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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

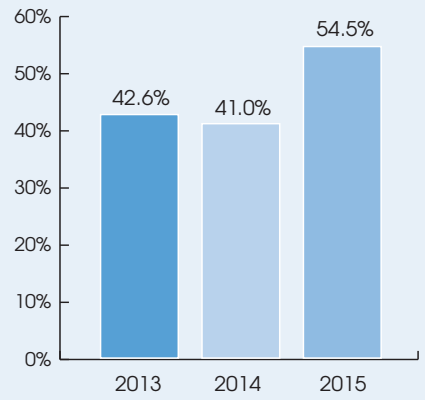
LABCORP'S BeaconLBS EYES TEXAS

UnitedHealthcare will soon be introducing BeaconLBS, a lab benefit management program owned by LabCorp, into the Texas market. For more details, see our exclusive interview with LabCorp's CEO David King on pages 6-7.

MDx TESTING MARKET CONTINUES TO SUFFER FROM HIGH CLAIM DENIALS

The percentage of molecular diagnostic (MDx) test claims denied by Medicare Part B contractors in 2015 jumped to 54.5%, according to an exclusive analysis of the latest available Part B data by *Laboratory Economics*. That compares with an average 41% denied MDx test claims in 2014 and 42.6% in 2013, and it towers above the average 5% to 10% denial rate for routine lab tests.

Medicare Part B Claims Denial Rates on Molecular Tests ($ millions)



Source: Medicare Part B aggregate denied claims vs. submitted claims for CPT codes 81200-81407, 81479, 81519, 81599, 88381 and G0452

The introduction of more specific codes in 2013 is allowing both Medicare Administrative Contractors (MACs) as well as commercial payers to deny claims for tests that they say lack adequate evidence of clinical utility.

Despite improvement, there is still a desperate need for greater code specificity. AMA is not keeping up with all the new tests being introduced, according to an executive at a large third-party claims processor who requested anonymity. "The strategy of some molecular labs is to throw a ton of junk [MDx test claims] against the wall [Medicare] and see what sticks. If Medicare doesn't pay the claim, then it's sent to a less-knowledgeable secondary payer. And if they don't pay, then the patient gets billed the full price," says our anonymous executive.
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MDx AND DRUG TESTS COULD GET A BOOST

Most routine clinical lab tests are likely to see their Medicare Part B rates reduced by 5% to 10% when CMS resets lab test prices based on private-payer rates (effective January 1, 2018). However, many molecular diagnostics and toxicology tests could see substantial price increases, according to an analysis of the private-payer rates received by 150 clinical labs by XIFIN Inc. (San Diego).
More details on page 4.

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HIGH CLAIM DENIALS FOR MDx TESTS (*cont'd from p. 1*)
The need for greater code specificity for MDx testing is illustrated by the fact CPT 81479 (unlisted molecular pathology procedure) was the single highest-paid MDx test code by the Part B system in 2015. Part B contractors paid a total of $167 million of allowed claims for CPT 81479 last year despite denying 74% of all submitted claims for this code (see table on page 3).

Lab companies billing Medicare most frequently for CPT 81479 include Ambry Genetics Corp. (Aliso Viejo, CA), Genomic Health (Redwood City, CA) and Crescendo Bioscience (South San Francisco, CA), according to the latest available Part B provider utilization data.

Top 10 Labs Billing for CPT 81479

LABORATORY NAME	LOCATION	VOLUME OF ALLOWED CLAIMS	AVG. MEDICARE ALLOWED AMOUNT	TOTAL ALLOWED PAYMENT
AMBRY GENETICS CORP.	ALISO VIEJO, CA	12,946	$1,254	$16,232,567
GENOMIC HEALTH	REDWOOD CITY, CA	4,702	$3,399	$15,979,790
CRESCENDO BIOSCIENCE	SOUTH SAN FRANCISCO, CA	11,043	$587	$6,477,311
CARE DX	BRISBANE, CA	2,070	$2,821	$5,839,470
CARDIODX	PALO ALTO, CA	3,345	$1,050	$3,511,518
ASSUREX HEALTH	MASON, OH	2,814	$1,136	$3,195,514
VERACYTE	SOUTH SAN FRANCISCO, CA	996	$3,191	$3,178,300
GENOPTIX	CARLSBAD, CA	5,707	$424	$2,419,216
BIOTHERANOSTICS	SAN DIEGO, CA	699	$2,932	$2,049,521
AGENDIA INC.	IRVINE, CA	440	$3,411	$1,500,824

Source: CMS Part B provider utilization data for calendar-year 2014

As a result of the confusion, most payers are now holding every single claim for CPT 81479 for manual review and demanding documentation showing medical necessity for testing. This is stretching out payment times to over one year for even legitimate MDx test claims.

