Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT®

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com

Vol. 12, Iss. 12, November 7, 2012

HIGHLIGHTS

Upcoming Conferences

Lab Leaders' Summit
Nov. 14, 2012
Union League Club of New York
New York City
www.lableaderssummit.com

Laboratory Investment Forum 2012
Give and Take in the Laboratory Market: Political and Market Forces Shaping the Investment Climate
Nov. 15, 2012
Bloomberg Tower
New York City
www.labinvestmentforum.com

Volume to Value
Redefining Lab Services in a Changing Market
Feb. 25-27, 2013
Westin Beach Resort & Spa
Fort Lauderdale, Fla.
www.g2labvalue.com

www.G2Intelligence.com

CMS Places New Molecular Codes on CLFS, Supports Gap-Fill, Cuts Surgical Pathology Payments

After months of waiting and suspense, the Centers for Medicare and Medicaid Services (CMS) has weighed in on the fate of scores of new molecular pathology test codes, and it appears the laboratory sector has gotten a substantial amount of what it had desired.

The 101 new molecular pathology test codes will be placed and priced on the clinical laboratory fee schedule (CLFS) in 2013, CMS has determined. The new codes will replace the current system of "stacking" older codes in order for labs to receive reimbursement for molecular testing.

It's an outcome favored by many in the laboratory industry over the codes being placed on the physician fee schedule (PFS), which would have reduced payments to laboratories.

The agency said after reviewing comments, it believed "that the molecular pathology CPT codes describe clinical diagnostic laboratory tests that should be paid under the CLFS because these services do not ordinarily require interpretation by a physician to produce a meaningful result."

Continued on page 2

Sandy Wreaks Havoc on Health Care Providers; Bellevue Hospital in N.Y. Shuts Down Lab

The superstorm known as Sandy wreaked havoc across much of the Eastern Seaboard last week, and laboratory operations were not spared.

Power at the headquarters of the nation's largest laboratory operator, Quest Diagnostics, was out for about two days, said Gary Samuels, corporate vice president of corporate communications. Quest is headquartered in Madison, N.J., about 25 miles west of New York City. Employees who had power in their homes worked remotely during the outages.

"Several of our facilities lost power, but it has all been restored," Samuels told *Laboratory Industry Report* on the morning of Nov. 2. That included lab facilities in Teterboro, N.J., and Syosset, N.Y. The latter was closed briefly as a result.

Continued on page 6

© 2012 Kennedy Information, LLC, A Bloomberg BNA Business, 973-718-4700. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

■ CMS Places New Molecular Codes on CLFS, *from page 1*

CMS posted its decision on its Web site on the afternoon of Nov. 1. Its decision can be found at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched.*

"The decision to keep molecular diagnostic tests on the CLFS will ensure that Ph.D. geneticists can bill for the services they provide within the clinical laboratory," said Alan Mertz, president of the American Clinical Laboratory Association, which applauded the decision.

The investment community also appeared pleased with the decision. "We believe this decision is a net positive for the laboratory industry as most industry stakeholders were pushing for the CLFS," said a statement issued by Piper Jaffray shortly after the decision was announced. However, Piper officials noted the final rule "should have little impact on the independent clinical labs." William Blair & Co. issued a similar positive statement.

However the College of American Pathologists (CAP), which had advocated for placement on the PFS, was less heartened. "CAP was . . . disappointed that CMS declined our request that it place the 101 new molecular pathology codes on the physician fee schedule and cited differences of opinion within the stakeholder community about whether the new codes covered services that require a physician interpretation as the reason for placing them on the clinical lab fee schedule," said CAP Gov. Richard Friedberg, M.D., who also chairs the organization's council of government and professional affairs.

For those tests that require a physician interpretation, CMS is creating a new code for use on the PFS—G code G0452—that will be used to pay pathologists for their professional work in interpreting results. While CMS said it does not believe molecular pathology tests are ordinarily performed by physicians, it acknowledged that in some cases a physician interpretation of a molecular pathology test may be medically necessary. For this code, CMS is assigning a work relative value unit of 0.37 and five minutes of preservice time, 10 minutes of intraservice time, and five minutes of post-service time.

