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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PAMA DATA REPORTING DEADLINE FUELS FEARS OF SKEWED LAB TEST PAYMENT

Passage of the May 30 deadline for clinical labs to report private-payer test payment data to the Centers for Medicare and Medicaid Services (CMS) has only increased industry fears that the information will result in skewed rates under the new payment system for lab tests scheduled to take effect January 1, 2018.

Julie Allen, Senior Vice President of the District Policy Group, tells *Laboratory Economics* that many NILA members had great difficulty submitting data to CMS. "Some labs were unable to do so because their data collection systems did not comport with CMS requirements," she says. "Others were concerned about the accuracy of the data they submitted given differences in how commercial payers pay for tests compared to CMS' reporting requirements." *Continued on page 4.*

UNITED TO REQUIRE PRIOR AUTHORIZATION FOR GENETIC AND MOLECULAR TESTING

United Healthcare is implementing a national online prior authorization requirement for genetic and molecular testing for its 7.7 million fully-insured commercial members effective October 1, 2017. Physicians ordering genetic or molecular testing, including BRCA1/2, hereditary cancer panels, pharmacogenomics testing, et al., will be required to complete the prior authorization process. *Laboratory Economics* estimates that the new requirement will affect more than $100 million per year of United's spending on lab tests. *Continued on page 2.*

EVICORE TO PAY $54 MILLION TO SETTLE FALSE CLAIMS SUIT OVER PRIOR AUTHORIZATIONS

CareCore National LLC., now known as eviCore Healthcare (Bluffton, SC), has agreed to pay $54 million to settle a whistleblower's False Claims Act suit accusing it of pretending to verify the medical necessity of diagnostic tests for patients covered by Medicare Advantage and Medicaid.

"CareCore blindly approved hundreds of thousands of medical procedures over a period of many years, leaving Medicare and Medicaid to foot the bill," according to Joon H. Kim, the acting U.S. Attorney for the Southern District of New York.

News of the settlement comes at a time when more and more health insurance plans are contracting with firms like eviCore for lab benefit management services. *Continued on Page 2.*

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UNITED TO REQUIRE PRIOR AUTHORIZATION (*cont'd from p. 1*)
United says it will be the participating lab's responsibility to determine if authorization has been received. Lab tests performed without authorization will be denied payment and the patient cannot be balance billed.

United says the new prior authorization program will apply to its fully-insured commercial members throughout the United States. The only exceptions will be Florida and Texas, where United is piloting a lab benefit management program managed by LabCorp's BeaconLBS.

United says it will use a separate vendor to manage the online prior authorization process. Labs that perform genetic or molecular testing will be asked to provide details on their molecular and genetic tests (i.e., test name, test ID number, codes used for billing, etc.) to its selected vendor. United hasn't announced the name of the vendor yet, but *Laboratory Economics* thinks it's likely to be eviCore Healthcare. United already uses eviCore's prior authorization programs for a number of other services, including diagnostic imaging, oncology and cardiology.

Update on BeaconLBS in Texas and Florida
In January, United announced it would indefinitely delay the implementation of the claims rejection component of the BeaconLBS lab benefit management program pilot in Texas (see *LE*, February 2017). This critical aspect, which had been scheduled to take effect on March 1, would have denied payment to labs when physicians failed to use the BeaconLBS system when ordering some 80 high-cost lab tests and pathology services for United's fully-insured commercial members in Texas.

United says it's making refinements to the program based on feedback from Texas physicians and that it will give at least 90 days' notice to labs and physicians before a new claims impact start date is set.

Meanwhile, bills (SB 1375/ HB 3217, HB 3990) that the Texas Society of Pathologists had filed to try to kill the BeaconLBS program made little progress in the current legislative session before the clock ran out for scheduling a vote.

Finally, United has been using the full BeaconLBS program in Florida, including the claims rejection component, since April 2015. However, a United spokesperson says the program is still considered a pilot and that United continues to work with its Florida network physicians to use the required decision support tool.

EVICORE TO PAY $54M TO SETTLE FALSE CLAIMS SUIT (*cont'd from p. 1*)
The initial lawsuit was filed in 2013 by whistleblower John Miller, a licensed practical nurse who worked at CareCore from 2005 until late 2012 when he was fired. The suit was later joined by the U.S. Attorney's Office and 21 states.

