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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

GOOD NEWS AND BAD NEWS IN PAMA FINAL RULE FOR REPRICING LAB TESTS

On June 17, CMS released the Final Rule for resetting reimbursement rates for lab tests paid through the clinical laboratory fee schedule (CLFS) as set forth under the Patient Access to Medicare Act (PAMA).

First the good news, CMS has pushed back the date that the revised Medicare payment rates will take effect to January 1, 2018 (versus the Proposed Rule's effective date of January 1, 2017).

The bad news is that although the Final Rule revised the definition of "applicable labs" that must report their private-payer payment rates, it still leaves out nearly all hospital-based labs from reporting. This means that the private-payer payment data submitted to CMS will be skewed toward data from the nation's biggest lab companies. As a result, Medicare rates for most clinical lab tests may decrease by as much as 10% in 2018. *More details on pages 5-8.*

UNITEDHEALTHCARE CONSTRUCTS NEW HURDLE TO DISCOURAGE OUT-OF-NETWORK LABS

Beginning September 1, 2016, UnitedHealthcare network physicians in Delaware, Massachusetts, New Hampshire, New York, Oklahoma, Pennsylvania, and Texas will be required to obtain written consent from UHC members before referring them to an out-of-network laboratory or pathologist.

"While this may appear like UnitedHealthcare is promoting patient responsibility, it looks more like another method to ration care by placing time-consuming obstacles in the path of the provider," notes Deb Larson, Executive Vice President at the lab billing firm TELCOR Inc. (Lincoln, NE). She says it's the first time she's seen this type of strategy to discourage out-of-network utilization. "More focus needs to be on improving network coverage and allowing more pathologists and laboratories to be in-network," adds Larson. *More details on Page 4.*

PROPOSED MEDICARE PFS SLAMS 88305-TC

The Proposed Medicare Physician Fee Schedule for 2017 includes a 15% cut to the technical component for CPT 88305, which, if finalized, would lower it to $29.34. The proposed rate for the professional interpretation for CPT 88305 is flat at $39.71. In a nutshell, the Proposed MPFS for 2017 includes some significant cuts to technical reimbursement for several key pathology codes, while proposed reimbursement for most professional services is little changed. CMS is accepting comments on the Proposed MPFS through September 6, 2016. Final rates are expected to be announced in October and become effective January 1, 2017. *Continued on page 2.*

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PROPOSED MEDICARE PFS SLAMS 88305-TC (*cont'd from page 1*)

CMS says the proposed 15% reduction to CPT 88305-TC relates to an update that reflects reduced costs for eosin stain supplies. For similar reasons, CMS has proposed significant TC rate reductions for 16 other pathology codes, including CPT 88302, 88304, 88307, 88309, 88323, 88325, 88364, 88365, 88366, 88367, 88368, 88369, 88373, 88374, 88377 and G0416.

Among other significant proposed changes are 19% reductions for the flow cytometry codes CPT 88184, 88185 and 88189. Further significant reductions to flow cytometry are expected in 2018 as well.

On the positive side, global reimbursement for digital pathology (CPT 88361) has a proposed hike of 4% to $155.98, including a 1% increase to $61.18 for the professional interpretation and a 7% increase to $94.80 for the technical component.

Proposed Medicare Rate Changes for Key Pathology Codes

CPT Code	Description	Proposed 2017*	Actual 2016**	Proposed% Change
88112-Global	Cytopath cell enhance tech	68.33	72.32	-6%
88112-26	Cytopath cell enhance tech	28.98	29.00	0%
88112-TC	Cytopath cell enhance tech	39.35	43.32	-9%
88184-TC only	Flow cytometry/1st marker	61.53	76.26	-19%
88185-TC only	Flow cytometry/each add'l marker	37.56	46.55	-19%
88189-TC only	Flow cytometry, read 16+	92.30	114.22	-19%
88305-Global	Tissue exam by pathologist	69.05	74.11	-7%
88305-26	Tissue exam by pathologist	39.71	39.74	0%
88305-TC	Tissue exam by pathologist	29.34	34.37	-15%
88307-Global	Level V, tissue exam by pathologist	269.03	312.21	-14%
88307-26	Level V, tissue exam by pathologist	87.65	87.36	0%
88307-TC	Level V, tissue exam by pathologist	181.38	224.85	-19%
88312-Global	Special stains, group 1	98.74	98.82	0%
88312-26	Special stains, group 1	28.26	28.29	0%
88312-TC	Special stains, group 1	70.48	70.53	0%
88313-Global	Special stains; group 2	70.12	69.10	1%
88313-26	Special stains; group 2	12.52	12.53	0%
88313-TC	Special stains; group 2	57.60	56.57	2%
88341-Global	Immunohistochemistry (Add'l stain)	90.15	90.23	0%
88341-26	Immunohistochemistry (Add'l stain)	28.26	27.93	1%
88341-TC	Immunohistochemistry (Add'l stain)	61.89	62.30	-1%
88342-Global	Immunohistochemistry (1st stain)	107.68	107.41	0%
88342-26	Immunohistochemistry (1st stain)	37.21	37.24	0%
88342-TC	Immunohistochemistry (1st stain)	70.48	70.18	0%
88361-Global	Tumor immunohistochem/computer	155.98	149.66	4%
88361-26	Tumor immunohistochem/computer	61.18	60.87	1%
88361-TC	Tumor immunohistochem/computer	94.80	88.79	7%
G0416-Global	Prostate Biopsy, any method	488.33	534.20	-9%
G0416-26	Prostate Biopsy, any method	184.96	157.90	17%
G0416-TC	Prostate Biopsy, any method	303.37	376.30	-19%

