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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UNITED TAKES TEETH OUT OF BEACONLBS IN FLORIDA

On December 31, UnitedHealthcare announced it was indefinitely delaying the claims rejection component of its BeaconLBS pilot program in Florida. The claims rejection component of BeaconLBS, which had been scheduled to start January 1, has now been delayed for a second time and no new effective date has been announced. Under this policy, UHC would have denied payment for certain high-volume lab tests if the ordering physician had not used the BeaconLBS software program. BeaconLBS is a wholly-owned subsidiary of LabCorp.

UHC says it will initiate the claims impact on a delayed schedule to be effective in the "near future." No specific start date has been given, although UHC says it will give labs and providers 30 days advance notice.

UHC's Elizabeth Calzadilla-Fiallo, Director of Public Relations for Florida, says the start date was delayed a second time in response to feedback received from physicians and pathologists. "I've never seen a pilot program receive so much interest," says Calzadilla-Fiallo. *Continued on page 4.*

LAB ANXIETY GROWING AS FDA MARCHES TOWARD REGULATION OF LABORATORY-DEVELOPED TESTS

Industry stakeholders are seeking further clarification from the Food and Drug Administration (FDA) on exactly how the agency expects to measure the risk that a laboratory-developed test poses to consumers. In a public workshop held Jan. 8-9 in Bethesda, Maryland, more than 80 laboratories, IVD manufacturers and trade groups testified. The biggest concern is "How will the FDA determine which LDTs are riskiest and therefore be required to go through the time-consuming and expensive premarket approval process?" *Continued on page 8.*

ROCHE BUYING MAJORITY STAKE IN FOUNDATION HEALTH AT RECORD VALUATION

Roche, the world's largest seller of cancer drugs, is spending $1.03 billion to buy a 56% stake in Foundation Medicine (Cambridge, MA), which markets gene sequencing tests to help select drugs for cancer patients. The deal places an enterprise value on Foundation of approximately $1.6 billion, an amount equal to 26 times the company's 2014 revenue of $61 million. That's a record high valuation for a laboratory company, smashing through the previous record of Quest Diagnostics' purchase of Athena Diagnostics for 7 times revenue in 2011. *Continued on page 2.*

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HAPPY NEW YEAR!

ROCHE BUYING MAJORITY STAKE IN FOUNDATION (*cont'd from page 1*)

Roche is buying 15.6 million Foundation shares at $50 each, about twice the stock price before the deal was announced, on the open market and will purchase another 5 million newly issued shares from Foundation at $50 per share. Foundation will continue to function as an independent publicly-traded company. Despite its majority stake, Roche will have only 3 of 9 seats on Foundation's board. "We both feel it's important for Foundation to maintain its independence and its entrepreneurial spirit," according to Foundation's Michael Pellini, who will remain CEO.

Foundation's main product, called FoundationOne, sequences more than 200 genes in a sample of a solid tumor, such as a lung or breast tumor. Often a particular mutation indicates a tumor would be vulnerable to attack by a particular drug. A newer product, FoundationOne Heme, is for blood cancers. The list prices for the tests are $5,800 for FoundationOne, and $7,200 for FoundationOne Heme. However, actual collected revenue averages approximately $3,600 per test.

Both tests are marketed as laboratory-developed tests and neither has been cleared by the FDA. Foundation performs the tests at its CLIA-certified and CAP-accredited lab in Cambridge, Massachusetts. Foundation markets the tests directly to oncologists through a direct sales force of about 50 sales reps and managers.

In addition to purchasing an equity stake in Foundation, the agreement includes a five-year comprehensive R&D collaboration that includes three key features:

1. Gives Roche access to Foundation's testing technology in the development of drugs in Roche's pipeline. This includes a guaranteed $85 million commitment by Roche to purchase FoundationOne tests over a five-year period.

2. Includes an agreement to co-develop new tests, including cancer blood tests (aka liquid biopsies) as well as tests that could be used in conjunction with drugs that enable the body's immune system to fight cancer. In addition, the companies plan to co-develop companion diagnostics for Roche products (both existing and those in development). Roche has committed to $74 million in royalty and milestone payments for this aspect of the R&D collaboration.

3. Finally, both companies plan to enter into a definitive agreement to co-develop an IVD kit version of Foundation's tests.