CareCore provides outpatient utilization management services, including pre-authorization determinations, for numerous private insurance companies including Aetna, AmeriChoice, BCBS of New Jersey, Coventry and United Healthcare. These private insurance companies have contracts to serve Medicare and Medicaid beneficiaries.

CareCore's contracts with private insurance companies included a timing provision that required CareCore to approve or deny each request for pre-authorization for diagnostic services (e.g., CAT scans, MRIs and obstetric ultrasounds) to a given beneficiary as medically reasonable and necessary within two days of request; or within three hours if the case was designated as "urgent."

If CareCore failed to meet the time constraints, the contracts called for CareCore to be fined $3,000 per pre-authorization request.

According to the lawsuit, CareCore specifically directed its nursing personnel ("clinical reviewers") to auto-approve hundreds of cases per day, and many days up to 2,000 cases, in an effort to keep up with volume and avoid the $3,000 penalty per case. "As a result, defendants caused the submission of millions, if not billions, of dollars of false claims to government programs," according to the lawsuit.

As part of the settlement, CareCore admitted that its auto-approval process was formalized into a corporate policy named "Process as Directed," or "PAD" program. CareCore admitted that it "padded" between 200,000 and 300,000 prior authorization requests from 2007 through June 2013. "CareCore directed its employees to PAD cases on a daily basis, despite marketing itself as an evidence-based utilization management company," according to the lawsuit.

For his participation as whistleblower, Miller is set to receive 20%, or about $10.5 million, of the CareCore settlement amount.

In a statement, eviCore said, "Our most important goal is ensuring patients get the care they need. After more than three years of researching and discussing this with the government, we decided to agree to a settlement so we can put this matter behind us and focus on serving our clients with industry-leading quality and cost management programs."

Miller's initial lawsuit had also named more than a dozen health insurers (Aetna, Coventry, United Healthcare, Wellcare, et al.), claiming that they failed to conduct proper audits of CareCore and "turned a blind eye to CareCore's practices" in order to save time and money. However, the government is not pursuing claims against the insurers named in Miller's complaint.

eviCore's Lab Management Services

CareCore merged with MedSolutions in December 2014 and renamed itself eviCore Healthcare in June 2015. eviCore is owned by the private investment firms General Atlantic and TA Associates.

eviCore was initially focused on utilization management of diagnostic imaging services, but has expanded into cardiology, oncology, post-acute, musculoskeletal, ultrasound and sleep study management. Altogether, eviCore says it helps manage the benefits of more than 100 million people.

More recently, eviCore has been expanding into and winning contracts to provide laboratory benefit management services. Its services include prior authorization for high-cost tests such as BRCA testing, carrier screening panels, cancer panels, pharmacogenomics, immunohistochemistry and flow cytometry. eviCore says it will expand its services to include cardiovascular risk panels, allergy testing and toxicology testing.

In addition, eviCore has indicated plans to begin offering lab network management services.

Finally, eviCore's majority owner General Atlantic is reportedly seeking a sale of the company or an initial public offering, hoping for a valuation of more than $4 billion. eviCore is hoping an auction for the company will attract some of the large U.S. health insurers that are seeking to diversify their business, according to a news report from *Reuters* (5/4/2017).

PAMA DATA REPORTING DEADLINE FUELS FEARS (*cont'd from page 1*)

Allen represents the National Independent Laboratory Association (NILA), which consists of community and regional laboratories.

Julie Allen

The concern about accuracy is due in part to the fact that most small laboratories don't have set contracts with payers and thus there is no uniformity on what payers remit, says Allen. The labs must manually comb through old data sets to determine what they have been paid for different tests by different payers. In some cases, payers cluster reimbursement, which makes it difficult to break out individual amounts as required by CMS.

"There are instances where labs bill for all of the tests performed, and instead of getting paid individually, they get paid one lump sum," she explains. "It's a big problem. CMS says a bundled payment can't be reported. If they had not been required to report retroactive data, labs could have designed a system to exclude bundled payments. But CMS did not give us that opportunity."