CMS also ruled that it would use the gap-filling methodology to price the molecular tests placed on the CLFS—in line with previous indications it would do so.

"While CAP does not agree with CLFS placement, we support the establishment of a G code to ensure that pathologists are recognized for their professional work associated with molecular pathology," Friedberg said.

Physicians can also continue to receive payment for the current clinical pathology consultation CPT codes 80500 and 80502 if the pathology consultation meets the definition of those codes.

CMS also ruled that it would use the gap-filling methodology to price the molecular tests placed on the CLFS—in line with previous indications it would do so. Under the gap-fill method, local Medicare contractors set the payment rate based on local pricing patterns.

 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business , 973-718-4700. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

88305 TC Cut Hard

In other actions, CMS cut payment on the technical component of surgical pathology code 88305 by 52 percent while increasing the professional component by 2 percent. The overall reduction will total 33 percent.

Mertz stated he was particularly concerned about this decision.

"ACLA disputes the assertion that there exists a 'typical' or 'atypical' clinical case for CPT 88305 on which to base pricing, since wide variations exist among patients and among laboratories in the types of tissue being biopsied . . . and the way specimens are handled," he said regarding the CMS's rationale behind its decision.

Medicare Payment for 88305

	2012	2013	Change
TC	$69.78	$33.70	-52.0%
PC	$36.08	$36.73	+2.0
Global	$105.86	$70.46	-33.4

Source: Centers for Medicare and Medicaid Services and William Blair & Co. estimate using 2012 conversion factor

This reduction is expected to hit pathologists especially hard as 88305 ranks as the highest-volume pathology procedure paid under Medicare Part B. CPT 88305 remains as the first and only pathology CPT code to top the $1 million mark in allowed charges for a single year.

CAP says the revaluation of the 88305 code is not surprising. As directed by the health care reform law, CMS has been focused on scrutinizing high-volume codes from all specialties as potentially overvalued services.

The final PFS also reduces Medicare payments to physicians by 26.5 percent as required under the Sustainable Growth Rate formula. However, Congress has overruled annual SGR-related reductions for nearly a decade now as the result of intense lobbying by the American Medical Association and other groups representing medical professionals. It is widely expected to nullify this payment cut as well.

Western Connecticut Health Network Expands Lab

Western Connecticut Health Network has expanded its laboratory reach by opening a satellite center in Bethel, Conn.

The center, which focuses on outpatient lab services, is the sixth in Western Connecticut's network and is serving the towns of Bethel, Danbury, and Newtown. It offers services such as phlebotomy-related draws and specimen collection. Physicians can also electronically submit or hand carry lab orders to the center.

Paul Fiedler, M.D., Western Connecticut's chairman of laboratory medicine, said the opening of the center was part of an overall plan to centralize laboratory services for Western Connecticut's two primary hospitals, Danbury Hospital and New Milford Hospital. The two facilities affiliated and created Western Connecticut Health in 2010.

In 2011, Western Connecticut affiliated with Mayo Medical Laboratories, the Mayo Clinic's reference laboratory, to improve its ability in making more challenging diagnoses. About 3 percent of its test volume is handled and analyzed by Mayo Medical.

Overall, Western Connecticut performs 2.3 million laboratory tests a year.

 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business 973-718-4700. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

Inside The Lab Industry

How to Leverage Health Plans in the Long Term

The Blues have packed up their suitcase—and they're not coming back. That's not the first line in a rare upbeat country western song, but rather a more somber message Mike Snyder delivered to a capacity audience at last month's Lab Institute 2012 in Arlington, Va.

Snyder, a principal with Clinical Lab Business Solutions, a New Jersey-based consulting firm, noted that the Blue Cross Blue Shield Association has eliminated its legendary "suitcase" symbol for interstate durable medical equipment, pharmacy, laboratory businesses.

In other words, labs can no longer bill the 39 different Blue Cross Blue Shield Association plans for lab services in one state if the specimen was drawn in another.

