments were due by Nov. 24, 2015.

By law, labs were to begin reporting their private payer rates to CMS from Jan. 1, 2016, through March 31, 2016. But since CMS has not issued a final regulation or any guidance on how to report, reporting has not yet begun. This means that the new payment system, which is to be based on those private payer rates, is not likely to begin Jan. 1. 2017.

"At this point, labs have not received any instruction about what to report," says Peter Kazon, an attorney with Alston & Bird (Washington, D.C.). "This is a very complicated exercise, so labs want to make sure that when the rule does come out, they have sufficient time to gather the data they need and report it accurately."

"I think there's a decent shot that [the new payment system] will be delayed until 2018," says Dennis Weissman, president of Weissman & Associates, a laboratory consulting company. "It might be delayed only six months, but I think 12 months is more likely."

Julie Khani, senior vice president for the American Clinical Laboratory Association (ACLA), agrees. "The implementation timeline in the proposed rule was very aggressive and was based on the assumption that a final rule and all sub-regulatory guidance would have been published by now," she tells *Laboratory Economics*. "Given that a final rule has still not been published, it seems nearly impossible for the new prices to be in effect on Jan. 1, 2017."

What About Hospital Labs?

Weissman also believes that in the final rule, CMS will expand the universe of labs that will need to report pricing data. The proposed rule excludes most hospital labs from reporting their data, which would lower the average private-payer rate calculated by CMS. Laboratory and hospital industry groups have called on CMS to include hospital laboratories in the calculations so that the new payment rates will more accurately reflect the market.

In its comments to the proposed rule, ACLA argued that the rule's definition of "applicable laboratory" would exclude much of the laboratory market in reporting pricing and is at odds with both the statutory language and Congressional intent.

Khani notes that the overwhelming majority of comments submitted to CMS were critical of the agency's proposed applicable laboratory definition. Members of the House and Senate, as well as the chair and ranking member of the Senate Finance Committee, which has jurisdiction over PAMA, have also been highly critical of CMS's approach. "We believe CMS will be responsive to these comments and alter the applicable laboratory definition so more hospital labs will be included in PAMA reporting," she says.

Drug Testing Codes

Questions have been raised about whether the new drug testing codes would be included in the new payment system once finalized since there is no prior private payer pricing information to be reported. At this point, there is no answer, though Kazon notes that much will depend on what the actual reporting period is. "There are going to be a lot of these code-specific types of issues that are likely to be very complicated to try to resolve," he says.

HEALTH NETWORK LABS BUYS TWO FORENSIC LABS

Health Network Laboratories (HNL-Allentown, PA) has acquired two lab companies—Fairfax Identity Laboratories and Mitotyping Technologies—that perform forensic DNA testing services for immigration, estate settlements, paternity and criminal investigations. The two acquired labs had themselves recently merged and are located in State College, Pennsylvania.

According to HNL President Peter Fisher, MD, the acquisition gives HNL a national and international presence. Both Fairfax Identity and Mitotyping Technologies will remain in State College, with oversight by HNL's Scientific Officer Jeff Wisotzkey, PhD.

HNL is an independent lab with 900 employees and 50 PSCs in Pennsylvania and southern New Jersey. HNL is owned by Lehigh Valley Health Network, which includes four hospitals.

MORE BAD NEWS FOR THERANOS

It's hard to keep up with the bad news piling up for Theranos Inc. (Palo Alto, CA) these days. But here's a summary of some key issues:

- Theranos recently submitted a proposed plan of correction to CMS to address issues found during an onsite CLIA survey of the company's lab in Newark, California, on November 20, 2015. That inspection determined that the lab's analytics and staffing—in particular, its testing personnel, technical supervisor, and laboratory director—did not meet CLIA conditions of certification. In addition, the inspection found that deficient practices for its hematology testing posed an immediate jeopardy to patient health and safety. Until recently, the company's Newark laboratory was being directed on a part-time basis by a dermatologist who also managed a busy dermatology practice.
- Walgreens has suspended Theranos lab services at its store in Palo Alto, California. However, Theranos continues to operate blood-drawing sites at about 40 Walgreens stores in Arizona.
- The Theranos website continues to cite the company's "partnership" with the Cleveland Clinic, which was announced one year ago (see *LE*, March 2015). The agreement was supposed to allow Cleveland Clinic to perform a study comparing Theranos' technology with traditional blood-testing systems. However, to date, the Cleveland Clinic and Theranos have been unable to reach an agreement on the terms of such a study. The Cleveland Clinic sent three employees to Theranos last month and while they were shown the company's proprietary technology, they got no sense of how it worked, according to a spokeswoman for Cleveland Clinic.
- There are now two law firms investigating a potential class action lawsuit against Theranos. Chimicles & Tikellis LLP (Haverford, PA) is soliciting patients that have paid for blood tests performed by Theranos. And Kessler Topaz Meltzer & Check, LLP (Philadelphia and San Francisco) is investigating a potential action concerning investors of Theranos.
- Theranos is seeking to hire a Senior Litigation Counsel to "provide strategic advice and counsel to senior management on legal issues and risks," according to a job advertisement on the Theranos website. This position will "Manage Theranos' overall litigation strategy at every stage of a case, including document collection, discovery, court filings, hearings, settlement negotiations, and trial."

LAB STOCKS DOWN 22% YTD

Sixteen lab stocks have declined by an unweighted average of 22% year to date through February 12. In comparison, the S&P 500 Index is down 8.8% and the Nasdaq is down 13.4%. The top-performing lab stock so far this year is Psychemedics, up 9%. Meanwhile, LabCorp is down 17% and Quest Diagnostics is down 13%.

Company (ticker)	Stock Price 2/12/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	2.27	3.30	-31%	31	NA	1.3	0.9
CombiMatrix (CBMX)	5.12	10.95	-53%	4	NA	0.5	0.6
Enzo Biochem (ENZ)	4.30	4.50	-4%	198	33.3	2.1	4.3
Exact Sciences (EXAS)	5.87	9.23	-36%	566	NA	21.2	1.6
Foundation Medicine (FMI)	14.22	21.06	-32%	490	NA	5.7	1.8
Genomic Health (GHDX)	26.53	35.20	-25%	863	NA	2.9	6.1
Invitae (NVTA)	6.33	8.21	-23%	202	NA	25.0	1.5
LabCorp (LH)	103.02	123.64	-17%	10,430	22.5	1.3	2.1
Myriad Genetics (MYGN)	34.21	43.16	-21%	2,440	25.7	3.3	3.2
NeoGenomics (NEO)	5.57	7.87	-29%	338	NA	3.6	5.7
Opko Health (OPK)	7.89	10.05	-21%	4,300	NA	18.1	2.2
Psychemedics (PMD)	11.09	10.14	9%	60	39.6	2.1	4.8
Quest Diagnostics (DGX)	61.90	71.14	-13%	8,870	12.7	1.2	1.9
Rosetta Genomics (ROSG)	0.80	1.23	-35%	15	NA	2.3	0.7
Sonic Healthcare (SHL.AX)	17.79	17.87	0%	7,350	20.7	1.7	2.1
Veracyte (VCYT)	5.60	7.20	-22%	155	NA	3.1	2.6
Unweighted Averages			-22%		25.7	5.9	2.6

Source: Capital IQ

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