NILA and other lab groups are continuing to urge CMS to delay implementation of the new payment system. Not only are these groups concerned about the data collection process and data integrity, but they also continue to argue that the regulatory definition of "applicable laboratory" must be reassessed. Under the current definition, most hospital outreach labs are not required to report their payment data. As a result, payment amounts under the new system will not reflect the full laboratory market and will be skewed toward the largest volume discounts reflected in the limited data received.

In addition to urging for a delay in implementation and an expansion of "applicable laboratory" to include hospital outreach labs, NILA has also recommended that CMS allow for prospective reporting and simplify the reporting process, provide access to the proposed revised CLFS rates and the associated data used to determine the proposed rates at least six months in advance of setting final rates, allowing for stakeholder feedback to address possible errors in the data.

Outreach Laboratories Worried

Hospital outreach laboratories are also concerned about the prospect of lower payment amounts under the revised clinical laboratory fee schedule. "CLFS adjustments based on incomplete or skewed market data may challenge the financial viability of outreach laboratory programs serving small or rural markets and could result in access and continuity of care issues for Medicare beneficiaries and commercial health plan members," according to John Kolozsvary, Chief Executive Officer of Joint Venture Hospital Laboratories (Allen Park, MI).

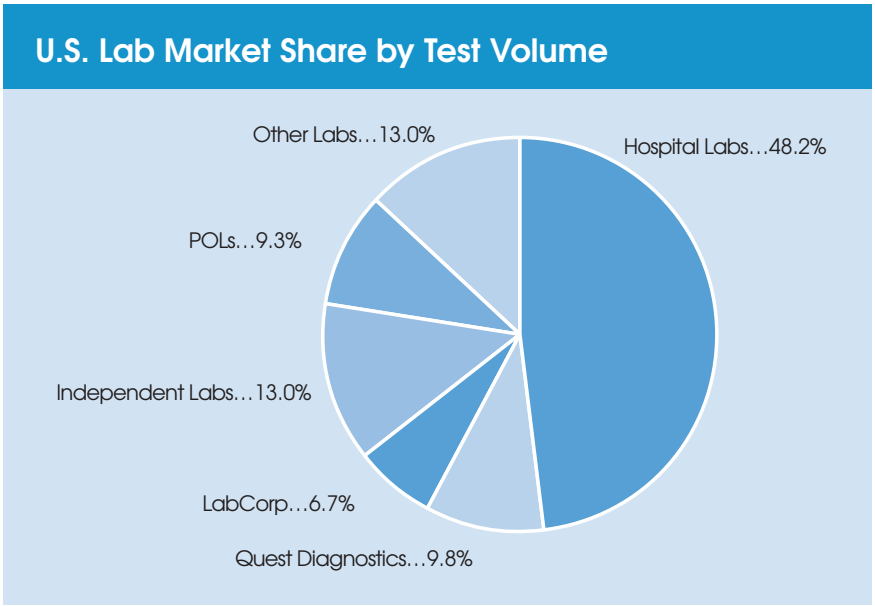
The American Clinical Laboratory Association (ACLA) has also been vocal in calling for a delay in implementation and changes to the definition of applicable laboratory. In comments submitted to the House Ways and Means Health Subcommittee in June, President Julie Khani noted that the current definition of "applicable laboratories" is so narrow and restrictive that a September 2016 Health and Human Services Office of Inspector General (OIG) report estimated that only 5% of clinical laboratories will be required to submit private market data under PAMA.

Allen and Khani say they are continuing to have discussions with CMS staff about their concerns and remain optimistic that the agency will make the needed fixes without congressional or legal intervention.

Laboratory Economics' requests to CMS for information on how many labs submitted data and whether the agency is considering a delay in implementation of the new payment system were not answered.

HOSPITAL LABS STILL DOMINATE IN VOLUME OF TESTING

Despite the hundreds of lab acquisitions made by Quest Diagnostics and LabCorp over the past 25 years, the U.S. lab market still remains highly fragmented, according to an exclusive analysis by *Laboratory Economics* of CMS CLIA test volume data as of March 31, 2017.