"It has caused massive confusion for labs operating across state lines," Snyder said. As an example, Snyder discussed a lab in Tennessee that is testing a patient whose tissue was drawn in Florida, but enrolled in a plan based in New Jersey. The claim is denied because the claims system says the patient is not a member of the plan. So the plan in New Jersey is billed instead, and that claim is rejected for being out of network. And while the lab may be entitled to payment, the specific Blues plan's claims processing system can't handle the changeover.

"We've created a mess," he said.

Tightening of Reimbursement

Such a changeover is part of an overall tightening of provider networks by the payer community, according to Snyder. It is demonstrated not only by the change in the Blues Association policy, but in cost-reducing shifts to managed care for government programs such as Medicaid and the introduction of commercial health plans with so-called "high-performance networks" that have shrunk the traditional pool of providers through means of price transparency intended to root out cost outliers.

"There is a purposeful movement of shrinking down the network," Snyder said, adding that the implementation of the Patient Protection and Affordable Care Act (ACA) and the cost-shifting over to patients are among the primary drivers for the trend.

However, employer groups have begun pushing back on the issue. "They're saying that they can't cost-shift anymore" without risking a backlash, Snyder observed.

"I have heard from labs who are getting calls from patients, actually asking how much a test is going to cost them," Snyder said with a little astonishment. The only solution left, it appears, is to ratchet down on provider reimbursements. However, it is the health plans rather than the labs that have the clout. "They're in the driver's seat right now," he said.

That is compounded by a growing allegiance on the part of payers toward national labs. Snyder noted that Aetna, one of the nation's largest health insurers, recently terminated contracts with a variety of freestanding labs—part of what is expected to be a multipart "wave" of contract cancellations. Aetna is instead throwing its business to Quest Diagnostics. More terminations are expected to follow.

 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business, 973-718-4700. All Rights Reserved. Reproduction Prohibited by Law.

And the actions by the Blues plans are also part of a larger plan to get independent labs to offer their services via a group purchasing organization—one that Quest and LabCorp have declined to participate in.

"[Payers are] trying to get you down to the lowest price, and still with no guarantee you will [get business]," Snyder said. "You're giving your best price, and they may come back and say, 'well that was your benchmark,' and make you go a little lower."

Meanwhile, LabCorp's formation of Beacon LBS to manage networks on behalf of health plans is not likely to bode well for the independents either, Snyder added."We have a lot of folks who want to be a gatekeeper to your business, but it's not good if the gatekeeper is one of your competitors," he said.

Figuring Out What Plans Want

This has put the labs in the position of trying to figure out what the health plans want. According to Snyder, labs should offer a broad menu of services, multiple geographically convenient locations, electronic interface with hospitals and physicians, electronic claims submissions, willingness to participate in closely managed networks, and a willingness to submit lab data to the health plans for analysis.

Down the line, offering price transparency for employer groups will be important. Snyder noted that participation in Web portals such as Castlight, which offer quick price checks for consumers, will be crucial.

"It's coming to you soon and will make a big difference in how you work," Snyder said.

Not every opportunity for labs is being ushered away in a suitcase. However, that means labs need to reposition themselves as providers of value and technology rather than just testing services. "We need a total solution in terms of contracting," Snyder said.

He noted that under the ACA, most plans are being capped at spending 15 percent of their premiums on their direct administration costs. That means there is an incentive to shift some services over to other parties and claim it as part of the overall cost of medical care. That includes services laboratories can provide, such as decision support for physicians and hospitals.

Another key service is utilization management—employing lab data to cut down on health care costs. Snyder said it is the "holy grail" for laboratories.

Data Is Key

But perhaps the biggest chance to wrestle the suitcase back lies in data. However, Snyder noted a lot of labs still struggle to aggregate their data in a useful manner. And he also noted that few labs communicate well with patients, seek collaborations with employers, or do something daring such as participating in demonstration projects that show results without "ginning up" utilization.

"There is a real opportunity to up our service—and get paid more if we do it right," he said.

 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business, 973-718-4700. All Rights Reserved. Reproduction Prohibited by Law.