Foundation's preliminary report for 2014 shows the company generated $61.1 million of revenue last year, an increase of 111% from $29 million recorded in 2013. A total of 24,271 FoundationOne clinical tests were reported to ordering physicians for the full year ended December 31, 2014, a 167% increase over the 9,095 tests reported in 2013. Despite the strong growth, Wall Street analysts estimate that Foundation had a net loss of approximately $54 million in 2014.

The investment in Foundation follows several other genetic testing deals made by Roche in the past year. It bought DNA sequencing system developer Genia Technologies Inc. (Mountain View, CA) in June 2014 for $350 million. Last month, Roche acquired sequencing data manager Bina Technlogies Inc. (Redwood City, CA) for an undisclosed price as well as the prenatal testing lab Ariosa Diagnostics (San Jose, CA).

MERGER & ACQUISITION SUMMARY FOR 2014

An estimated $1.9 billion was spent on 29 lab acquisitions in 2014, according to research by *Laboratory Economics*. Quest Diagnostics spent a total of $748 million on three deals: Solstas Lab Partners, Summit Health and Steward Health's outreach lab. LabCorp spent a total of more than $100 million on five deals, including Covance Genomics Laboratory, LipoScience Inc., Bode Technology and two divisions purchased from Laboratory Partners. In addition, LabCorp is near completing its biggest acquisition ever—the $6 billion purchase of Covance Inc. The deal has passed through a 30-day period of review by the Federal Trade Commission with no objections. Shareholders will be able to vote on the deal and finalize it soon.

Laboratory Acquisition & IPO Summary for 2014 ($ millions)

Lab Type	Date	Buyer	Target	Purchase Price	Acquired Revenue	Price/ Revenue
Esoteric	Pending	Roche	Foundation Health	$1,600	$61	26.2
Clin. Trials	Pending	LabCorp	Covance Inc.	$6,000	$2,500	2.4
Esoteric	Dec-14	Roche	Ariosa Diagnostics	NA	80	NA
Esoteric	Dec-14	Eurofins Scientific	Boston Heart Diagnostics	200	95	2.1
Routine	Dec-14	Dominion Diagnostics	Aurora Greensboro Clinical Lab	NA	1	NA
Esoteric	Dec-14	LabCorp	Bode Technology	NA	NA	NA
Pathology	Nov-14	PDI Inc.	RedPath Integrated Pathology	23	10	2.3
Pathology	Nov-14	Aurora Diagnostics	West Georgia Pathology LLC.	NA	NA	NA
Esoteric	Nov-14	LabCorp	LipoScience Inc.	63	42	1.5
Pathology	Sep-14	Aurora Diagnostics	Arizona Dermatopathology	NA	NA	NA
Esoteric	Sep-14	Veracyte Inc.	Allegro Diagnostics	17.1	NA	NA
Routine	Aug-14	Medytox Diagnostics Inc.	Epinex Diagnostics Laboratories	1.3	NA	NA
Pathology	Jul-14	NeoGenomics	Path Logic Inc.	5.8	10	0.6
Pathology	Jul-14	Incyte Diagnostics	Accupath Laboratory Services	NA	NA	NA
Clin. Trials	Jul-14	Cancer Genetics Inc.	Gentris LLC.	5.0	5.5	0.9
Pathology	Jun-14	Aurora Diagnostics	Hallmark Pathology PC.	NA	NA	NA
Pathology	Jun-14	Aurora Diagnostics	Mid-Atlantic Pathology Services	NA	NA	NA
Esoteric	May-14	Eurofins Scientific	Viracor/IBT Laboratories	255	NA	NA
Pathology	May-14	CellNetix	Highline Pathology Associates	NA	NA	NA
Pathology	May-14	Incyte Diagnostics	Medical Center Laboratory	NA	NA	NA
Routine	May-14	American Health Associates	MedLab Nursing Home Labs	5.5	NA	NA
Toxicology	May-14	BelHealth Invest. Partners	Precision Toxicology Inc.	NA	NA	NA
Routine	Apr-14	Quest Diagnostics	Summit Health	151	80	NA
Routine	Apr-14	Quest Diagnostics	Steward Health outreach lab	34	NA	NA
Routine	Mar-14	Quest Diagnostics	Solstas Lab Partners	563	390	1.4
Routine	Mar-14	LabCorp	Medlab Inc. (Indiana labs)	10.5	NA	NA
Toxicology	Mar-14	ABRY Partners	Aegis Sciences Corp.	NA	NA	NA
Esoteric	Feb-14	Myriad Genetics	Crescendo Biosciences	259	40	6.5
Clin. Trials	Jan-14	LabCorp	Covance Genomics Laboratory	10.4	NA	NA
Esoteric	Jan-14	ACM Medical Laboratory	Phoenix Pharma Central Services	NA	NA	NA
Routine	Jan-14	LabCorp	Laboratory Partners, Talon Division	11.9	NA	NA