Hospital labs account for 48.2% of the total 9.2 billion lab tests performed annually in the United States. Quest Diagnostics has a 9.8% share and LabCorp has a 6.7% share. Thirteen percent of testing volume is performed at 4,866 independent lab sites. And 79,198 physician-office labs perform 9.3% of testing volume.

U.S. Lab Market Share by Test Volume

Laboratory Type	*# Locations*	*Annual Volume*	*Share*
Ambulatory surgery center-based lab	2,800	25,278,112	0.3%
Ancillary testing site	2,509	94,701,547	1.0%
Blood bank	408	109,512,111	1.2%
Community Clinic	4,889	84,538,734	0.9%
End stage renal disease (ESRD) facility	3,985	20,612,858	0.2%
Federal health lab	2,025	15,746,026	0.2%
HMO-owned lab	475	133,334,198	1.4%
Hospital lab	8,667	4,454,625,952	48.2%
Independent lab (excluding LabCorp and Quest)	4,866	1,197,276,683	13.0%
LabCorp	410	615,111,235	6.7%
Skilled nursing facility	10,579	121,002,550	1.3%
Pharmacy-based lab	3,540	17,163,518	0.2%
Physician-office lab	79,198	854,958,125	9.3%
Public health lab	549	69,080,287	0.7%
Quest Diagnostics	316	906,525,558	9.8%
Other labs	32,962	515,086,245	5.6%
Grand total	158,178	9,234,553,739	100.0%

Note: Analysis included every CLIA-certified laboratory facility performing more than 500 tests per year (total of 158,178 labs).
Source: *Laboratory Economics* from CMS CLIA database (as of March 31, 2017)

POPLAR HEALTHCARE BUYS GENETICS OF MEMPHIS

Poplar Healthcare (Memphis, TN) has acquired Genetics of Memphis, Inc., a small cytogenetics reference laboratory. Genetics of Memphis is also licensed by the State of Tennessee Board of Education as an accredited cytogenetics training facility. It is one of only five such schools in the United States.

Poplar says that Genetics of Memphis' President and Lab Director, Sugandhi Tharapel, PhD, and Avirachan Tharapel, PhD, Consulting Cytogeneticist, as well as its three cytogenetic technologists, will join Poplar's professional staff.

Last month, Poplar paid $6.5 million to acquire the assets of Bostwick Laboratories (Uniondale, NY) from out of bankruptcy (see *LE*, May 2017).

PATHGROUP TO CONSOLIDATE NASHVILLE LABS

PathGroup (Brentwood, TN), which currently operates three labs in the Nashville area, has announced plans to consolidate its lab and back office operations into an existing building located just south of the Nashville International Airport. PathGroup expects to invest $18 million into the new lab facility and complete the move in third-quarter 2018. The executive offices of the company will remain at 5301 Virginia Way in Brentwood.

PathGroup has approximately 1,200 employees, including more than 80 pathologists. The company provides anatomic pathology and clinical lab services to more than 1,600 physician office clients and has 70 hospital contracts across the United States. Annual revenue is more than $230 million.

In August 2016, the private equity firm Pritzker Group (Chicago) acquired a majority stake in PathGroup. Other owners include PathGroup's management and pathologists and Vesey Street Capital Partners (New York).

AURORA BUYS TIME WITH $200 MILLION DEBT REFINANCING

Aurora Diagnostics (Palm Beach Gardens, FL) has completed its refinancing of approximately $200 million of unsecured 10.75% senior notes that had been scheduled to come due January 15, 2018. The unsecured senior notes were exchanged for new notes bearing interest at 12.25%, with their maturity extended by two years to January 15, 2020. In addition, the note holders have been given penny warrants to purchase a 12.5% equity stake in Aurora.

The purpose of the exchange was to prevent an early maturity provision under Aurora's senior secured credit facility with Cerberus Business Finance, LLC. (New York City). Aurora's owes Cerberus a total of $212 million that is secured by essentially all of Aurora's assets and acquired subsidiaries. This debt matures on July 14, 2019, but would have been subject to an accelerated maturity date of October 14, 2017, if Aurora's unsecured debt had not been refinanced.

So Aurora now has about two years (till July 2019) to try to figure out how to get out from under the $412 million of total debt it is carrying at a cost of more than $40 million per year in interest payments.