*Proposed conversion factor for 2017 is 35.7751

**Conversion factor for 2016 is 35.8043

Source: Proposed Medicare Physician Fee Schedule 2017

CALIFORNIA'S MEDI-CAL CUTS LAB RATES AGAIN

For the second year, California's Medicaid program, known as Medi-Cal, has cut clinical lab and anatomic pathology reimbursement rates based on private-payer payment data collected from labs. The new rates, which became effective July 1, 2016, include an average cut of roughly 1-2% for clinical lab tests and roughly 10% for anatomic pathology codes, according to an analysis by *Laboratory Economics* (see table below). A total of 252 lab test codes were reduced and no codes were increased. The new rate-setting process used by Medi-Cal bears watching because it is very similar to the process that the national Medicare program will use to revamp its Clinical Laboratory Fee Schedule, notes Kristian Foy, legal counsel for the California Clinical Laboratory Association.

Among the Medi-Cal cuts is an 11.5% decrease to CPT 88305, lowering it to global rate of $40.99 effective July 1, 2016. Reimbursement for digital pathology (CPT 88361) also took a big hit—a 15.9% reduction to a global rate of only $80.16.

Medi-Cal now pays clinical lab tests at approximately 60% to 65% of Medicare rates, while the anatomic pathology codes are paid at roughly 50% to 60%. These rates apply to approximately three million Medi-Cal recipients enrolled in fee-for-service (FFS) plans.

Medi-Cal Lab Test Rate Comparison

CPT/Description	Medi-Cal New Rates July 1, 2016	Medi-Cal Old Rates July 1, 2015	Percent Change	National Medicare Rates Jan 1, 2016	Medi-Cal as Percent of Medicare
80048/Basic Metabolic Panel	$7.27	$7.41	-1.9%	$11.52	63%
80061/Lipid Panel	11.54	11.63	-0.8%	18.24	63%
80299/Quantitative Assay Drug	12.59	12.66	-0.6%	18.66	67%
81001/Urinalysis	2.77	2.84	-2.5%	4.32	64%
83036/A1C	8.54	8.65	-1.3%	13.22	65%
84153/Total PSA	16.47	16.51	-0.2%	25.06	66%
84403/Testosterone	22.80	23.16	-1.6%	35.17	65%
84443/TSH	14.76	14.95	-1.3%	22.89	64%
85027/CBC	5.71	5.74	-0.5%	8.81	65%
85610/Prothrombin Time	3.49	3.53	-1.1%	5.36	65%
86141/HS CRP	11.19	11.69	-4.3%	17.63	63%
87591/Gonorrhea	31.07	31.47	-1.3%	47.80	65%
88175/Liquid Pap	23.50	24.34	-3.5%	36.09	65%
88304/Global-Tissue Exam	30.48	31.06	-1.9%	46.19	66%
88305/Global-Tissue Exam	40.99	46.34	-11.5%	74.11	55%
88313/Global-Special Stains	38.56	40.84	-5.6%	69.10	56%
88331/Global-Path Consult	44.52	51.65	-13.8%	97.03	46%
88361/Global-Digital Pathology	80.16	95.37	-15.9%	149.66	54%
88346/Global-Immunofluor Study	56.05	59.67	-6.1%	93.81	60%
88300/Global-Surgical Path gross	8.37	8.79	-4.8%	15.40	54%
Averages			-4.0%		62%

Source: *Laboratory Economics* from California DHCS and CMS

Overall, the Medi-Cal program spent approximately $220 million on FFS lab tests (clinical lab and pathology tests) in the fiscal year ended June 30, 2016. The new rate-setting method is saving Medi-Cal an estimated $18 million annually, according to Katharine Weir, Information Officer for the California Department of Health Care Services.