Source: *Laboratory Economics*

UNITED TAKES TEETH OUT OF BEACONLBS (*cont'd from page 1*)

The BeaconLBS pilot project is being widely criticized by physician groups in Florida as well as the Florida Society of Pathologists (FSP). "We as a group feel that neither UnitedHealthcare nor LabCorp Beacon is competent nor sanctioned to direct how diagnosis should proceed," FSP President Brett Cantrell, MD, tells *Laboratory Economics*. Cantrell says that many medium-sized independent labs do not have the manpower in subspecialty-boarded pathologists to fulfill all the pilot's requirements.

"United has delayed the denial of claims to date to first address some of the electronic interface problems with various lab computer systems, provider EMR's, and United's notification system. If the delay is also to retool, modify, or even abandon the program, they have not made that public information," notes Cantrell.

Meanwhile, UHC's Calzadilla-Fiallo says UHC is looking for ways to reduce overutilization throughout all areas of medical spending, not just lab testing. "Overutilization is waste, and waste drives up premiums," says Calzadilla-Fiallo. Below are UHC's responses to specific questions from *Laboratory Economics*.

Will the denial of claims component of BeaconLBS be implemented within 3 months, 6 months, or 1 year?
UnitedHealthcare continues to integrate additional EMRs with the Beacon system, and we will communicate to network providers 30 days prior to a claims impact becoming active.

How many UnitedHealthcare members in Florida does the BeaconLBS pilot program apply to?
Our pilot program with Beacon is being used with our commercial fully-insured health plans, which is roughly 430,000 UnitedHealthcare members in Florida.

What should a laboratory do if it gets a lab test order from an in-network physician that did not use the BeaconLBS system to order one of the 80 tests that require prenotification?
The laboratory should reach out to the ordering provider letting them know that the member's test requires Physician Decision support and they are required to submit notification. The ordering provider has 10 business days from the date of service to submit notification if it was not submitted with the original lab request.

Does United have any plans to expand the BeaconLBS pilot program into additional states?
Our current focus is on our pilot program in Florida. Our goal is to create a lab program that is easy for physicians and labs to use while improving quality and lowering costs for our members.

Approximately how fast in percentage terms is United's lab testing expense growing per year?
The cost of outpatient laboratory services is growing at about double the rate of core medical costs. [Note: UHC's commercial-member medical cost trend was approximately 6% in 2014.]

How were the 80 tests that require prenotification chosen?
Based on a combination of high growth rate, excessive utilization and/or high expense. Some tests were chosen because they match all three criteria and some because they have high overutilization and are unmanaged.

How many physicians and labs have left United's network because they are upset with the BeaconLBS pilot program?
We continue to work with network providers who have questions or may be dissatisfied with the pilot program to resolve their issues. To date we have not had any nonrenewals (of a physician's or lab's contract) based upon the pilot program.

How do you respond to the protest from pathologists who say that requiring a second opinion on cancer cases infringes upon their medical-decision making?
There has been a lot of published clinical evidence from specialty societies and other groups that have found that second and subspecialist pathology reviews reduce diagnosis discrepancies and are a benefit to patient outcomes.

PALMETTO TO PUBLISH FINAL LCD ON SPECIAL, IHC STAINS

Despite opposition from the College of American Pathologists (CAP) and other industry groups, Palmetto GBA intends to publish a final local coverage determination (LCD) on special stains on or around Jan. 22, with an effective date 45 days later.

