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HIGHLIGHTS

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CMS Relents on Crosswalking Molecular Codes For 2016 CLFS

The feds have walked back the crosswalk.

That was the news that awaited the laboratory sector late last month, when the Centers for Medicare & Medicaid Services (CMS) released its final molecular coding rationale for 2016 as part of the Clinical Laboratory Fee Schedule (CLFS).

Earlier in the year, the CMS had proposed crosswalking many of the molecular codes to existing codes, a process that would have led to payment cuts for the tests ranging from about 30 percent to more than 90 percent.

For example, CareDx, a California-based lab that provides molecular testing to provide surgeons data on potential heart transplant patients, could have seen the Medicare payment for its AlloMap assay dropped from $2,821 to $644.

However, the laboratory sector engaged in a fairly intense lobbying effort to get CMS to reverse course, and it succeeded.

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ACLA, AHA Submit Comments to CMS Regarding PAMA Final Rules

The laboratory and hospital sector's primary lobbies have submitted comments to the Centers for Medicare & Medicaid Services prior to the agency finalizing regulations for the Protecting Access to Medicare Act (PAMA).

Both the American Clinical Laboratory Association and the American Hospital Association (AHA) are particularly concerned regarding which laboratories will be included in the rate-setting methodology, which is intended to create more parity among Medicare and private payer rates. The Office of Management and Budget has concluded that moving closer to commercial rate parity would save the Medicare program as much as $360 million for fiscal 2017 and as much as $5 billion over the next decade.

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ACLA, AHA Submit Comments to CMS Regarding PAMA Final Rules, *from page 1*

Final rules for PAMA were supposed to have been issued by the end of this year, but the consensus is that CMS likely will not issue them until at least early 2016.

> *"The proposed rule's definition of 'applicable laboratory' would exclude much of the laboratory market in reporting pricing, and is at odds with both the statutory language and Congressional intent."*
>
> — Alan Mertz, President, ACLA

Under PAMA, laboratories receiving at least $50,000 annually in payments through the Clinical Laboratory Fee Schedule would have to submit payment data next year. But under the current proposal, most hospital laboratories would be excluded from reporting. This has raised concerns from both the lab and hospital sector because hospital-based labs are generally paid at higher rates than standalone facilities.

In its comments, the ACLA noted that one-quarter of Part B payments made by the Medicare program were payments to hospital-based labs.

"The proposed rule's definition of 'applicable laboratory' would exclude much of the laboratory market in reporting pricing, and is at odds with both the statutory language and Congressional intent," said ACLA President Alan Mertz in a statement. "This flawed definition will result in skewed data and Medicare rates that do not reflect the market."

The AHA, which represents a large majority of the nation's 4,000-odd not-for-profit hospitals and hospital systems, was similarly troubled.

"We are concerned that the new CLFS rates would not be representative of overall market rates. This would cause hospitals to see precipitous declines in Medicare payments for laboratory services, which could harm patient access to laboratory testing in many communities," said the letter, which was addressed to CMS Acting Administrator Andrew Slavitt and penned by AHA Executive Vice President Thomas P. Nickels. "Specifically, while payments for most hospital laboratory tests furnished to Medicare beneficiaries are packaged into their inpatient and outpatient prospective payment systems rates, reimbursement for community outreach testing services is made under the CLFS."

ACLA also asked CMS to change its definition of an advanced diagnostic laboratory test (ADLT) to include protein biomarkers. The AHA asked for relaxation of some of the proposed ADLT guidelines in order for more hospital labs to be able to claim their own ADLTs.

Both the ACLA and AHA asked the CMS to curb the issuance of unique billing codes for any ADLT or an FDA-cleared test in order to keep billing issues to a minimum. ACLA also asked that most dialysis labs be excluded from reporting, since few receive revenue under the CLFS.

CMS was also asked by ACLA to lengthen its timetable for the collection and reporting of data, with the new pricing regime not being put into place until 2018.

Takeaway: Despite PAMA's final rules being close to finalized, the Centers for Medicare & Medicaid Services continues to be intensely lobbied by both the laboratory and hospital sectors. G2

Boston Heart Diagnostics Makes Statin Adherence Test More Consumer Friendly

Statins, the enzyme-inhibiting medications that have helped millions of Americans keep their cholesterol in check for the past 25 years, often leave patients with a benign but debilitating effect: Muscle aches and fatigue.

"Personalized medicine should be a critical piece of the process for managing cardiovascular disease—one in four people have risk of muscle pain on a statin, and this is the only commercially available genetic test to identify a patient's likelihood of experiencing this side effect."

— Susan Hertzberg, CEO, Boston Heart

As a result, although some 50 million Americans under current medical guidelines could wind up taking statins to preserve their cardiovascular health, many wind up avoiding or abandoning the drug regimen entirely because of how it makes them feel. Boston Heart Diagnostics wants to change that.