■ **Sandy Wreaks Havoc on Health Care Providers**, *from page 1*

According to a statement issued by Quest, "we were able to maintain operations at many of our major clinical laboratories, ranging from Chantilly, Va., in the south to Cambridge, Mass., in the north, during the bulk of the storm." Backup generators were deployed when needed, according to Samuels.

The surrounding road and parking lot at another Quest administrative facility in Lyndhurst, N.J., was affected by flooding. It remained closed as of late last week.

Quest also has a variety of service centers in the Greater New York area, but Samuels was unable to immediately say if they had experienced service disruptions or damage from winds or flooding. He also declined to say if the services provided by Quest to New York-area hospitals were impacted by the storm.

"We don't talk about specific client relationships," he said.

The Quest statement noted that "during the storm, key laboratory personnel at most of our major facilities were able to transport and test specimens and deliver critical and timely diagnostic information to our customers in spite of the significant challenges they faced."

Meanwhile, two major medical centers in New York City—NYU Langone Medical Center and Bellevue Hospital Center in lower Manhattan—were forced to shut down and evacuate due to flooding and remain closed. Three other New York-area hospitals were either evacuated or closed as precautionary measures.

Although officials with NYU and Bellevue did not respond to repeated e-mail and telephone queries, it has been confirmed through other media reports that Bellevue's laboratory services were shut down as a result of the storm.

Bellevue is the site of the Carnegie Laboratory, the very first pathology laboratory in the United States when it opened in 1884.

Generators Failed

The decision to evacuate Bellevue was made after fuel pumps for its backup generators were damaged by flooding from the storm, according to information released by the New York City Health and Hospitals Corporation (NYHHC), which operates both Bellevue and Coney Island Hospital, which also shut down and was evacuated as a precautionary measure. Although Bellevue's generators are located on the 13th floor of its 25-story hospital building, their fuel pumps are located in the basement, which was flooded with about 17 million gallons of water, according to reports.

Alan Aviles, president of the NYHHC, said at a media briefing last week that Bellevue could be closed for several weeks. "Nothing has happened like this in Bellevue's 275-year history," he said.

The closure of NYU Langone's clinical laboratory could not be definitively confirmed, but its research laboratories were very heavily damaged due to flooding. Its basement, which like Bellevue houses some components of its backup generators, took upward of 8 feet of water, according to published reports.

In addition to those three hospital closures, New York Downtown Hospital and the Veterans Affairs campus in Manhattan were also evacuated, as was Palisades Medical Center in North Bergen, N.J. G2

 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business , 973-718-4700. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

Palmetto Believes MolDx Will Go National by Mid-2013

It's been both tumultuous and hopeful times for Palmetto GBA, the Columbia, S.C.-based firm that provides Medicare contracting services to the Centers for Medicare and Medicaid Services (CMS).

In September, CMS awarded the contract to handle Medicare Part A and Part B fee-for-service claims in Jurisdiction E (California, Nevada, Hawaii, and U.S. Pacific Island territories) to Noridian Administrative Services instead of Palmetto, which has had the contract for years. Palmetto is undertaking the onerous process of appealing the decision.

However, Palmetto officials firmly believe the decision will not affect another pact it has with CMS—the MolDx program. Under that contract, which is separate from its Medicare oversight contract, Palmetto is tracking the utilization of molecular diagnostic tests and setting coverage policies and reimbursement rates for Jurisdiction E (formerly Jurisdiction J1). Laboratories have to register each assay and be assigned a unique identifier, either a McKesson Z code or Palmetto code, as well as provide clinical evidence as to each test's efficacy.

Palmetto is currently operating MolDx in just Jurisdiction E, but Mike Barlow, vice president of operations for Palmetto and MolDx program manager, believes CMS will take the program national no later than mid-2013.

Barlow noted that more than 3,000 assays have already been registered under MolDx, and about 19 have been approved for payments to date based on clinical data. So far, CMS has realized savings of about 20 percent on payments for those tests as a result, according to Barlow.