Aurora Diagnostics at a Glance
(as of March 31, 2017, in $ millions)

Annual revenue	$284
Total debt	$412
Tangible assets	$66
Pathology practices	29
Employed/managed pathologists	200

Source: Aurora Diagnostics

QUEST TO BUY MED FUSION AND CLEARPOINT LABS

Quest Diagnostics has signed definitive agreements to acquire two related lab businesses, Med Fusion and ClearPoint Diagnostic Labs, based in Lewisville, Texas (just north of Dallas/Fort Worth).

Med Fusion is a reference lab focused on cancer testing and women's health (e.g., cystic fibrosis screening, breast cancer and HPV testing). It was formed in 2010 by four partners: Baylor Health Care System, US Oncology, Texas Oncology and Pathologists Biomedical Laboratories.

ClearPoint was formed by Med Fusion in 2011 to provide routine clinical lab tests in North Texas.

Both Med Fusion and ClearPoint are located at a 130,000-square-foot lab and office facility in Lewisville and share the same management team. Med Fusion/ClearPoint have a total of approximately 450 employees and estimated annual revenue of $75+ million.

The acquisitions (expected to close by September 30) will bring Quest:

1. A preferred provider relationship to perform advanced oncology diagnostics for US Oncology and its affiliated Texas Oncology. The US Oncology Network has 1,400 physicians with expertise in medical oncology, hematology, radiation oncology and other specialties. They practice at more than 400 sites in 19 states and serve more than 750,000 patients annually.
2. A nonexclusive preferred provider relationship for its full range of services for the inpatient and outpatient testing for 12 hospitals of Baylor Scott & White Health in North Texas.

In addition, Quest plans to maintain the Med Fusion/ClearPoint lab facility as a center of excellence for oncology testing. Quest also operates existing full-service labs in Irving and Houston, TX.

HARTFORD HEALTHCARE TO SELL 12 PSCS TO QUEST DIAGNOSTICS

The Hospital of Central Connecticut, which is part of Hartford Healthcare (HHC), is negotiating to sell 12 lab outreach patient service centers to Quest Diagnostics. The proposed transaction was detailed in Certificate of Need applications filed with the state in late May.

The move is part of HHC's exit from the laboratory outreach business and follows Quest's $135 million acquisition of HHC's independent lab Clinical Laboratory Partners (Newington, CT) in February 2016. With the sale of the 12 PSCs, expected to close late this year, HHC will no longer operate any lab outreach locations. The 12 sites collected specimens from approximately 171,000 patients in 2016.

HHC says it's selling its outreach PSCs "to focus on core strengths and services and shed those that can be performed better and more efficiently by other parties, such as Quest Diagnostics."

SPOTLIGHT INTERVIEW: JAMES HERNANDEZ OF MAYO CLINIC IN ARIZONA

Mayo Clinic operates several laboratories throughout the country. In addition to the main laboratories in Rochester, Minn., Mayo also has labs in Arizona, Florida and the Mayo Clinic Healthcare System in Minnesota and Wisconsin. Altogether, the labs employ more than 2,350 people and perform 27.6 million tests annually. *Laboratory Economics* recently spoke with James Hernandez, MD, Medical Director of Laboratories and Chair, Division of Laboratory Medicine, for Mayo Clinic in Arizona, which has about 300 employees. Dr. Hernandez is also an associate professor of laboratory medicine and pathology at the Mayo Clinic College of Medicine.

James Hernandez, MD

How does the Arizona laboratory fit in with Mayo's other labs?
The laboratories in Arizona function as a part of a converged and mostly standardized enterprise-wide practice that shares similar processes, platforms and procedures. I compare the labs at the different sites (Mayo Clinic in Rochester, MN, Arizona, Florida and the Mayo Clinic Healthcare System in Minnesota and Wisconsin) to ships in a fleet. We have some local flexibility in our local labs as long as we follow where the fleet is going (the overall Mayo Clinic strategic plan). We share the same laboratory information system and we will be implementing the same electronic health record soon.