The Framingham, Mass.-based laboratory has tweaked its existing genomic test that identifies the presence of SLCO1B1, a gene that directs the processing of statins in the liver and is an indicator of the likelihood of suffering side effects for taking the medication. According to Boston Heart Chief Executive Officer Susan Hertzberg, individuals who carry the SLCO1B1 mutation are 4.5 times more likely to suffer side effects from taking statins and 17 times more likely if that gene has an identical pair.

As opposed to a blood-based test available only through a physician's office, consumers can now order the $99 StatinSmart test online at statinsmart.com and provide a swab from their mouths as a test specimen. The swab is mailed to Boston Heart, and the test is performed and reviewed by a contracting physician. The turnaround time is 48 to 72 hours. Boston Heart officials say making the test more consumer friendly will help with its goal of improving cardiovascular health. "We want to reduce (patients dropping their medications)," Hertzberg said. "What we're currently doing is not successful, and we keep watching the cost of heart disease going up." The company cited studies saying as many as half of patients with cardiovascular disease stop taking their statins due to muscle pains.

"Personalized medicine should be a critical piece of the process for managing cardiovascular disease—one in four people have risk of muscle pain on a statin, and this is the only commercially available genetic test to identify a patient's likelihood of experiencing this side effect," Hertzberg said. "We know that patients are struggling with managing the side effects of statin medications, and StatinSmart can help guide patients and their healthcare providers in selecting a treatment plan to lower cholesterol without suffering through the trial-and-error process of painful side effects."

Hertzberg added that a positive reading for intolerance for a particular class of statins can guide a physician to prescribe another medication, helping to keep the patient healthier if they are more likely to adhere to the regimen. Some new cholesterol-lowering drugs that have recently come onto the market have far fewer side effects than statins, but they are significantly more expensive.

Boston Heart is also working with a hospital and a payer to study whether patients taking the StatinSmart test are more likely to stay on their medications and the related health care outcomes. Hertzberg declined to name those parties, saying it is too early in the study process to release such information.

Takeaway: Boston Heart wants to cut the cost of heart disease by using an assay to improve medication adherence. G2

Inside The Lab Industry

FDA Issues Report Saying Many Laboratory-Developed Tests Are Dangerous

The U.S. Food and Drug Administration (FDA) has taken its gloves off when it comes to the matter of handling laboratory-developed tests (LDTs).

The issue has been a fractious one in the laboratory sector. There are thousands of LDTs on the market, and many laboratory operators see a move by the FDA to regulate them as a threat to the way they have done business for decades. They fear lengthy delays to obtain approvals for LDTs if the FDA begins regulating them.

The report took some lab executives by surprise. "*It was shocking*," said Susan Hertzberg, chief executive officer of Boston Heart Diagnostics, which markets several LDTs related to cardiac health.

Most laboratory lobbying bodies have said that the Clinical Laboratory Improvement Amendments (CLIA), which were developed in the 1980s, serve as a perfectly fine set of regulations for LDTs. However, the FDA has been insistent that the ever-growing complexity of LDTs means that they require closer regulation.

In addition to its attempt to regulate LDTs, the FDA has also announced its intent to regulate assays that rely on next-generation sequencing, which has also created consternation within the lab sector. It also issued a 43-page guidance document last year outlining how it would regulate LDTs. Many would be subject to an approval process similar to that of point-of-care tests or medical devices, dependent primarily on how each test scores in a risk-assessment process that would determine their ability to impact care and potentially harm patients.

The issue of the FDA's presence in laboratory testing prompted the American Clinical Laboratory Association (ACLA) last year to retain the services of Laurence H. Tribe and Paul Clement, two of the most prominent appellate attorneys in the nation, strongly suggesting it would litigate the matter of the FDA's authority in the federal courts. Such a move is the equivalent of bare-knuckle sparring in lobbying circles. That may be among the reasons why the FDA issued a far-ranging report suggesting that many LDTs had the potential to endanger patients by prompting them to seek unnecessary care.

The report took some lab executives by surprise. "It was shocking," said Susan Hertzberg, chief executive officer of Boston Heart Diagnostics, which markets several LDTs related to cardiac health. The FDA cited a cardiac test related to the KIF6 gene, although Boston Heart does not offer that on its menu. Altogether, the report cited 20 different LDTs as potentially dangerous. Some have never been brought to market or were withdrawn, but they include several tests currently being used on an ongoing basis.