Other MDx test codes with high denial rates include the molecular pathology procedures, levels 1-9, with denial rates ranging between 45% and 87%, and CYP2D9 genotyping at 87% claims denied.

Deb Larson, Executive Vice President at the revenue-cycle-management firm TELCOR Inc. (Lincoln, NE), says that MDx test denial rates for third-party commercial payers like Aetna, Cigna and UHC were actually higher (ranging between 50% and 80% depending on the payer) than the denial rates at Medicare Part B in 2015. Larson adds that while denial rates from commercial payers seem to have declined slightly in 2016, they are still very high—ranging between 40% and 70%.

Samuel K. Caughron MD, FCAP, Chair of the Economic Affairs Committee at the Association for Molecular Pathology (AMP-Bethesda, MD), says that while there has been some minor improvement in local coverage determinations by MACs, major issues have not been addressed. He notes that the MolDx program, started by Palmetto, has been adopted by several other MACs and, as a result, has become almost a de facto national coverage determination. Palmetto's MolDx program is now being followed by MACs administering claims in 24 states covering about 50% of all Medicare recipients.

"Coverage determination processes appear flawed and often hinge on a very narrow understanding of clinical utility. In some situations, tests that physicians believe to be medically necessary and had been using for years are now being denied coverage," according to Caughron.

Furthermore, Caughron says that some MACs continue to impose restrictions that have nothing to do with whether a procedure is medically reasonable and necessary, such as requirements for labs to report patient outcomes to a registry. "There remains a great lack of transparency to how coverage policy is determined, and AMP is concerned that the medical expertise required to adequately evaluate and determine good coverage policy for patient care is not being listened to."

Meanwhile, Caughron says that private insurers (including Aetna, Cigna, Humana, United Healthcare and most BlueCross plans) are increasingly adopting the use of pre-authorization programs to reduce what they see as possible unnecessary utilization and to preempt large numbers of claim denials.

Denied Claims for 25 High-Volume Molecular Tests in 2015

CPT	Short Description	Submitted Claims	Denied Claims	Percent Denied	Allowed Charges
81479	Unlisted molecular pathology procedure	516,396	382,847	74.1%	$166,949,529
81226	CYP2D6 genotype	229,508	89,140	38.8%	$62,981,600
81519	Oncology breast mRNA, gene expression	17,788	968	5.4%	$57,438,641
81211	BRCA1,BRCA2 full sequence analysis	23,514	4,320	18.4%	$41,695,519
81225	CYP2C19 genotype	246,739	107,121	43.4%	$40,601,005
81241	Factor V gene analysis	238,490	58,183	24.4%	$14,978,570
81240	Factor II gene analysis	228,968	54,476	23.8%	$11,671,582
81291	MTHFR gene analysis	277,045	92,608	33.4%	$10,947,518
81213	BART Testing	22,044	3,866	17.5%	$10,557,860
81401	Molecular pathology procedure, Level 2	533,731	464,140	87.0%	$9,569,682
81317	PMS2 gene analysis	10,595	3,976	37.5%	$5,154,570
81227	CYP2C9 genotype	231,463	202,024	87.3%	$5,128,444
81404	Molecular pathology procedure, Level 5	34,649	15,746	45.4%	$4,978,471
81235	EGFR mutation analysis	17,152	4,598	26.8%	$4,227,344
81206	BCR/ABL1	17,977	3,530	19.6%	$3,140,721
81400	Molecular pathology procedure, Level 1	82,979	58,362	70.3%	$2,993,614
81270	JAK2 gene analysis	30,514	11,953	39.2%	$2,300,659
G0452	Molecular pathology interpretation	151,280	34,595	22.9%	$2,235,564
81403	Molecular pathology procedure, Level 4	41,538	24,425	58.8%	$2,106,990
81210	BRAF gene analysis	14,023	3,943	28.1%	$1,856,785
81275	KRAS mutation analysis	15,771	6,538	41.5%	$1,852,866
81207	BCR/ABL1 translocation analysis	12,216	2,555	20.9%	$1,729,674
81292	MLH1 gene analysis	4,836	2,864	59.2%	$1,259,521
81406	Molecular pathology procedure, Level 7	9,857	7,771	78.8%	$1,143,085
81201	APC gene analysis, full sequence	2,361	847	35.9%	$1,110,868
	TOTAL TOP 25 MDx TESTS	3,011,434	1,641,396	54.5%	$468,610,682
	TOTAL ALL MDx TESTS*	3,160,304	1,721,161	54.5%	$479,388,757