Does the Arizona laboratory have a specific area of specialty?
Our practice is primarily focused on transplant, hematology/oncology, neurology/neurosurgery and cardiovascular diseases. We have a limited pediatric practice (predominantly proton beam patients) and no obstetric patients. Our lab is specialized to meet the needs of these patients.

What are the volumes of the Arizona laboratory?
In 2016, we performed 4.6 million tests.

Which areas of laboratory testing are driving growth?
We have a competitive growth plan that is focused on transplant, hematology/oncology, neurology/neurosurgery and cardiovascular diseases, so much of our growth is driven by these areas. In addition, we have an extremely busy Emergency Department and our Mayo Clinic Hospital is frequently at capacity. We are also experiencing more testing in genomics, which we send to Mayo Medical Laboratories in Rochester, MN.

Many laboratories are moving to a value-based model, where they emphasize value added services beyond simply performing lab tests. Has your lab adopted this model?
We have been moving from practicing volume to practicing to value for several years. We believe that quality = outcomes + safety + service divided by cost over time. Our lab is heavily involved in lab test utilization with our counterparts at other Mayo Clinic labs and in collaboration with our clinicians. Pathologists and scientists actively participate in refining lab order sets in the new electronic health record so that the appropriate tests are ordered up front.

What are the biggest challenges your lab faces?
Like other labs, we are asked by upper leadership to do the same job with the same or fewer resources. Space constraints are our predominant challenge on the Arizona campus and we are in a very competitive market. We are also beginning a new Mayo Clinic School of Medicine in Arizona. This is part of our mission (practice, education and research). However, we don't get significant time or extra resources for our medical staff to fulfill our educational tasks, including teaching and mentoring the medical students.

QUEST, LABCORP REBUFF CLASS-ACTION SUITS ON PRICING

Quest Diagnostics and LabCorp are each seeking to have separate class-action lawsuits filed against them dismissed, arguing that it is perfectly legal to charge different prices to different customers. Both lawsuits were filed by the law firm Wolf Popper LLP (New York City), which specializes in class-action suits. The cases are nearly identical and allege that the two big labs overcharged patients for lab tests that their health insurance plans did not cover (see *LE*, May 2017). Wolf Popper is seeking class action certification for each case and recoupment of alleged overpayments by consumers and punitive damages.

In both cases, Quest and LabCorp note that the plaintiffs don't claim they were charged for tests they didn't perform or question the quality of the test results.

In its response, Quest argues that "The fact that patients with insurance pay less than those without is widely known, and certainly not unique to the clinical laboratory industry." Quest noted that it accepts less than its full charge from health insurers because of their significant negotiating power due to their size and ability to ensure prompt payment. LabCorp's response noted that "differential pricing" is a "nearly universal practice" in many industries, including car dealerships, hotels and airlines, and is not illegal.

The suits claim that Quest and LabCorp charge individuals full list prices, or "rack rates," for tests that are frequently more than 10 times greater than the prices paid by Medicare and private health insurers. Plaintiffs assert that they should be entitled to pay the same prices as insurers, or what they deem "fair market value" prices.

However, the big labs contend that this is an inaccurate definition of fair-market value rates because it does not take into account the benefits provided by health insurers (volume and prompt payment). "Precedent legal decisions have concluded that courts are ill-equipped to sit as rate regulators and rule on the 'fairness' of charges for healthcare services," according to Quest's response.

Quest is being represented by Gibbons PC (Newark, NJ) and Sidley Austin LLP (Chicago, IL). LabCorp's law firms are Jones Day (New York City) and Parker Poe (Charlotte, NC).

ADVAMED ISSUES PLAN FOR DEMONSTRATING VALUE IN DIAGNOSTICS

The Advanced Medical Technology Association (AdvaMed) has released a report aimed at helping diagnostic test manufacturers communicate the value of their products to different groups in the healthcare system. The report, entitled *A Framework for Comprehensive Assessment of the Value of Diagnostic Tests*, comes just months before CMS is scheduled to realign Medicare's Clinical Lab Fee Schedule with private-payer rates. This shift could slash average Medicare reimbursement for lab tests by as much as 30% over the next three years, 2018-2020.

"The core challenge is that the value of a diagnostic test or technology lies in the value of the information generated by the test, which is dependent on whether and how that information is used in a multitude of decision pathways to inform and influence care," according to the report.