In addition, Foy says that the process of collecting private-payer data and submitting it to the California Department of Health Care Services (DHCS) was very difficult and time consuming for labs.

Under California law (AB 1494) any lab provider, including hospital-based labs, with annual Medi-Cal lab test claims totaling $100,000 or more, or claims volume of 5,000 or more, is required to submit its private-payer data each year to DHCS. However, most labs lack the staff and computer capabilities needed to collect and organize the data required by DHCS, notes Foy.

There are roughly 17,500 clinical laboratory providers serving Medi-Cal and approximately 750 labs met one or both of the thresholds requiring them to submit data, according to Weir. She says that for the latest data collection period ending March 18, 2016, DHCS received data from only 56 labs. But Weir says that the labs that did submit data represent a majority of the total Medi-Cal FFS claims for lab tests.

Finally, Foy notes that although the new rates became effective July 1, 2016, they have not yet been installed in the Medi-Cal FFS payment system. DHCS estimates that the payment system update will occur sometime in September 2016. This means that labs will continue to be paid the old Med-Cal rates for the period of July 1, 2016 up to the date of the expected payment system update in September. Labs will then be required to make Erroneous Payment Corrections (EPC) and pay back Medi-Cal for retroactive rate adjustments for the period of July through September. This has added another layer of cost and complexity for labs serving Medi-Cal FFS patients, explains Foy.

UNITEDHEALTHCARE CONSTRUCTS NEW HURDLE (*cont'd from page 1*)
The new UHC policy covers specimens collected in-office and sent to an out-of-network laboratory or pathologist; and providing a member with a prescription, requisition or other form to obtain laboratory or pathology services. UHC announced the new protocol in a bulletin issued to its participating physicians in late May/early June. The bulletin states:

Prior to any referral to, or the inclusion of, a non-network laboratory or pathologist in a UnitedHealthcare member's care, you must:

- Discuss network and non-network care provider options with them and provide them with a copy of UnitedHealthcare's Laboratory and Pathology Services Consent Form. This form is separate from the Member Advance Notice Form for Involvement of a Non-participating Provider.
- After the discussion, the member must complete the Laboratory and Pathology Services Consent Form indicating whether they wish to use a network or non-network laboratory or pathologist.
    - If the member indicates on the consent form that they choose to use a non-network laboratory or pathologist, then:
        - If the member has non-network benefits, the non-network laboratory/pathology claim will be paid according to their non-network benefits and any non-network cost shares will apply.
        - If the member does not have non-network benefits, they will be responsible for the full cost of the non-network laboratory/pathology services.

In conjunction with the new policy, UHC also sent a letter to its members warning them: "When you go outside the network, you'll likely end up paying more for the same services. Sometimes lots more. In fact, if your plan doesn't cover out-of-network services, you could owe the entire cost!"

The letter then lists a number of lab companies that are in-network with UHC, including LabCorp, Quest's AmeriPath, ARUP Labs, BioReference Labs, et al. Interestingly, Theranos is also

listed as a national in-network lab for UHC. And that's got to be exasperating to the many reputable independent labs and pathology groups that have been kicked out of the UHC network over the past few years, notes *Laboratory Economics*.

GOOD NEWS AND BAD NEWS IN PAMA FINAL RULE (*cont'd from p. 1*)
The Final Rule states that "applicable labs" must collect their private-payer payment data from the six-month period January 1 to June 30, 2016 and report it to CMS by March 31, 2017. CMS will use the weighted median of these reimbursements to set fees for these services provided to Medicare patients effective with the 2018 CLFS.

CMS defines an applicable laboratory as a lab that receives more than 50% of its total Medicare revenue from payments made under the Medicare CLFS and Physician Fee Schedule based upon its National Provider Identifier (NPI). Furthermore, the Final Rule states that labs that receive less than $12,500 under the CLFS during a six-month data collection period are excluded from reporting.

The problem is that the overwhelming majority of hospital-based labs do not have their own NPI. Instead they bill for their services through the main hospital's NPI. As a result, nearly all hospital-based labs do not fall under the definition of an applicable laboratory and will not be required to report their private-payer payment data. That's a problem because hospital-based lab test rates are generally much higher than those at the national labs. The consulting firm Avalere, for example, published a study based on 2012 rates that showed that hospital lab rates for private insurance companies were 176% higher than Medicare.