*Includes CPT codes 81200-81407, 81479, 81519, 81599, 88381 and G0452
Source: *Laboratory Economics* from CodeMap LLC. and CMS

MDx AND DRUG TESTS COULD GET A BOOST (*cont'd from p. 1*)

XIFIN analyzed 2016 pricing data from 150 of its lab clients on specific lab procedure codes and calculated weighted-average pricing for each code using the same method that CMS will use. XIFIN Chief Executive Lale White presented the data during *Laboratory Economics'* special teleconference, "Getting Final Guidance on Medicare's Market-Based Lab Payment System," on October 6.

As expected, the XIFIN analysis showed that Medicare Part B reimbursement rates for most routine clinical lab tests are likely to decrease as a result of their alignment with private-payer rates. However, the XIFIN data also showed the potential for significant price increases for many high-priced MDx tests. For example, Medicare's national rate for MTHFR gene analysis (CPT 81291) is currently set at $59, but private payers reimburse this code at an average of $130, indicating the potential for 118% rate hike.

The same situation applies to many of the new drugs-of-abuse testing codes. In an effort to discourage unnecessary utilization, CMS established new bundled codes that slashed reimbursement rates for drugs-of-abuse tests effective January 1, 2016. However, many private payers have not yet adjusted to Medicare's new coding system and are paying an average 40+% higher for drugs-of-abuse testing.

The PAMA rule limits price reductions for any particular lab test code to 10% per year for the first three years (2018-2020) and then 15% per year for the next three years (2021-2023). But there is no upward cap on how high rates can be raised.

As a result, an unintended consequence of the new payment system may be that routine clinical labs get smacked with a 5% to 10% cut in Medicare reimbursement in 2018, while specialized molecular and toxicology labs enjoy price increases of 20% to 50% or more for the lab tests they offer.

Private-Payer Rates vs. Medicare for Sample of 12 MDx and Toxicology Tests

CPT	Short Description	Private-Payer Weighted Avg. Rate	2016 Medicare National Limit	Percentage Difference
81211	BRCA1,BRCA2 full sequence analysis	$2,573	$2,180	18%
81225	CYP2C19 genotype	$423	$291	45%
81226	CYP2D6 genotype	$737	$451	63%
81227	CYP2C9 genotype	$281	$175	60%
81291	MTHFR gene analysis	$130	$59	118%
81401	Molecular pathology procedure, Level 2	$262	$134	95%
81404	Molecular pathology procedure, Level 5	$315	$164	92%
G0479	Drug test presumptive	$102	$79	29%
G0480	Drug test definitive 1-7 classes	$112	$80	40%
G0481	Drug test definitive 8-14 classes	$167	$123	36%
G0482	Drug test definitive 15-21 classes	$244	$166	47%
G0483	Drug test definitive 22+ classes	$458	$215	113%

Source: XIFIN Inc. and Medicare CLFS for 2016

HOW MANY LABS WILL ACTUALLY REPORT THEIR LAB PAYMENT RATES?

"New payment rates [for lab tests on Medicare's CLFS starting in 2018] will be based primarily on private payer data from independent labs," according to a new report from the Office of Inspector General titled *Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress*. The report confirms what many labs that rely on Medicare reimbursement had feared, namely that new Medicare rates for lab tests will be formulated mostly from pricing information supplied by Quest Diagnostics, LabCorp and Bio-Reference Labs rather than a fair representation of the overall lab market.

Generally, no hospital labs will be required to report, except in the rare instances when a hospital lab has its own National Provider Identification number.

Furthermore, physician office labs and small independent labs are sure to be unrepresented because: 1) they do not meet the reporting threshold of having received at least $12,500 from Medicare Part B for lab tests during the first half of 2016; or 2) they are unable or unwilling to go through the difficult task of collecting and reporting their private payer pricing information to CMS.