The report suggests that value metrics for measuring clinical utility of a diagnostic test may include:

- % changed clinician decisions post-implementation of diagnostic vs. prior.
- The resulting difference in endpoints or outcomes from a changed clinical decision (i.e., reduced number of repeat procedures, response to treatment, or best treatment selected initially).

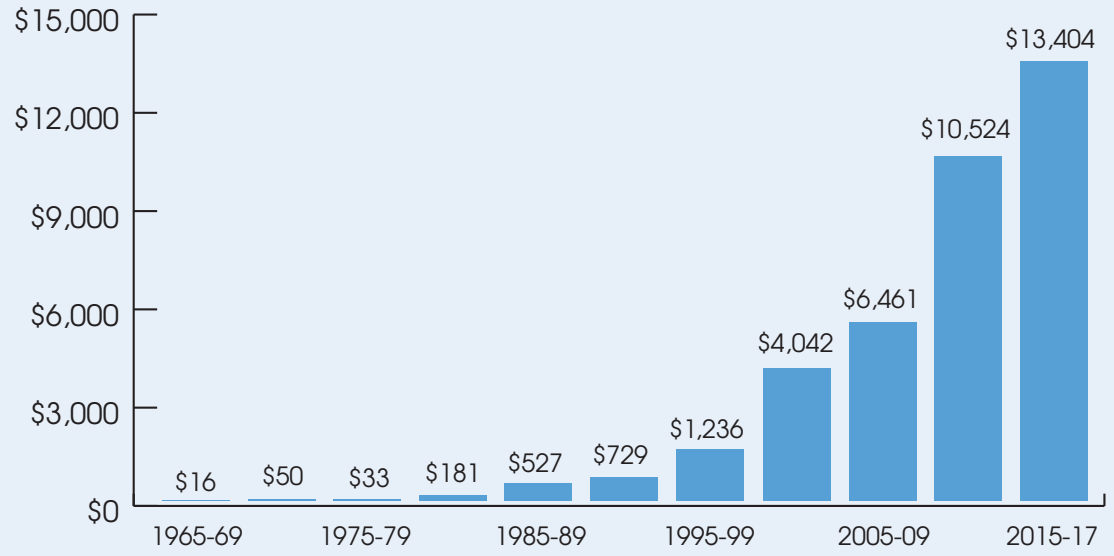
In an effort to illustrate how value metrics could be used in the real world, AdvaMed also published several case studies of medical technologies and diagnostics. One example involved Abbott Molecular's Vysis ALK Break Apart FISH Probe Kit, which is used to identify the ~5% of non-small cell lung cancer patients with an ALK rearrangement who would benefit from treatment with the targeted drug Xalkori (*crizotinib*).

Although not its intent, this case study illustrates the gross imbalance between the cost of oncology drugs and the reimbursement received by labs for related testing, observes *Laboratory Economics*.

Xalkori costs approximately $10,000 a month in the United States, or $120,000 for patients who take it for a year. This compares with the relatively trivial $150-$300 that labs are reimbursed to perform ALK rearrangement FISH testing.

New cancer drugs being introduced in the U.S. today now cost an average of more than $13,000 per month, or $156,000 a year. Pricing for new cancer drugs has risen by an average of approximately 13% annually over the past 50 years, according to data from the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center.

Median Monthly Price for New U.S. Cancer Drugs (per 5-year period)



Source:Peter B. Bach, MD, Director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center. Data was updated by *Laboratory Economics* to include pricing information for new drugs cleared by FDA so far in 2017

FBI RAIDS PROOVE BIOSCIENCES OFFICES IN FRAUD INVESTIGATION

FBI agents and officers from the Inspector General's Office of the Department of Health and Human Services on June 14 searched the offices of Proove Biosciences (Irvine, CA), and took away boxes of documents. In a press conference, FBI spokeswoman Cathy Kramer said the raid was part of an ongoing investigation concerning healthcare fraud. No arrests were made.

Proove markets a laboratory-developed test under the brand name The Proove Opioid Risk Profile. The test involves analyzing the cytochrome P450 and other genes from cheek-swab samples to gauge whether patients are at risk of becoming addicted to opioids. Proove claims its test can predict, with 93% accuracy, which patients will become addicted to or misuse prescribed opioid pain pills.