Laboratory Economics searched the Medicare Part B provider utilization database and found that only a few dozen of the nation's largest hospital-owned laboratories have their own NPIs. These labs tend to operate like independent labs and several have either been acquired or partnered with Quest Diagnostics or LabCorp (see table on page 7). These labs will need to report their pricing data to CMS. However, their private-payer fee schedules are probably not too much different than those at the nation's largest lab companies.

"Under the final rule, CMS violates the statute, announcing plans to conduct only a limited market assessment, excluding a large percentage of laboratories, including hospital laboratories, and basing its rates off a purposefully skewed data assessment," according to Marc Birenbaum, PhD, Administrator for the National Independent Laboratory Assn. "The largest players in the laboratory market—the two national publicly-traded laboratories—will drive the test volumes, and their rates will dominate CMS's evaluation."

"The PAMA repricing process is just another form of competitive bidding but under a different moniker," adds Julie S. Allen, Senior Vice President at Drinker Biddle & Reath LLP and the Washington representative for NILA. She believes CMS has deliberately excluded higher-paid hospital labs to secure more savings for Medicare. "It's prime for a legal challenge and that's being explored," adds Allen.

Meanwhile, Alan Mertz, President of the American Clinical Laboratory Assn., notes that the Final Rule allows hospital outreach labs to obtain a unique NPI (separate from the hospital) to become an "applicable lab" so they can report their private-payer payment data to CMS. "I can't overemphasize the importance of hospital labs getting their own NPI so they get included in CMS's calculations," he told listeners on a special July 7 teleconference sponsored by *Laboratory Economics*.

But most hospital administrators may be wary of getting a separate NPI for their lab given the time and complexity involved with collecting and reporting their payment rates, says Barry Portugal, President of the lab consulting firm Health Care Development Services Inc. (Nokomis, FL).

"It would be a tortuous process for most hospital billing departments and a headache most may choose to avoid."

The Final Rule states that applicable labs will need to collect, format, organize, validate and submit their private-payer fee-for-service rates for each test (after all discounts and price concessions) on the CLFS and the volume of tests paid at each rate, according to Lale White, Chief Executive of the billing firm XIFIN Inc. (San Diego).

White says that reporting labs will need to have a system in place that can capture at minimum:

- Date(s) paid
- Payer/payer type
- Number of tests for each procedure code
- Number of units billed vs. paid for each procedure code
- Amount allowed - $ paid by insurer plus patient share of cost
- Contractual rates, where applicable, including volume and other discounts
- Aggregate data in timely buckets: e.g., payments received 1/1/16 - 6/30/16

It will be an "exceptionally difficult process" given that there are some 1,000 different lab test codes on the CLFS and that even smaller independent labs contract with dozens of different private insurance plans, says White.

CMS will use the submitted private-payer data to calculate a weighted median price for each lab test code. The agency plans to release preliminary 2018 rates in September 2017, with release of final rates in November 2017. The new rates will become effective January 1, 2018, and will not be subject to any geographic adjustment or CPI inflation update.

CMS will phase in potential reimbursement reductions to each lab test code to a max 10% cut per year between 2018 and 2020. Price cuts will be capped at 15% per year between 2021 and 2023.

In the Final Rule, CMS estimates that approximately 12,400 physician office labs and 1,200 independent labs will fall into the category of applicable lab. The agency expects to collect a total of 600 million price data points from these labs.

Based on the broad assumption that Medicare pays 20% more than private payers, CMS has estimated that the average CLFS lab test code will be cut by about 6% in 2018 resulting in an approximate savings to the Medicare program of $390 million, followed by more cuts each year through 2026.

Labs expected to be hurt the most are those focused on routine clinical lab tests, including nursing home labs and smaller independent labs, according to XIFIN's White. In addition, she says that although most hospital labs will not be required to report their price data, they will have to live with the new lowered rates on the Part B CLFS. And this may accelerate the trend for hospitals to sell their lab outreach businesses, notes HCDSI's Portugal.