According to the OIG's report, "CMS does not plan to independently verify whether all applicable labs report their private payer data as required." In addition, the report notes that for labs that do report, "CMS does not plan to independently verify the data's completeness or accuracy." As a result, OIG concludes that "Absent processes to verify whether applicable labs report their data or to verify the quality of data that labs report, CMS may not be in a position to use its authority to pursue potential CMPs [civil monetary penalties]."

Which Labs Will Be Required to Report Their Private Payer Data?

Independent Labs

Independent labs that received at least $12,500 from Medicare Part B for lab tests during the first half of 2016 or any labs that performed advanced diagnostics lab tests will be required to report

1,398 out of 3,211:
Estimated number of labs that will be required to report.

$3.8 billion out of $3.9 billion:
Medicare payments to reporting labs.

Physician Office Labs

Physician office labs that received at least $12,500 from Medicare Part B for lab tests during the first half of 2016 will be required to report.

11,149 out of 235,928:
Estimated number of labs that will be required to report.

$1.0 billion of $1.4 billion:
Medicare payments to reporting labs.

Hospital Labs

Generally, no hospital labs will be required to report, because 50% or less of their Medicare revenue is from the Clinical Laboratory Fee Schedule or Physician Fee Schedule.

0 out of 6,994:
Estimated number of labs that will be required to report (excludes hospital outreach labs that operate as independent labs with their own NPI).

$0 of $1.7 billion:
Medicare payments to reporting labs.

Source: OIG analysis of Medicare Part B lab test payments, 2016.

WHAT HAPPENS TO THE CLFS NEXT YEAR?

The new Medicare rates based on private-payer data are scheduled to take effect on January 1, 2018. But what happens in 2017? Alan Mertz, President of the American Clinical Laboratory Assn., says either the CLFS will be unchanged in 2017, or it will get a 1% increase for inflation. Mertz says we won't know for sure until late November when CMS releases the final CLFS for 2017.

SPOTLIGHT INTERVIEW WITH LABCORP'S DAVID KING

David King

Laboratory Corporation of America (Burlington, NC) has completed several high-profile acquisitions in the 18 months, including Covance, Sequenom and ClearPath Diagnostics, and continues to grow at a healthy pace. *Laboratory Economics* recently spoke with LabCorp CEO David King about his company and changes in the lab industry. Here's a summary of our discussion:

Has BeaconLBS helped UnitedHealthcare lower its lab spend in Florida?
I believe that BeaconLBS has been a terrific success in Florida. The spending measured by total dollars and also by RVUs per member has come down. The amount of volume going through the preferred lab network has increased, and the out-of-network volumes have decreased. Physician adherence to guidelines has increased. BeaconLBS is a decision support tool that the physician encounters at the point of order entry, so it is transparent, it's not a back-end process that nobody sees. It allows the physician to know whether they are following the evidence guidelines the health plan wants them to follow. We are in the process of incorporating a number of improvements, such as expanding the decision support tools and integrating Beacon into additional EMRs.

Will UnitedHealth expand BeaconLBS to other states?
Yes, the plan is to expand Beacon to other states. United has said it will expand it to its commercial members in Texas effective March 1, 2017, and we are looking forward to a broader rollout going forward.

Was the acquisition of Covance made to help LabCorp diversify away from pricing risks associated with clinical lab testing business?
That was not a primary aspect of the Covance acquisition. We had been talking with our board for several years about expanding our position in life sciences and being more than just a pure lab business. We had taken steps to expand the business into decision support tools, ancillary services connected with the lab and having a broader portfolio. Covance came along and offered us a terrific opportunity to capitalize on the data and to establish a market-leading position in the clinical trials central lab business. For us it was broadening our life sciences portfolio and enhancing our position as the go-to companion diagnostic partner for pharmaceutical companies. All of those were higher on our agenda than minimizing industry pricing risk.

How has Covance performed for you?
It's been great. It got off to a bumpy start in early 2015, but the business has been very solid. We've seen exactly the kind of growth and expansion that we expected in the central lab business. The data combination has won us over $200 million in lab business alone; the companion diagnostic business has grown significantly.