According to Elaine Jeter, M.D., medical director for Palmetto, the Medicare contractor for jurisdiction J11, the final LCD is modified slightly from the draft, but the intent is the same: To prevent medically unnecessary utilization of special histochemical and immunohistochemical (IHC) stains.

In particular, the LCD will take aim at the following:

- Reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist.
- Use of special stains and/or IHC stains without clinical evidence that the stain is actionable or provides the treating physician with information that changes patient management.
- Use of stains when the diagnosis is already known based on morphologic evaluation.
- Situations where H&E staining is included in the billing CPT code and is not separately billable.

Numerous studies and articles have pointed to excess use of special or IHC stains, notes Jeter, including a study published in the January 2015 issue of the *American Journal of Clinical Pathology* that found the practice of upfront staining for Helicobacter pylori in gastric biopsy specimens is not indicated. The draft LCD, published in October, also cites a number of other studies as evidence that special stains are being overutilized.

"There is unequivocal evidence that special stains are being overused," Jeter tells *Laboratory Economics*.

According to the draft LCD, ordering special stains or IHC stains prior to review of the routine H&E stain is not reasonable and necessary. Examples of special stains or IHC stains that are not reasonable and necessary on every specimen include:

- Esophagus – fungal stains, trichrome, DPAS, CDX-s, or other mucin stains
- Gastric – AB-PAS, D-PAS, CDX-s, or other mucin stains or special stains or IHC for H. pylori, or neuroendocrine markers such as synaptophysin or chromogranin
- Duodenum – AB-PAS, D-PAS, CD3, and trichome, or other mucin stains
- Colon – CD3, p53 trichrome
- Hyperplastic polyps – Ki67, CK20, p53, CEA, BRAF
- Tubular or tubulovillous adenoma – Ki-67, CK20, CEA, p53, MMR

"Overutilization of special stains also has been observed with duodenal biopsies where CD3 and AB/D-PAS are reportedly used to help exclude intraepithelial lymphocytosis and gastric metaplasia," says the draft LCD. "Both of these conditions, if present, are easily recognizable on H&E morphology. Mucin stains such as AB-PAS or DPAS would be reasonable and necessary in limited circumstances, and rarely is CD3 warranted on duodenal biopsies which show villous architectural abnormalities."

Publication of the final LCD on stains comes despite CAP urging Palmetto to withdraw the draft. According to a Dec. 24 letter sent by CAP President Gene Herbek, MD, to Jeter, the draft LCD's purported evidence base lacks credibility and encroaches on matters of pathologist medical judg-

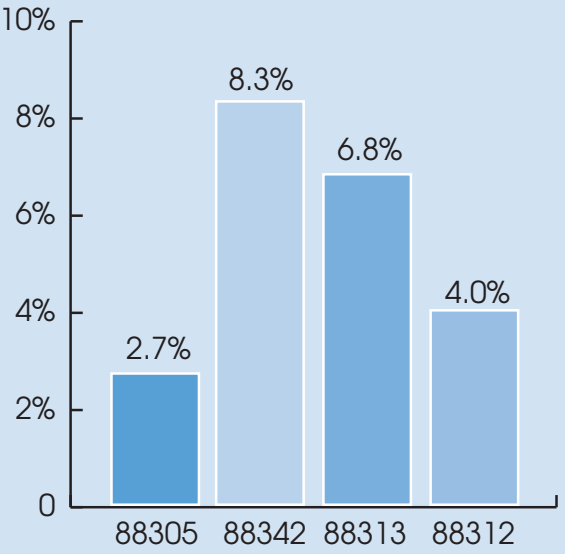
ment. What's more, as a result of its lack of clarity and reliance on retrospective claims evaluation, neither providers nor patients are able to prospectively determine if a particular service is covered for a particular patient, argues CAP.

While it is up to other Medicare contractors whether to follow Palmetto's coverage decisions, many do. Jeter tells *LE* she does not know whether other contractors will adopt this special stain LCD.

National Medicare Part B Volume Growth for Pathology Services, 2008-2013

During the five-year period, 2008-2013, the volume of CPT 88305 units of service billed to Medicare Part B grew by an average of 2.7%. Over the same time frame, the utilization of IHC and special stains has grown much faster. For example, volume growth for CPT 88342 (IHC) grew by 8.3% per year; CPT 88313 (special stains, group 2) increased 6.8% per year; and CPT 88312 (special stains, group 1) grew by 4.0% per year.