LARGE HOSPITAL-OWNED LABS AND JOINT VENTURES

LABORATORY NAME	OWNER	LOCATION	TOTAL MEDICARE ALLOWED AMOUNT, 2014
SOLSTAS LAB PARTNERS GROUP	QUEST DIAGNOSTICS	GREENSBORO, NC	$76,204,173
SONORA QUEST LABORATORIES	BANNER HEALTH AND QUEST DIAGNOSTICS	TEMPE, AZ	$49,583,583
ACL SERVICES	AURORA AND ADVOCATE	WEST ALLIS, WI	$21,995,887
NORTH SHORE LIJ HEALTH SYSTEMS LABS	NORTHWELL HEALTH	NEW HYDE PARK, NY	$15,172,576
PATHOLOGY ASSOCIATES MEDICAL LABS (PAML)	PROVIDENCE HEALTH AND CATHOLIC HEALTH	SPOKANE, WA	$14,929,075
REGIONAL MEDICAL LABORATORY	ST. JOHN HEALTH SYSTEM	TULSA, OK	$12,363,341
DIAGNOSTIC LABORATORY OF OKLAHOMA	INTEGRIS HEALTH AND QUEST DIAGNOSTICS	OKLAHOMA CITY, OK	$12,201,257
LABONE OF OHIO	QUEST DIAGNOSTICS	CINCINNATI, OH	$12,081,071
CLINICAL LABORATORY PARTNERS	QUEST DIAGNOSTICS	NEWINGTON, CT	$11,655,395
HEALTH NETWORK LABORATORIES	LEHIGH VALLEY HEALTH NETWORK	ALLENTOWN, PA	$10,886,849
MARSHFIELD CLINIC	MARSHFIELD CLINIC	MARSHFIELD, WI	$9,830,350
PEACEHEALTH	PEACEHEALTH	SPRINGFIELD, OR	$8,238,300
COMPUNET CLINICAL LABORATORIES	LOCAL HOSPITALS AND QUEST DIAGNOSTICS	MORAINE, OH	$7,920,551
MID AMERICA CLINICAL LABORATORIES	LOCAL HOSPITALS AND QUEST DIAGNOSTICS	INDIANAPOLIS, IN	$7,498,332
SUTTER VALLEY MEDICAL FOUNDATION	SUTTER VALLEY MEDICAL FOUNDATION	SACRAMENTO, CA	$7,101,116
SCRIPPS HEALTH	SCRIPPS HEALTH	SAN DIEGO, CA	$6,966,554
TRICORE REFERENCE LABORATORIES	UNIVER. OF NM HLTH AND PRESBYTERIAN HLTH	ALBUQUERQUE, NM	$6,224,172
TEXAS HEALTH PHYSICIANS GROUP	TEXAS HEALTH	DALLAS, TX	$5,748,784
MAYO CLINIC JACKSONVILLE	MAYO CLINIC	JACKSONVILLE, FL	$5,718,703
CLINICAL LABORATORIES OF HAWAII	SONIC HEALTHCARE	EWA BEACH, HI	$5,679,834
WISCONSIN DIAGNOSTIC LABORATORIES	FROEDTERT HEALTH	MILWAUKEE, WI	$5,313,486
ASSOCIATED CLINICAL LABORATORIES	LOCAL HOSPITALS AND QUEST DIAGNOSTICS	ERIE, PA	$5,127,287
COVENANT HEALTHCARE LAB	COVENANT HEALTHCARE	LAKE CITY, FL	$5,025,515
DMC UNIVERSITY LABORATORIES	DETROIT MEDICAL CENTER	DETROIT, MI	$4,722,126
CENTREX CLINICAL LABORATORIES	LABCORP	UTICA, NY	$4,685,635
UNIVERSITY HOSPITALS LABORATORY SERVICES	UNIVERSITY HOSPITALS OF CLEVELAND	CLEVELAND, OH	$4,628,728
SAINT FRANCIS OUTREACH SERVICES	SAINT FRANCIS HEALTH SYSTEM	TULSA, OK	$4,378,360
LABORATORY ALLIANCE OF CENTRAL NEW YORK	LOCAL HOSPITALS	LIVERPOOL, NY	$3,899,402
WATSON CLINIC	WATSON CLINIC	LAKELAND, FL	$3,895,725
NORDX	MAINEHEALTH	SCARBOROUGH, ME	$3,850,689

Source: CMS Part B Provider Utilization Data 2014

Special Rules for "Advanced Diagnostic Laboratory Tests"

The PAMA regulations did create special rate-setting rules for a category of tests dubbed "advanced diagnostic laboratory tests (ADLTs)." ADLTs are tests that are offered by a single laboratory and not sold for use by a laboratory other than the developing lab or successor owner. The final rule defines a "single laboratory" as the lab itself as well as other labs that own or are owned by the lab (multiple CLIA certificates).

In the proposed rule published last September, CMS had defined an ADLT as "a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)." However, in response to comments, the Final Rule expanded the definition of ADLT to include both molecular pathology and protein-only based tests.