LabCorp has also made a number of other acquisitions in the last year, including Sequenom. What exactly are you seeking with the acquisitions?
Historically, our acquisitions have been focused on strengthening our geographic footprint, broadening our test menu or adding specialty capabilities. Every acquisition was purposeful in terms of what we were trying to do with complementing our core strengths. We have an excellent women's health portfolio, but we felt the opportunity to acquire the innovator and the market leader in non-invasive prenatal testing with a platform that we could continue to build upon would put us

in the premier position in terms of an overall women's health portfolio for the lab industry. We think women's health is an area where there will be significant growth over time.

LabCorp revenues were up 6.7% for the first six months of this year, including 2% gained from acquisitions. Do you anticipate that the company will be able to continue this level of growth in the coming years?

The 6.7% is a combination of the diagnostics and the drug development businesses. We think of the diagnostics business to be the slow grower, in the low to mid-single digits. We think the drug development business is a mid- to high single digit grower. We should be able to put up mid-single-digit growth in the coming years.

LabCorp Acquisition Summary, 2015-2016 ($ millions)

Lab Type	Date	Target	Purchase Price	Acquired Revenue	Price/ Revenue
Pathology	Oct-16	ClearPath Diagnostics	NA	NA	NA
Genetic Testing	Sep-16	Sequenom	$371	$115	3.2
Pathology	Jan-16	Pathology Inc.	NA	NA	NA
Routine	May-15	Physicians Reference Lab	NA	$60	NA
Clinical Trials	Feb-15	Covance Inc.	6,100	2,542	2.4

Source: *Laboratory Economics'* estimates and LabCorp

Many in the lab industry have expressed concern that data from LabCorp and Quest will dominate the data used to set new Medicare pricing for lab tests under the payment system scheduled to take effect Jan. 1, 2018. Do you have any concern that it will force smaller independent labs out of business?

Let me frame it a little more broadly. My concern is that CMS is not faithfully carrying out what Congress intended in the statute. Congress wanted Medicare pricing to be comparable to the overall market, which they were clear includes pricing for hospital laboratories. We know that commercial pricing for hospitals is multiple times that of independent laboratories. The concern is that CMS has not taken seriously what Congress asked it to do, but instead created a rule that will minimize the amount of information it gathers from hospitals and be heavily weighted toward independent labs, which have lower prices. The risk is that this will skew the prices down.

The system that CMS is creating does not accurately reflect the market. I worry about beneficiary access in any area, nursing homes, rural areas, inner cities. If the pricing is reduced dramatically, beneficiary access is going to suffer and even hospitals are going to struggle to provide beneficiary access.

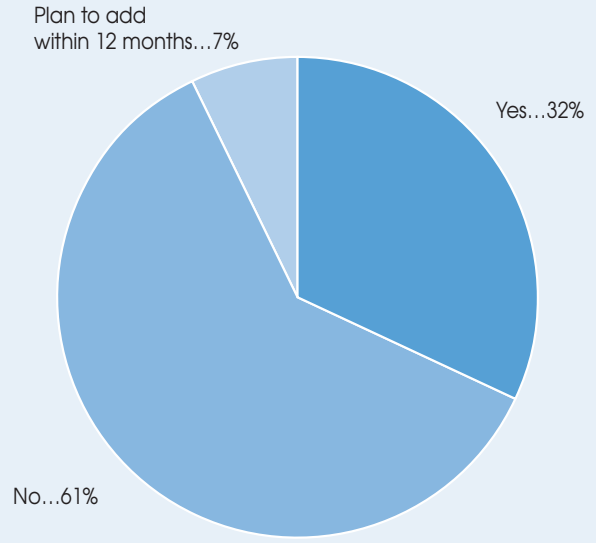
LABCORP BUYS CLEARPATH DIAGNOSTICS

Shore Capital Partners (Chicago, IL) sold ClearPath Diagnostics (Syracuse, NY) to LabCorp for an undisclosed amount. ClearPath markets pathology services, with an emphasis on Pap and HPV testing, in the northeast. Shore Capital is a private equity firm that purchased ClearPath's lab operations and partnered with its founding pathologists, Michael Jozefczyk, MD, and Michael Mazur, MD, in late 2011. ClearPath then expanded its geographic reach beyond the local Syracuse market into Connecticut, Pennsylvania and Massachusetts. It also expanded its sales force from one sales rep to nine reps. The sale to LabCorp closed on October 3.