"In some cases, due to false-positive tests, patients were told they have conditions they do not really have, causing unnecessary distress and resulting in unneeded

Inside The Lab Industry

20 Laboratory-Developed Tests The FDA Has Suggested Are Dangerous

Test Name	FDA Comments	Test's estimated cost impact per patient	Status
Lyme Disease Diagnostic Tests	Consistent false positives for test	$1,226.00	No longer available
OvaCheck Ovarian Cancer Test	Inaccurate Results	NA	Never brought to market
OvaSure Ovarian Cancer Test	Inaccurate Results	$12,578 (per ovary removal)	No longer available
PreOvar KRAS-Variant Ovarian Cancer Test	Insufficient validation	$12,578 (per ovary removal)	Available
Pertussis Diagnostic PCR Test	False Positives	NA	Not widely available
Oncotype DX	Poor Sensitivity; False Negatives	$775,278 (per patient with a false negative who does not obtain cancer treatment)	Widely available
SurePath HPV Test	False Negatives	NA	Not widely available
Prenatal cell-free DNA testing	False Positives	NA	Widely available
Fibromyalgia test	Biomarker not clearly associated with disease	NA	Available
KIF6 Genotyping Test to Predict Heart Disease/Statin Therapy Response	Unproven product claims	NA	Widely available
Target Now Cancer Biomarker Test	Treatments suggested by test not proven	NA	Available
Prolaris Prostate Cancer Biomarker Test	Marketing Claims Not Fully Validated	NA	Available
Chronic Fatigue Syndrome XMRV Test	Unproven Test Validity	NA	Available
CARE Clinics Autism Biomarkers Test	Unproven product claims	$66.1 MILLION	Available
Heavy Metal Chelation Challenge Test	Unproven product claims	NA	Available
Omapro Companion Diagnostic to Leukemia Medication	Research Behind Test Unreliable	NA	Available
Duke University Chemotherapy Assessment Test	Errors in Data Management and Analysis	NA	Never brought to market
Vitamin D Deficiency Test	Inadequate Validation	NA	Not widely available
OncoVue Genetic Breast Cancer Risk Test	Lack of Clinical Validation	NA	Available
BrafV600E Genetic Mutation Test	Unproven product claims	NA	Available

Source: U.S. Food and Drug Administration

Inside The Lab Industry

treatment," read the report's executive summary. "In other cases, the LDTs were prone to false-negative results, in which patients' life-threatening diseases went undetected. As a result, patients failed to receive effective treatments."

> *"Clinical laboratories and LDTs are currently highly regulated and when a small number of case studies are used to characterize an entire dedicated and compassionate industry, it detracts from the true task at hand—and that is to effectively strengthen the current regulatory framework for LDTs in a way that continues to advance diagnostic innovation."*
>
> — Alan Mertz, President, ACLA

Among the tests cited was OncotypeDX, developed by California-based laboratory Genomic Health to help determine whether certain drug regimens would be helpful to patients diagnosed with breast cancer, based on the presence and intensity of HER2 proteins.

"The underlying issue is that there is no demonstrated direct correlation between number of RNA copies of the gene, the basis for Oncotype DX (test) and the number of protein copies on the cell surface. As a consequence, it is not possible to infer that high or low amounts of RNA correspond to high or low amounts of HER2 protein," the FDA said in its report.

Genomic Health spokesperson Victoria Steiner criticized the FDA report, saying it mischaracterized the test's reliance on detecting HER2. "To address the misinformed and inaccurate characterization of Oncotype DX in this report, we will continue to work with the FDA to ensure they understand both the critical role that the Oncotype DX test plays in breast cancer treatment planning, and importantly, the wealth of evidence that has supported its use to help guide chemotherapy treatment decisions in more than 500,000 breast cancer patients to date," she said in an email.

The ACLA was also highly critical of the report saying in a statement that much of the data in the report "is not based on peer-reviewed literature (and) refer(s) to outdated data or tests no longer being offered ... the report also fails to make any comparison of degree or frequency between the alleged errors amongst LDTs relative to problems seen in the post-market of FDA approved or cleared products."

Added ACLA President Alan Mertz, "clinical laboratories and LDTs are currently highly regulated and when a small number of case studies are used to characterize an entire dedicated and compassionate industry, it detracts from the true task at hand—and that is to effectively strengthen the current regulatory framework for LDTs in a way that continues to advance diagnostic innovation," said Alan Mertz, President of ACLA. "The FDA's own proposed guidance to regulate LDTs would be highly disruptive to laboratory services and compromise patient care."

Takeaway: The FDA's new report on the potential dangers of laboratory-developed tests is likely to sharpen the battle over the agency's attempt to regulate such assays. G2

CMS Relents on Crosswalking Molecular Codes For 2016 CLFS, *from page 1*

CMS announced on Nov. 17 that it would use a gapfill methodology based primarily on the multianalyte assays with algorithmic analyses (MAAA) codes to set prices. It moves much of the grunt work for pricing in 2017 and beyond over to the regional Medicare contractors.