For new ADLTs, initial payment will be based on the actual list charge of the test for three calendar quarters; thereafter, the payment rate will be determined using the weighted median of private payer rates and associated volume reported every year. For new and existing tests for which CMS receives no applicable information to calculate a weighted median, it will determine payment rates by using crosswalking or gapfilling methods.

For tests furnished during the new ADLT initial period, Medicare will pay up to 130% of the weighted median private payer rate. If the actual list charge is subsequently determined to be greater than 130% of the weighted median private payer rate, CMS will recoup the difference between the list charge and 130% of the weighted median. The data collection for a new ADLT will begin on the first day of the first full calendar quarter following either the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

QUEST TO OPEN PSCs IN 12 SAFEWAY STORES

Quest Diagnostics has signed a deal to open company-branded PSCs in 12 Safeway locations in California, Colorado, Texas, Virginia and Maryland. These 400- to 500-square-foot centers will be adjacent to Safeway's in-store pharmacies and include a waiting room and a dedicated restroom with a sample pass-through. Quest spokesman Denny Moynihan says the company will soon be announcing the specific locations within the states listed above. The sites are expected to become operational by early September.

Moynihan says the status of direct-access testing regulations did not play a role in selecting the sites to provide our PSCs in Safeway locations. He says the new Safeway PSCs will serve patients with doctor-ordered lab tests and are aimed at enhancing access and convenience. Doctors will find no changes to lab requisitions, turnaround time or electronic health records. Other than the location change, employees will not experience any changes and will find the new PSCs very similar to their current location, notes Moynihan. Drug screenings and insurance exam testing will not be offered at the Safeway PSCs.

Quest Diagnostics' deal with Safeway follows a similar arrangement that its Sonora Quest Laboratories joint venture with Banner Health struck with Safeway in Arizona in late 2015 (see *LE*, December 2015, p. 8). Sonora Quest has been operating PSCs at two Safeway stores (Scottsdale and Phoenix, AZ) for the past six months. These PSCs provide service to patients with or without a physician order.

"We continue to be encouraged by the volume growth and positive feedback from patients in both locations," says Christina Noble, Vice President, Business Development at Sonora Quest. She says that that lab tests for wellness profiles and the monitoring of chronic disease have been most popular at the two Safeway locations.

THERANOS CEO BANNED FROM OPERATING LAB FOR TWO YEARS

CMS has revoked CLIA certification for Theranos' lab in Newark, California, and banned the company's CEO Elizabeth Holmes from owning or operating a laboratory for at least two years. In a July 7 letter to Theranos imposing the sanctions, CMS said the company continued to put patients in "immediate jeopardy," had provided conflicting information about when it stopped using its proprietary blood-testing system last summer, and kept inconsistent records of patient test results it voided or corrected.

The sanctions will take effect starting September 5, although Theranos could appeal CMS's decision. However, the company has indicated that it may simply shut down both its labs in California and Arizona, keep Holmes as CEO, and focus on development of its instrument system.

Theranos also faces eight consumer lawsuits seeking class action status and is under investigation by the Securities and Exchange Commission and the U.S. attorney's office in San Francisco.

CHINA'S NINGBO TO BUY ATHEROTECH FOR $19.6 MILLION

Ningbo Medical System Biotechnology Company, a Chinese manufacturer of IVD reagents and lab instruments, has agreed to purchase Atherotech Inc. (Birmingham, AL) out of bankruptcy for $19.6 million. A hearing will be held in late August where the bankruptcy court is expected to approve the transaction. Ningbo says it will use the Atherotech lab as a platform for expansion into the U.S. lab market. At its peak in 2014, Atherotech recorded over $100 million of revenue (see *Laboratory Economics*, May 2016, p. 1).

MAC FINDS HIGH ERROR RATE IN DRUG TESTING BILLING

Clinical laboratories in Iowa, Kansas, Missouri and Nebraska are not doing a great job in billing accurately for qualitative drug testing, concludes a recent WPS Government Health Administrators analysis of Comprehensive Error Rate Testing (CERT). WPS is the Medicare Part B administrative contractor for the J5 region.

The analysis found a high error rate and significant projected improper payment for numerous qualitative drug tests and quantitation of drugs screened (therapeutic drug assays and certain chemistry tests). The majority of the findings are due to lack of a valid physician order or documentation of intent and/or missing documentation to support the medical necessity of the services billed.

Medicare requires a valid physician order or progress note that supports physician intent and documentation to support medical necessity for diagnostic services to be considered for payment. WPS notes that it is the billing providers' responsibility to be aware of these requirements and to obtain the required supporting documentation in response to a Medicare contractor's request for a claim review.