DIGITAL PATHOLOGY SURVEY RESULTS

Market adoption of digital pathology in the U.S., especially for clinical use, is making evolutionary, not revolutionary, progress. Thirty-two percent of labs in the United States currently have a digital imaging system in place for analyzing patient specimens, and another 7% said they planned to add a system within 12 months, according to *LE's Anatomic Pathology & Clinical Lab Trends Survey* in September 2016. It should be noted that our survey was biased toward larger pathology groups/labs. There were 170 survey respondents with an average pathology group/lab size of 14.4 pathologists. And those pathology groups/labs that reported using digital pathology had an average size of 23.5 pathologists.

Does your pathology group/laboratory use digital imaging to analyze patient slides?



Source: *LE's Anatomic Pathology Market Trends Survey*, September 2016; n=170

Nationwide, there were an estimated 800 labs using digital pathology at mid-2016. However, only four labs are performing high volumes of digital pathology for clinical testing (i.e. greater than 10,000 cases per year): Oral Cancer Prevention International/CDx Labs, NeoGenomics/Clarient, Quest's Ameripath and LabCorp.

Among surveyed pathologists and labs using digital pathology, 57% are using it for quantitative immunohistochemistry for HER2 scoring, while 43% use it for ER/PR scoring. Forty percent use it for second opinions and/or consultations and 34% use it for education and/or training. Only 6% of survey respondents said they use digital pathology for primary clinical diagnosis, which compares with 20% from our survey in 2012. The decline is probably due to the FDA's announcement in early 2015 that digital slide scanners are subject to premarket review prior to use for primary diagnostic purposes. Several vendors are actively working on gaining FDA clearance, including Leica Biosystems and Roche's Ventana, but none has gained clearance yet.

What do you use digital pathology for?*	2016	2012
HER2 scoring	57%	56%
ER/PR scoring	43%	35%
Second opinions and/or consultations	40%	50%
Education and/or training	34%	54%
Archiving specimens	14%	19%
Primary clinical diagnosis	6%	20%
Contract research for clinical trials	3%	13%
Photography of autopsies	3%	8%

*Survey respondents were able to select multiple answers
Note: Survey participants included 47 hospital labs, 21 academic medical centers, 79 independent labs, 15 national labs and 8 physician office labs.
Source: *LE's Anatomic Pathology Market Trends Survey*, September 2016; n=170

LESSON FROM RML'S $1.1 MILLION SETTLEMENT: BEWARE OF CARVE-OUTS AND PULL-THROUGH ARRANGEMENTS

Despite the federal government's long-standing position that pull-through business could violate the anti-kickback law, some labs apparently haven't gotten the message.

Case in point: Oklahoma-based Regional Medical Lab (RML) recently paid $1.095 million to settle self-reported violations of the self-referral and anti-kickback laws for services performed between March 19, 2007, and March 19, 2013. RML provides onsite inpatient laboratory services for St. John Medical Center in Tulsa, as well as outpatient lab services for other hospitals, clinics and physician offices in the Tulsa metro area, northeastern, south and western Oklahoma and southeast Kansas.

The Health and Human Service Office of Inspector General alleged that RML paid remuneration to a medical group in the form of a profit-splitting arrangement related to on-site clinical reference laboratory services for non-governmental business that induced the referral of business. The OIG claimed that this arrangement induced the referral of business for which the government was the payer.

RML disclosed the conduct to the OIG on March 27, 2015, but did not admit liability. The settlement was announced May 19, 2016.

Karen Lovitch

Karen Lovitch, an attorney with Mintz Levin (Washington, DC) notes that for many years, the OIG has closely scrutinized what it refers to as "carve-outs," or business arrangements involving non-federal health care program business that are intended to "pull through" federal health care program business.

For example, in a June 2014 Special Fraud Alert, the OIG cautioned laboratories and physicians against entering into specimen processing arrangements involving only non-federal health care program business because, in the OIG's view, such arrangements may be intended to influence physicians' referrals of federal health care business to the laboratory.

Not Illegal Per Se

"However, it is important to note that carve-outs are not per se illegal," Lovitch tells *Laboratory Economics*. "A laboratory or other health care provider thus may decide to proceed with a carve-out arrangement in an effort to limit risk under the federal anti-kickback statute and other state and federal fraud and abuse laws, but should do so knowing that enforcement authorities may consider the arrangement to be suspect."