"We are pleased that the final 2016 CLFS reflects CMS's precedent over the past several years to delegate rate-setting for these complex tests to the MACs."

— Kim Popovits, CEO, Genomic Health

The news was greeted with a collective sigh of relief from many of the esoteric testing companies, whose stocks had been punished by CMS' prior crosswalking proposal.

"The reversal is a victory for transplant patients, not only for CareDx," said company chief executive officer Peter Maag. "We compliment CMS' consideration of the additional data, and its decision to apply the appropriate methodology to price AlloMap."

Another appreciative statement was issued by Kim Popovits, CEO of Genomic Health in Redwood City, Calif.

"We are pleased that the final 2016 CLFS reflects CMS's precedent over the past several years to delegate rate-setting for these complex tests to the MACs," she said. "The MAC-established rates for Genomic Health's Oncotype DX tests are consistent with the market-based rate-setting policies and procedures enacted by Congress under the Protecting Access to Medicare Act (PAMA)."

Amanda Murphy, an analyst with William Blair & Co., said the decision was a positive for the sector as a whole. "The gap-fill process puts the onus on the local Medicare contractors to price the test; Palmetto (considered to be the thought leader in molecular diagnostics) has in many cases performed rigorous evaluation of the analytical and clinical validity of the tests, and other contractors have adopted Palmetto's coverage decisions (including Noridian, the local contractor for many of the labs in question)," she wrote in a recent report. "Thus, under gap-fill pricing, we expect Medicare reimbursement rates to be retained close to current rates."

Bruce Quinn, M.D., a senior director at FaegreBD Consulting and a former director of the Medicare program in California, noted in a statement that tests such as AlloMap would likely wind up with final 2017 pricing no more than 10 percent lower than its current state. As a result, the stocks of many of the molecular labs rebounded significantly from their lows in recent months. Genomic Health's stock rose more than 40 percent, from about $20 a share to $29 in recent trading. Veracyte, which distributes the Afirma test for thyroid cancer testing, rose by about 50 percent. Myriad Genetics rose about 20 percent.

The lab sector was not entirely victorious in the decision. The CMS decided to continue crosswalking codes 81211 and 81213 to 81162, which impacts BRCA testing. Murphy believes it will impact Myriad Genetics the most, although the potential revenue losses are just a small proportion of the company's overall business.

Takeaway: Lobbying from the laboratory sector succeeded in getting the Centers for Medicare & Medicaid Services to relent on the use of crosswalking to set molecular test pricing for 2016. G2

INDUSTRY BUZZ

Sonora Quest Laboratories Enters Into Draw Center Deal With Safeway

Sonora Quest is now offering laboratory services to patients as they shop for groceries. The Arizona-based Sonora Quest, a joint venture between hospital operator Banner Health and Quest Diagnostics, has entered into an agreement with retail giant Safeway to place patient service centers in its stores. The first two patient service centers opened at Safeway stores in Scottsdale and Phoenix last month.

"The endeavor between Sonora Quest Laboratories and Safeway is an investment in innovative capabilities in this new era of health care consumerism," said Christina Noble, Sonora Quest's vice president of business development. "We are proud to work closely with Safeway to continue our mission of empowering consumers to manage their health by offering laboratory testing in a unique and convenient way through one of the largest food and drug retailers in the United States."

Financial terms of the agreement between Sonora Quest and Safeway were not immediately available.

Although Sonora Quest is by far the largest lab in Arizona, with more than 2,500 employees and facilities in five states, it has been facing some pretty keen consumer-oriented competition from upstart Theranos. That California-based lab, which claims to be able to perform hundreds of laboratory tests with just a few drops of blood, has opened up more than 40 locations at Walgreens pharmacies throughout much of the Phoenix area. The company also lobbied hard to get a change in state law to allow direct marketing of tests to patients. Theranos prices its assays at half of Medicare rates, with some tests available for less than $2. However, Theranos has been under intense media scrutiny of late and could slow down its plans for rapid growth. It was reported by the Wall Street Journal last month that Safeway was trying to extricate itself from a deal with Theranos to build testing centers in its stores. A Sonora Quest spokesperson declined to say if the lab was taking over any of the planned Theranos sites.

Although Sonora Quest Chief Executive Officer Dave Dexter told *Laboratory Industry Report* earlier this year that it is not competing with Theranos, it now offers about 100 tests directly to consumers, and has posted its prices at its draw centers.

Takeaway: Rising consumerism in health care delivery drives Sonora Quest to enter into a pact with a grocery giant. G2

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202-637-9466

Boston Heart Diagnostics
508-877-8711

Food and Drug Administration
888-463-6332

Genomic Health
650-556-9300

Myriad Genetics
801-584-3600

Quest Diagnostics
800-222-0446

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