"WPS Medicare closely monitors CERT error findings in our jurisdiction," states the MAC. "Providers with repeated error findings may be the subject of additional review or educational contacts by WPS Medicare for implementation of corrective action or may be referred to other CMS affiliated contractors."

The Centers for Medicare and Medicaid Services uses the CERT program to calculate the Medicare fee-for-service improper payment rate. The fiscal year 2015 Medicare FFS program improper payment rate was 12.1%, representing $43.3 billion in improper payments, according to the agency. While inpatient hospitals had a relatively low improper payment rate of 6.2% and durable

medical equipment providers had a high error rate of 39.9%, physicians/labs/ambulance had a moderate error rate of 12.7% ($11.5 billion).

Charles Root, president of CodeMap (Schaumburg, IL) tells *Laboratory Economics* that the issue of inaccurate billing for drug testing has been on the government's radar for some time and was the driving force behind development of the new G codes used by Medicare. "G codes were designed to curb the number of drug tests ordered, and they have really cut down on drug testing overall," says Root. "Plus, reimbursement has been cut, so there is little incentive to do as many tests."

HIGH COURT RULING OPENS DOOR FOR MORE FALSE CLAIMS CASES

A recent Supreme Court ruling upholding the legal theory of "implied certification" could open the door for more False Claims Act (FCA) cases to be brought and additional bases for liability to be asserted against healthcare providers, including clinical and anatomic pathology laboratories.

In a ruling issued June 16, the Supreme Court determined that in certain circumstances, the implied false certification theory can be a basis for FCA liability. Under the implied certification theory, a defendant may violate the FCA if it submits an otherwise proper claim for payment but nevertheless fails "to disclose noncompliance with material statutory, regulatory or contractual requirements."

Historically, courts have been reluctant to adopt the theory, concluding that it expands the FCA beyond its statutory terms. However, in agreeing to hear the case, *Universal Health Services Inc. v. ex rel. Escobar*, the Supreme Court agreed to resolve whether the implied-certification theory is viable and, if so, whether liability should be limited to situations where the violation affects an "express" condition of payment.

In the *Universal Health Services* case, the parents of a patient who died from a seizure at a mental health clinic sued the owner-operator of the clinic, Universal Health Services Inc. The parents alleged the clinic was unlicensed and out of compliance with state regulations requiring supervision. They argued the clinic implied compliance with these requirements as a condition of payment every time it submitted a claim for Medicaid reimbursement. As a result, the parents alleged, the clinic had been defrauding Medicaid for years.

While the court upheld the FCA theory of implied certification and rejected the bright-line rule that only an "express condition of payment" can provide the basis for liability, it did impose some restrictions on the application of the standard. The court ruled that "what matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision."

Thus, although the Court's ruling does not change the FCA intent standard, that a provider must act "knowingly" to violate the FCA (with either actual knowledge or "deliberate ignorance" or "reckless indifference" of "the truth or falsity of the information"), the court explained that a provider must have "actual knowledge" that it is material to the federal government's payment decision. Although the court did not specify how providers might know that a rule or regulation is material, it directed providers to consider whether the government has previously denied claims on that basis.

David Gee, an attorney with Davis Wright Tremaine (Seattle), tells *Laboratory Economics* that the Supreme Court ruling could lead those looking to file FCA lawsuits against clinical laboratories—especially whistleblowers—to more closely examine the accuracy of information submitted in support of their CLIA certification to see if there are errors or omissions that may be material to the government's payment determination.

"Given that this precedent is not specific to clinical and pathology labs, I can imagine a sophisticated qui tam relator might consider implied certification as a possibility," he says. "Labs should make sure the information on their CLIA certificate which may be material to government payment is accurate and up-to-date, including the testing procedures and subspecialties the lab is certified to perform. Make sure the information you file is timely and accurate--and be careful to dot your I's and cross your T's."

DAVIDSON AND CLARK RESPOND TO DARK LAWSUIT

Leslie Davidson and Justin Clark, owners of Pathology Webinars Inc., have each filed a response to a breach-of-contract lawsuit filed against them by Publisher Robert Michel's Dark Intelligence Group (see *LE*, June 2016, p. 1).

"This suit is an attempt to monopolize the business of providing webinars to pathologists and lab technicians," according to Davidson's response. Davidson had contracted with The Dark Intelligence Group (TDIG) during 2008 through 2012 to help produce audio conferences and webinars. However, none of her contracts with TDIG had non-competition clauses, according to Davidson. Furthermore, Davidson contends that since she does not live or work in Texas, TDIG has not met its initial burden to plead a Texas court's jurisdiction over her. She is seeking to have all TDIG's claims against her dismissed.