Source: CMS



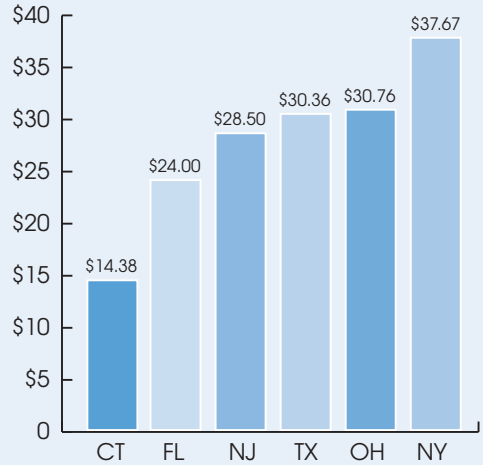
CONNECTICUT MEDICAID SLASHES PAP TEST REIMBURSEMENT

Connecticut's Medicaid program, which provides healthcare to 767,000 enrollees, has slashed rates for most clinical lab tests by 24% effective January 1, 2015. Its clinical lab reimbursement rates are now mostly set at 70% of Medicare's national Clinical Lab Fee Schedule.

However, Connecticut's reimbursement for thin-layer Pap testing (CPT 88175), the most common Pap testing method, has been cut by 36% and is now set at $14.38—the same rate as the conventional Pap smear (CPT 88164). At $14.38, Connecticut's reimbursement is set at about half that of neighboring New York, which pays $37.67, and New Jersey, which pays $28.50.

In addition, Connecticut's Medicaid rates for anatomic pathology services have been cut by 20% and are now equivalent to 50% of Medicare rates. For example, CPT 88305 is now reimbursed by Connecticut at a global rate of $35.42 versus Medicare's national rate of $73.03.

Thin-Layer Pap Test* Medicaid Reimbursement Comparison



*Current Medicaid reimbursement rates for CPT 88175 (Pap test, automated thin-layer preparation; with screening by automated system and manual rescreening or review, under physician supervision)

Source: *Laboratory Economics* from state Medicaid programs

Connecticut's Department of Social Services says it lowered its reimbursement rates "to more closely reflect pricing in other Medicaid programs and the commercial sector." Connecticut estimates that the changes will reduce its Medicaid expenditures by approximately $10.1 million in 2015 and $13.8 million in 2016.

Although Connecticut's Medicaid program allowed a short comment period on its new lab fee schedule, there is a low probability of political blow back, according to Robert Babkowski, MD, Chair, Department of Pathology, and Laboratory Medical Director at Stamford Hospital (Stamford, CT). "Most labs will just accept these low rates and the state just moved another inch to solving its budget deficit," says Babkowski. "Commercial and independent labs should ask themselves if it's worth it to continue doing Medicaid work in Connecticut. They can, and should, walk away from this book of business."

Connecticut Medicaid Lab Rates for Key Lab and Pathology Tests

Code	Description	2015	2014	% Chg.
80053	Comprehensive metabolic panel	$10.09	$13.33	-24%
80055	Obstetric panel	15.06	18.82	-20%
88164	Conventional Pap Test	14.38	12.98	11%
88175	Thin-layer Pap test, auto screen and manual redo	14.38	22.46	-36%
87491	Chylmd trach DNA amp probe	33.51	44.26	-24%
87529	Herpes Simplex DNA amp probe	33.51	44.26	-24%
87591	N.gonorrhoea DNA amp prob	33.51	44.26	-24%
87623	HPV low-risk types	30.98	NA	NA
87624	HPV high-risk types	30.98	NA	NA
87625	HPV types 16 & 18 only	30.98	NA	NA
88305-Global	Tissue exam by pathologist	35.42	44.27	-20%
88305-26	Tissue exam by pathologist	17.71	22.14	-20%
88305-TC	Tissue exam by pathologist	17.71	22.14	-20%
88312-Global	Special stains; Group 1	27.23	34.04	-20%
88313-Global	Special stains; Group 2	19.89	24.86	-20%

Source: Connecticut Dept. of Social Services

Separately, *Laboratory Economics* notes that Medicaid reimbursement rates are becoming increasingly important to labs, pathologists and other providers. That's because a major component of the Affordable Care Act (aka Obamacare) has been Medicaid expansion. Since October 2013, 9.7 million people have been added to Medicaid programs, bringing the national total to 68.5 million. More than one-fifth of Americans are now covered by Medicaid.