"Any laboratory or other provider who chooses to implement a carve-out arrangement should take steps to ensure that it is not offered to induce the referral of federal health care program business and that the carve-out arrangement is otherwise compliant. If even one purpose of a business arrangement is to induce the referral of federal health care program business, the federal anti-kickback statute could be violated," Lovitch continues. "Before entering into a carve-out arrangement, knowledgeable health care regulatory counsel should be consulted on potential legal risks and strategies for reducing those risks." The OIG's advisory opinions are available at www.oig.hhs.gov.

THERANOS SHUTS DOWN LABS, CUTS 340 JOBS

Theranos (Palo Alto, CA) has decided to close its clinical labs and patient service centers and has laid off 340 lab employees in Arizona, California, and Pennsylvania. The company says it will now focus on its "miniLab" point-of-care testing system, which is not FDA-cleared.

Theranos had little choice but to leave the business of operating labs. This past July, after finding a number of violations at the company's Northern California lab, federal regulators banned the company's CEO, Elizabeth Holmes, from owning or running any medical lab for two years.

Hedge Fund Sues Theranos

Meanwhile, one of Theranos' largest investors, Partner Fund Management LP (PFM-San Francisco), has filed a lawsuit against the company and Holmes in an attempt to get its money back. The suit, filed in Delaware under seal, alleges that Theranos deceived PFM in order to receive a $96 million investment from the hedge fund in 2014.

"Theranos and its principals knowingly and repeatedly lied that they had developed proprietary technologies that worked, were on the cusp of receiving all necessary regulatory clearances and approvals, and concealed the truth about the commercial viability of their technologies and methods," the hedge fund said in a statement.

The letter goes on the explain that Holmes and her colleagues assured PFM that Theranos' blood testing technology worked and was close to getting approvals from federal regulators. PFM, a 12-year-old fund that manages $4 billion, said it has never before been involved in a lawsuit and only filed in order to protect its investors.

In a statement, Theranos said the suit "is without merit, the assertions are baseless, and the plaintiff is engaging in revisionist history."

HDL BANKRUPTCY TRUSTEE SUING FORMER EXECUTIVES

The trustee appointed to manage the liquidation of what remains of Health Diagnostics Laboratory (HDL) has filed a lawsuit seeking to claw back more than $600 million in damages from former executives and shareholders in order to repay the company's unsecured creditors.

HDL filed for bankruptcy in June 2015 after it agreed to pay the U.S. Department of Justice at least $47 million to settle an investigation into HDL's practice of paying a "process and handling" fee of $20 to ordering physicians (see *LE*, June 2015).

The new lawsuit (Case 16-03271-KRH) was filed by trustee Richard Arrowsmith in federal bankruptcy court in Richmond on September 16 and alleges 76 counts against 105 defendants. Heading the list are HDL co-founders Tonya Mallory, Joseph McConnell and Russell Warnick.

Charges against the various defendants include allegations of fraud, breach of fiduciary duty, corporate waste and unjust enrichment. HDL's officers and directors "squandered tens of millions of dollars through a series of self-dealing and improper transactions," according to the lawsuit.

Among the numerous allegations, the suit says former CEO Mallory was improperly paid $18 million in shareholder distributions in addition to $7 million in salary and bonuses between 2008 through 2015. Furthermore, the suit says that Mallory resigned from HDL in late 2014, but should have been terminated "for cause" because of "misconduct injurious to HDL and breach of fiduciary duty." Instead, the suit says the board agreed to pay her a severance package of $2.7 million, representing 36 months of her salary.

MEDICARE SPENDING ON INDEPENDENT LABS INCREASING BY 6.1%

Medicare Part B carrier spending on laboratory services paid to independent labs and POLs increased by an average of 6.1% per year from 2011 to 2016, according to estimates from CMS's recently published 2016 Medicare Trustees Report. This growth rate is higher than the overall growth rate for total Medicare spending of 4.5% per year for the same five-year period.

By far, the fastest-growing segment of Part B lab spending is for drug testing. The increase in drug testing coincides with efforts to monitor prescription drug abuse, but could also signal medically unnecessary drug testing. Some of the increase in drug testing is likely legitimate efforts by physicians to monitor their patients' drug use. However, the prescription drug abuse epidemic may also be providing a cover for some labs that are fraudulently billing Medicare for unnecessary drug testing. Oddly, Medicare reimbursement rates for drug tests could get a substantial increase when CMS resets lab test prices based on private-payer rates effective January 1, 2018 (see separate story pages 1, 4).