In Clark's separate response, he contends that TDIG's lawsuit is insufficiently specific when, for example, it purports to state a claim for "misappropriation of proprietary information" and alleges that Clark "wrongly appropriated TDIG's trade secrets, trade dress, and other proprietary information." Clark had been employed by TDIG from June 2008 through May 2012 where he, among other things, worked on TDIG webinars. Clark has asked the court to dismiss all TDIG's claims and award him reimbursement for his attorneys' fees.

TDIG's lawsuit (case no. D-1-GN-16-001965) was filed on May 6 in District Court of Travis County, Texas. It is seeking a permanent injunction to stop Clark and Davidson from offering webinars in the clinical laboratory and anatomic pathology space. With neither side backing down, the case is now headed toward the discovery phase.

What Happened to The PathologyBlawg?

After several years of critical reporting on the clinical lab and pathology business, The PathologyBlawg mysteriously and abruptly ceased publication in late 2015 (see *LE*, November 2015, p. 10). The TDIG lawsuit and responses from Davidson and Clark have helped shed some light on what happened next to The PathologyBlawg.

First, Davidson began managing webinars for The PathologyBlawg in 2013. She then partnered with Clark to form Pathology Webinars Inc. in 2015. After the PathologyBlawg ceased publication, Pathology Webinars Inc. purchased The PathologyBlawg's email database in early 2016 for an undisclosed sum. They also agreed to pay the owner of The PathologyBlawg, an anonymous young pathologist from Missouri, 10% of the revenue derived from their webinars each month starting February 2016. Neither The PathologyBlawg nor its former pathologist-owner are being sued by TDIG.

CORRECTION

An article in the June 2016 of *Laboratory Economics* incorrectly listed the CPT codes that will be subject to prior authorization by Highmark. Codes that will require pre-authorization under Highmark's contract with eviCore include molecular pathology tests (81161-81479) and multianalyte assays with algorithmic analyses (81490-81599, 001M-0010M). Molecular cytopathology procedures, cytogenetics and molecular pathology procedures will not be subject to pre-authorization. Highmark announced June 27 that it would delay implementation of the prior authorization program for those molecular and genomic tests when performed in an outpatient setting. The program, initially slated to start July 1, will now begin August 1, 2016.

LAB STOCKS DOWN 1% YTD

Sixteen lab stocks have declined by an unweighted average of 1% year to date through July 14. In comparison, the S&P 500 Index is up 3.8%. The top-performing lab stocks so far this year are Enzo Biochem, up 41%, Exact Sciences, up 39%, and Psychemedics, up 39%. Among the two biggest national labs, LabCorp is up 10% and Quest Diagnostics is up 17%.

Company (ticker)	Stock Price 7/14/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.06	$3.30	-38%	$33	NA	1.7	1.0
CombiMatrix (CBMX)	3.26	10.95	-70%	4	NA	0.4	0.4
Enzo Biochem (ENZ)	6.36	4.50	41%	294	16.7	2.9	5.5
Exact Sciences (EXAS)	12.81	9.23	39%	1,250	NA	25.0	4.3
Foundation Medicine (FMI)	21.77	21.06	3%	753	NA	7.2	3.1
Genomic Health (GHDX)	27.50	35.20	-22%	908	NA	3.0	6.6
Invitae (NVTA)	8.35	8.21	2%	267	NA	24.0	2.3
LabCorp (LH)	136.32	123.64	10%	13,960	23.7	1.6	2.7
Myriad Genetics (MYGN)	31.15	43.16	-28%	2,190	21.0	2.9	2.9
NeoGenomics (NEO)	9.22	7.87	17%	711	NA	5.2	3.5
Opko Health (OPK)	9.85	10.05	-2%	5,390	67.5	7.2	2.7
Psychemedics (PMD)	14.07	10.14	39%	76	63.0	2.8	6.9
Quest Diagnostics (DGX)	83.56	71.14	17%	11,820	16.2	1.6	2.5
Rosetta Genomics (ROSG)	1.09	1.23	-11%	23	NA	2.2	1.4
Sonic Healthcare (SHL.AX)	21.81	17.87	22%	9,050	24.6	2.0	2.5
Veracyte (VCYT)	5.11	7.20	-29%	142	NA	2.8	3.3
Unweighted Averages			-1%		33.2	5.8	3.2

Source: Capital IQ

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