LAB ANXIETY GROWING AS FDA MARCHES TOWARD REGULATION (*cont'd from p. 1*)
More than 80 stakeholders testified during the two-day workshop, with many opposing efforts by the FDA to regulate LDTs. A number of participants asked agency officials to do a better job of explaining its risk-classification categories and explain how the agency will coordinate its oversight with the Clinical Laboratory Improvement Amendments (CLIA). Even Andrew Fish, executive director of AdvaMed, which has largely supported FDA oversight of LDTs, said that the agency needs to publish a document laying out how it plans to assess risk.

The FDA on Oct. 3 issued a draft framework for regulation of LDTs based on three risk classifications, with the highest-risk assays, Class III, and the more moderate-risk Class II LDTs requiring premarket approval and reporting of adverse events. Class I low-risk tests would be subject to enforcement discretion. The draft framework would allow for a modest number of operational exemptions from the FDA's plan to regulate LDTs based on their potential risk to patient safety. The FDA would not consider a test to be an LDT if:

- An entity that owns several clinics creates a test that is then transferred to another lab within its network;
- An academic institution develops a test that it then licenses to a private venture that owns a CLIA-certified laboratory, which then begins manufacturing and distributing the test; and
- An entity that creates LDTs and medical devices will continue to follow the existing regulations for medical devices.

The FDA maintains that while CLIA is essential for ensuring that labs and their personnel maintain standards of high quality, compliance with CLIA regulations alone does not ensure that LDTs themselves are safe and effective as required by the Food, Drug, and Cosmetic Act. Specifically, CLIA does not require that labs prove their LDTs are clinically valid and does not require the removal of unsafe tests from the market.

The FDA estimates that there are some 11,000 LDTs on the market that have been created by more than 2,000 different labs, but industry sources say that number is much higher, especially if you count lab tests that have been modified by labs for their own purposes. To get a handle on the actual number of LDTs, the agency has asked labs to report all the LDTs they provide, regardless of risk class.

Stakeholder Concerns
Many of the comments presented during the workshop related to the fact that labs already have to comply with quality systems regulations (QSRs) under CLIA and would have to meet separate QSRs under the FDA proposal.

"In the draft LDT guidance, the FDA proposes to require a vast variety of laboratories to comply with QSRs but provides scarce details on how those QSRs will be applied to LDTs generally and to different laboratories more specifically," said Sheila Walcoff, CEO of the consulting firm Goldbug Strategies. Walcoff spoke on behalf of the Coalition for 21st Century Medicine, which represents the interests of diagnostic companies and venture capital firms.

In the draft guidance, the FDA proposes to continue to exercise enforcement discretion with respect to QSR requirements until a manufacturer of a given LDT submits a premarket application or the FDA issues a 510(k) clearance order for the LDT. Under this enforcement policy, the lab manufacturing and using the LDT will be responsible for having a quality system in place that meets the minimum requirements.

LDT Oversight Framework Summary: Requirements FDA Intends to Enforce

Category	Registration and Listing	Manufacturer Reporting Requirements	Premarket Review Requirements	Quality System Regulation Requirements
LDTs solely used for forensic (law enforcement) purposes LDTs used in a CLIA-certified, high-complexity histocompatibility laboratories for transplantation				
LDTs used for rare diseases	X	X		
Traditional LDTs	X	X		
LDTs for unmet needs	X	X		
LDTs with the same intended use as a cleared or approved companion diagnostic LDTs with the same intended use as an approved Class III medical device Certain LDTs used to determine safety efficacy of blood or blood products	X	X	Enforced for currently marketed LDTs that have not made a premarket submission within 12 months of finalization of this guidance document Enforced for new LDTs initially marketed after finalization of the guidance document	Enforced once PMA submitted or FDA issues a clearance order
LDTs for infectious agents (donor screening tests) used in blood and blood components and HCT/Ps	All requirements currently enforced			
Class III (high risk) LDTs	X	X	Enforced on a risk-based, phased-in basis FDA plans to announce priority list within 24 months of finalization of this guidance document	Enforced on a risk-based, phased-in basis until a manufacturer of a given LDT submits a PMA
Class II (moderate risk) LDTs	X	X	Enforced on a risk-based, phased-in basis Enforced after FDA has completed the phase-in of Class III FDA plans to announce the priority list for Class II within four years of finalization of this guidance	Enforced on a risk-based, phased-in basis until FDA issues a 510(k) clearance order for the LDT
Class I (low risk) LDTs	X	X		