Proove has come under scrutiny for paying doctors to enlist patients into clinical trials of its tests. A marketing brochure from Proove shows the company offered to pay doctors $30 for every patient they enrolled in a study.

Proove says that it reimburses "participating investigators" (i.e., ordering physicians) only for the time they spend providing research services and that no payment is tied to the number of tests ordered. Proove says that it paid study investigators an average of $6,400 in 2016, or approximately $550 per month.

A *Laboratory Economics'* analysis of Medicare Part B data shows that Proove is by far the top biller of CPT 87150 (Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed). In 2015, Medicare paid Proove for 101,264 units of CPT 87150, or an average of 12 units per Medicare beneficiary served.

Top 10 Labs for Medicare Part B Allowed Volume for CPT 87150 in 2015

Lab Name	City	Allowed Services	Number of Medicare Beneficiaries	Average Services Per Beneficiary	Average Medicare Allowed Amount	Total Allowed Payment	Average Payment Per Beneficiary
Proove Medical Labs	Irvine, CA	101,264	8,427	12	$46.99	$4,758,375	$564.66
LabCorp	Burlington, NC	394	382	1	$34.74	$13,688	$35.83
LabCorp	Birmingham, AL	220	216	1	$30.68	$6,750	$31.25
LabCorp	Raritan, NJ	172	170	1	$47.76	$8,215	$48.32
LabCorp	Dublin, OH	168	164	1	$47.76	$8,024	$48.92
Mayo Clinic	Rochester, MN	157	61	3	$47.76	$7,498	$122.92
LabCorp	San Diego, CA	133	123	1	$47.76	$6,352	$51.64
PAML	Spokane, WA	127	13	10	$47.76	$6,066	$466.58
Galaxy Diagnostics	Morrisville, NC	123	48	3	$33.38	$4,106	$85.54
LabCorp	Dallas, TX	97	96	1	$47.76	$4,633	$48.26

Source: *Laboratory Economics* from CMS

LAB STOCKS UP 36% YTD

Sixteen lab stocks have risen by an unweighted average of 36% year to date through June 14. In comparison, the S&P 500 Index is up 9%. The top-performing lab stocks so far this year are Cancer Genetics, up 174%; Exact Sciences, up 140%; and Foundation Medicine, up 127%. At the two largest public labs, LabCorp is up 10% and Quest Diagnostics is up 17%.

Company (ticker)	Stock Price 6/14/17	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	3.70	1.35	174%	73	NA	2.6	3.5
CombiMatrix (CBMX)	5.00	2.65	89%	15	NA	1.1	2.4
Enzo Biochem (ENZ)	10.61	6.94	53%	491	14.9	4.6	5.6
Exact Sciences (EXAS)	32.09	13.36	140%	3,570	NA	26.9	11.5
Foundation Medicine (FMI)	40.15	17.70	127%	1,430	NA	12.5	11.3
Genomic Health (GHDX)	32.11	29.39	9%	1,103	NA	3.3	6.8
Invitae (NVTA)	9.46	7.94	19%	400	NA	12.7	4.9
LabCorp (LH)	141.11	128.38	10%	14,440	19.4	1.5	2.6
Myriad Genetics (MYGN)	23.04	16.67	38%	1,570	49.2	2.1	2.1
NeoGenomics (NEO)	8.11	8.57	-5%	643	NA	2.6	3.8
Opko Health (OPK)	6.52	9.30	-30%	3,650	NA	3.0	1.7
Psychemedics (PMD)	22.03	24.99	-12%	120	14.8	2.8	7.3
Quest Diagnostics (DGX)	107.23	91.90	17%	14,670	21.9	1.9	3.2
Rosetta Genomics (ROSG)	1.94	5.04	-62%	5	NA	0.5	0.8
Sonic Healthcare (SHL.AX)	24.08	21.40	13%	10,090	21.8	2.0	2.7
Veracyte (VCYT)	7.89	7.74	2%	267	NA	3.9	5.0
Unweighted Averages			36%		23.7	5.2	4.7

Source: Capital IQ

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