Meanwhile, Part B spending for lab tests performed by hospital labs has decreased by an average of 5.1% per year during 2011 to 2016. The decline is due to the switch to bundled payment for lab tests provided to hospital outpatients which became effective January 1, 2014. As a result of the change, hospital labs are now essentially only reimbursed through the CLFS for their lab outreach testing.

Combined Part B lab spending (hospitals, independents and POLs) will total an estimated $9.2 billion this year representing only 1.3% of overall Medicare program expenditures.

The Medicare Trustees Report is compiled by actuaries from the Centers for Medicare and Medicaid Services (CMS). This annual report is required by law and constitutes the government's official report on the status of the Medicare program.

The 2016 report estimates the depletion date for the Hospital Insurance trust fund (aka Medicare Part A) is 2028, two years earlier than in last year's report. "The Trustees recommend that Congress and the executive branch work closely together with a sense of urgency to address the depletion of the HI trust fund and the projected growth in HI (Part A) and SMI (Parts B and D) expenditures," concludes the report.

Medicare Part B Spending on Lab Services for Calendar Years 2011-2016E ($ millions)*

	2016E	2015	2014	2013	2012	2011	1-Year Change	5-Year CAGR
Carrier Labs (independents and POLs)	$6,227	$5,929	$5,608	$5,213	$5,142	$4,631	5.0%	6.1%
Intermediary Labs (hospitals)	2,955	2,836	2,738	3,960	4,033	3,835	4.2%	-5.1%
Total Part B Lab Spending	9,182	8,765	8,346	9,173	9,175	8,466	4.8%	1.6%
Total Medicare Expenditures	683,200	647,600	613,300	582,900	574,200	549,100	5.5%	4.5%
Lab Spend as % of Medicare	1.3%	1.4%	1.4%	1.6%	1.6%	1.5%		

*Part B reimbursement amounts on an incurred basis for the calendar year; **CAGR=compound annual growth rate
Source: 2016 Medicare Trustees Report

LAB STOCKS UP 1% YTD

Sixteen lab stocks have risen by an unweighted average of 1% year to date through October 14. In comparison, the S&P 500 Index is up 5%. The top-performing lab stocks so far this year are Exact Sciences, up 99%, Psychemedics, up 91%, and Enzo Biochem, up 25%. Meanwhile, LabCorp is up 10% and Quest Diagnostics is up 17%.

Company (ticker)	Stock Price 10/14/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	1.66	3.30	-50%	27	NA	1.2	0.9
CombiMatrix (CBMX)	2.65	10.95	-76%	6	NA	0.6	0.6
Enzo Biochem (ENZ)	5.63	4.50	25%	260	14.7	2.6	4.9
Exact Sciences (EXAS)	18.33	9.23	99%	1,980	NA	31.4	7.2
Foundation Medicine (FMI)	22.10	21.06	5%	772	NA	7.0	3.5
Genomic Health (GHDX)	29.30	35.20	-17%	978	NA	3.1	7.1
Invitae (NVTA)	7.77	8.21	-5%	251	NA	16.8	2.7
LabCorp (LH)	135.79	123.64	10%	13,890	22.6	1.5	2.6
Myriad Genetics (MYGN)	18.63	43.16	-57%	1,290	10.9	1.7	1.7
NeoGenomics (NEO)	7.38	7.87	-6%	575	NA	3.3	2.8
Opko Health (OPK)	9.45	10.05	-6%	5,260	39.5	4.9	2.6
Psychemedics (PMD)	19.40	10.14	91%	106	40.7	3.6	8.9
Quest Diagnostics (DGX)	83.17	71.14	17%	11,560	14.5	1.5	2.6
Rosetta Genomics (ROSG)	0.76	1.23	-38%	16	NA	1.4	1.3
Sonic Healthcare (SHL.AX)	21.71	17.87	21%	9,030	19.9	1.8	2.5
Veracyte (VCYT)	7.58	7.20	5%	211	NA	3.9	6.3
Unweighted Averages			1%		23.3	5.4	3.6

Source: Capital IQ

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