Source: FDA, Framework for Regulatory Oversight of Laboratory Developed Tests, Oct. 3, 2014

During the workshop, presenters expressed concerns about whether labeling an LDT with an intended use would mean they would be responsible for ensuring physicians don't use the test off-label. Speakers also sought clarification on when a lab would need to submit a premarket approval application for a test that has already been approved by the FDA but that has been modified by the lab in some way.

The American Society for Clinical Laboratory Science (ASCLS) recommended that the agency focus its efforts on those tests that truly are novel and that pose the greatest risk. "We believe that the most important concern that should be kept in mind when formulating guidance is the need to demonstrate the clinical validity and medical applicability of a highly complex/high-risk LDT," said ASCLS President Susanne Zanto.

While some groups believe that some form of FDA oversight may be inevitable, others – including the American Clinical Laboratory Association (ACLA) – maintain that FDA should have no role in regulating LDTs and that the proposed guidance be withdrawn. In a white paper released the day before the workshop, legal experts retained by ACLA argue that LDTs are not medical devices subject to FDA oversight, that FDA regulation of LDTs will interfere with the practice of medicine, and that FDA's use of guidance documents circumvents the requirements of the Administrative Procedures Act.

BUNDLING PAYMENT FOR HOSPITAL OUTPATIENT SERVICES

Effective January 1, reimbursement for the technical component of pathology services provided to hospital outpatients is no longer paid separately by Medicare. On January 13, *Laboratory Economics* sponsored a teleconference: *Bundling Payment for Hospital Outpatient Services: Don't Let Your Lab Get Squeezed Out In 2015 & Beyond*. The teleconference featured two expert speakers: Jane Pine Wood, attorney at McDonald Hopkins, and Dennis Padget, lead consultant for APF Consulting Services, Inc. Here are some highlights:

Which pathology codes have been bundled?
Dennis Padget: It's easier to talk about the codes that are not bundled. There are basically only three anatomic pathology codes that will continue to be paid separately for hospital outpatients. Those are: 1) gross and micro-level six 88309; 2) electron-microscopy code 88348; and 3) intraoperative cytologic preparation 88333. Everything else is now bundled, including all technical component reimbursement for non-gyn cytology, fine needle, gross and micro (except 88309), all special stains, all immunohistochemistry, all FISH testing and all flow cytometry.

Do bundled payments apply to ambulatory surgery centers (ASCs)?
Jane Pine Wood: The bundling applies only to hospital outpatient services; it does not apply to independent ASC services. In other words, bundled payment applies to outpatient pathology services performed at place-of-service code 22, but not for place-of-service code 24. But it is going to be important if you are dealing with surgery centers to know whether it's actually an independent surgery center (code 24) or is a surgery center that might be classified as a hospital outpatient department (code 22).

Are the new bundled payments for primary procedures sufficient?
Dennis Padget: In theory, CMS would have gone through some sort of a modeling approach by which it would have taken the 2014 APC rates, added in the savings from not separately paying the anatomic pathology technical components anymore, and then added a 2% inflation factor, and this would be the new 2015 APC.

I tested the hypothesis that this is indeed what Medicare did. I looked at 10 surgical procedures frequently performed in a hospital outpatient basis and did a comparison of the 2014 APC plus the anatomic pathology technical components that were separately paid to the hospital in 2014, compared with the actual 2015 APC for that same surgical procedure.

It looks to me like the only credit that was given by CMS in 2015 was for the inflation. Now I'm sure CMS, as it's often done on the inpatient side, will argue that it's factored everything into the new rates. But it just doesn't look to me like CMS has accounted for the packaged pathology and other services.