Barlow compared it to the agency's 2009 decision not to cover genetic testing for sensitivity to the blood thinner warfarin. The decision was driven by data analytics, which concluded the test's $3,000 cost was too expensive and was no better than closely monitoring patients and adjusting their warfarin dosages accordingly.

PGXL Labs, Essential Molecular Testing Enter Into Partnership

PGXL Laboratories and Essential Molecular Testing Corp. have entered into a long-term partnership and have formed a distribution company called PGXL Partners. The partnership will create a new sales force channel for PGXL Laboratories' molecular tests, which focus primarily on drug sensitivity.

"We've jumped from selling hundreds of tests a month to thousands [and] this partnership gives PGXL national distribution," says PGXL President Roland Valdes Jr., who is also senior vice chair of the Department of Pathology and Laboratory Medicine at the University of Louisville in Kentucky.

The sales force will promote the test in conjunction with an interpretative report product PGXL Laboratories has developed for clinicians planning to utilize its laboratory tests.

According to a statement issued jointly by PGXL Laboratories and Molecular Testing, it expects the former to have performed 50,000 tests ordered via PGXL Partners by the end of calendar 2012.

 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business 973-718-4700. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

INDUSTRY BUZZ

Quest Begins Certifying EHR Systems

Providers picking an electronic health record (EHR) system may experience a feeling similar to confronting a Las Vegas buffet: Too much stuff and no idea where to start.

Literally scores of companies offer EHR systems, with many of them unable to communicate with other systems. That can pose a problem when trying to share records among medical groups, other hospitals—or labs.

Quest Diagnostics is trying to simplify the process—it recently certified the first batch of 20 systems under its Health IT Quality Solutions Program.

"Laboratory data provides a significant basis for health care decisions made by clinicians for patients. Yet, a lack of clear implementation and interoperability standards by which EHR systems transact and manage laboratory data hampers the ability of physicians to experience fully the capabilities of different EHR solutions," said Keith C. Drake, who oversees Quest's Health IT quality program.

According to data from the Centers for Disease Control and Prevention, 55 percent of physician practices had adopted an EHR system as of last year, spurred on in part by federal subsidies offered under the HITECH portion of the stimulus package. Among those physicians who use an EHR system, 50 percent said being alerted to a significant lab value was beneficial to their practice.

Under the program, Quest tiers EHR vendors under three categories: platinum, gold, and silver. They must meet 24 criteria to receive a silver rating and 18 more to receive gold. They include standards such as demonstrating they can process standard laboratory orders and results within Quest's Web-based data exchange network and demonstrating their systems can reduce laboratory costs. Platinum designees also work with Quest on copromotions.

Ten of the initial group of vendors each received a gold and silver designation. They included systems such as MediTouch, Emdeon Clinician, Office Ally, DocAssistant, Medgen, and SmartClinic. Drake said more vendors would receive approvals later in the year, including some platinum designees.

References

American Clinical Laboratory Association
202-637-9466

Clinical Lab Business Solutions
908-237-2807

College of American Pathologists
847-832-7000

Danbury Hospital
203-739-7000

New York City Health and Hospitals Corporation
212-639-9675

NYU Langone Medical Center
212-263-7300

Palmetto
800-633-4227

PGXL
502-569-1584

Quest Diagnostics
800-222-0446

To subscribe or renew *LIR*, call now +1-973-718-4700, 800-401-5937
(AAB and NILA members qualify for a special discount, Offer code: LIRNI1)

Online: www.G2Intelligence.com/LIR

Email: customerservice@G2Intelligence.com

Mail to: G2 Intelligence
1 Phoenix Mill Lane, Fl.3,
Peterborough, NH 03458-1467 USA

Fax: +1-603-924-4034

Multi-User/Multi-Location Pricing?
Please email jping@G2Intelligence.com or call 973-718-4703.

November 7, 2012 © 2012 Kennedy Information, LLC, A Bloomberg BNA Business, 800-401-5937. All Rights Reserved. Reproduction Prohibited by Law.

Notice: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to $150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *Laboratory Industry Report* (ISSN 1060-5118) is published by G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Tel: 800-401-5937. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Ron Shinkman, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO and Publisher

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.