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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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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.