How will bundling affect independent labs that provide pathology TC services to hospitals?
Jane Pine Wood: We have to deal with the reality of the financial situation and the reality is there's not a lot of extra money here for the hospitals.

From a legal standpoint, because the hospital is a source of referrals to the laboratory for these technical component services, we implicate the Medicare and Medicaid anti-kickback law. Now, it's a federal fraud and abuse statute, has civil and criminal penalties, and both parties are equally at risk under the law if it is violated.

If a hospital demands that a laboratory provide these outpatient technical component services for free or at a significantly discounted below-cost rate in exchange for the referral of other work to that laboratory or to that pathology practice that might own that laboratory, now we have a potential violation of the Medicare and Medicaid anti-kickback law. It's the same issue that we face in dealing with negotiations between hospitals and laboratories on the inpatient side. The hospital may feel as though it's not adequately paid by Medicare for the technical component of services but that doesn't mean that the hospital is able to avoid paying the recipient of its referrals fair market value for those services. The issue, of course, is "What is fair market value?" and that's going to be topic of negotiation.

I expect most of these discussions to arise when a contract comes up for renewal, but that's probably not the time to begin the discussion initially. I think you need to lay the groundwork, because I would expect some difficult discussions with hospitals on pricing whenever these contracts come up for renewal.

It's important to remember that we were talking about Medicare, but the non-Medicare work is still work that the laboratory can bill directly to the payers. If the hospital is looking to outsource and send out an RFP and try to find the lowest bidder for the technical component work, that lowest bidder might not be in-network with all the payers that you are. That means patients could be hit with significant out-of-network balances. That would not be a good thing from a patient perspective, so you might be able to parlay that in your hospital contract negotiations.

Will private payers follow Medicare and start bundling payments?
Jane Pine Wood: It's really going to be incumbent upon the hospitals, to be very mindful of their private-payer contracting because as we have seen happen with many inpatient services, I would expect private payers to jump on the bandwagon and try to put language into their hospital contracts that says the hospital's payment for these outpatient services include the technical component of anatomic pathology services. So, I certainly suggest that pathology labs work with the hospitals to make sure that the hospital's payer contracting personnel, whoever works on its managed care contracts, are diligent to make sure that those hospital contracts, with the private payers, clarify that the hospital's payment does not include payment for these services and that the laboratory can continue to bill independently for these services.

LAB STOCKS UP 9% YTD

Fourteen lab stocks have increased by an unweighted average of 9% year to date through January 16. In comparison, the S&P 500 Index is down 2%. The top-performing lab stock so far this year is Foundation Medicine, which has jumped 115% on news that Roche is buying a majority stake in the company (*see page 1*). Meanwhile, Quest Diagnostics is up by 1% and LabCorp is up 7%.

Company (ticker)	Stock Price 1/16/15	Stock Price 12/31/14	2015 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$32.32	$32.13	1%	$904	19.0	1.1	2.8
Cancer Genetics Inc. (CGIX)	8.00	6.68	20%	77	NA	9.0	2.0
CombiMatrix (CBMX)	1.38	1.29	7%	16	NA	1.2	1.9
Enzo Biochem (ENZ)	3.42	4.44	-23%	162	NA	1.6	4.5
Foundation Medicine (FMI)	47.68	22.22	115%	1,346	NA	25.4	13.8
Genomic Health (GHDX)	31.98	31.97	0%	1,043	NA	3.7	7.3
LabCorp (LH)	114.92	107.90	7%	9,890	18.9	1.7	3.6
Myriad Genetics (MYGN)	39.45	34.06	16%	2,840	21.3	3.9	4.0
NeoGenomics (NEO)	4.05	4.17	-3%	241	NA	2.5	4.1
Psychemedics (PMD)	14.77	15.15	-3%	77	22.9	2.7	6.0
Quest Diagnostics (DGX)	67.52	67.06	1%	10,080	17.2	1.4	2.4
Response Genetics (RGDX)	0.34	0.32	6%	13	NA	0.7	6.3
Sonic Healthcare (SHL.AX)	17.90	18.50	-3%	7,185	18.6	1.9	2.3
Veracyte (VCYT)	7.97	9.66	-17%	185	NA	4.8	3.8
Unweighted Averages			9%		19.6	4.4	4.6

Source: Bloomberg

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