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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FINAL MEDICARE PFS CUTS 88305-TC BY 13%

The Final Medicare Physician Fee Schedule for 2017, which was released on November 2, cuts the technical component for CPT 88305 by 13% to a national rate of $29.79 (unadjusted for geography). The final rate for the professional interpretation for CPT 88305 is flat at $39.84. In short, the final MPFS for 2017 includes some significant cuts to technical reimbursement for several key pathology codes, while reimbursement for most professional services is little changed. *Continued on pages 3-4.*

PATHOLOGISTS HAVE OPTIONS FOR AVOIDING PENALTIES UNDER MACRA

Pathology reimbursement could be significantly reduced by new quality payment programs that will begin in 2017 and will begin affecting Medicare reimbursement in 2019. However, there is an easy way for pathologists to prevent any payment reductions – by reporting just one quality measure to Medicare. *Full details on pages 5-6.*

FDA OVERSIGHT OF LDTS UNLIKELY UNDER TRUMP

Proposed guidance on Food and Drug Administration (FDA) oversight of lab-developed tests is unlikely to be finalized under a Trump administration, according to lab industry expert Dennis Weissman, President of Dennis Weissman & Associates LLC. Trump is expected to issue a freeze on all new regulations effective Jan. 21, the day after the inauguration. "There will be new leadership coming to FDA and the Department of Health and Human Services who are likely to be anti-regulatory, so I don't see a shot at an FDA under Trump finalizing guidance on oversight of LDTs," says Weissman. "I think it's dead." *Continued on page 11.*

CELLNETIX TO ACQUIRE PUGET SOUND INSTITUTE OF PATHOLOGY

Puget Sound Institute of Pathology (PSIP) has signed a letter of intent to merge into CellNetix Pathology & Laboratories (Seattle, WA). The deal will create one of the largest pathologist-owned anatomic pathology groups, with a combined 70 pathologists, in the United States. The transaction is expected to close in the first quarter of 2017. Financial terms have not been disclosed. *More details on page 2.*

Contents

HEADLINE NEWS
Final MPFS Cuts 88305-TC by 13% 1, 3-4
Pathologist Options for Avoiding MACRA Penalties 1, 5-6
FDA Oversight of LDTs Unlikely Under Trump 1, 11
CellNetix to Acquire PSIP 1-2

SPOTLIGHT INTERVIEW
NorthWell's James Crawford, MD, PhD 7-8

BEACONLBS
More Details on BeaconLBS Rollout in Texas 9-10

MOLECULAR DIAGNOSTICS
PGXL Laboratories Files for Bankruptcy 11

DIRECT-ACCESS TESTING
Walgreens Sues Theranos 11

FINANCIAL
Lab Stocks Up 7% 12

CELLNETIX TO ACQUIRE PSIP (*continued from page 1*)

PSIP is owned by its 17 pathologists and has 90 employees at its freestanding technical lab in Seattle, which serves 11 hospitals and health systems throughout Washington. It was founded more than 50 years ago and is the oldest independent pathology lab in the Puget Sound Region.

CellNetix has 53 pathologists and more than 300 employees at its main lab in Seattle and in offices in Spokane, Everett, Olympia and Anchorage, Alaska. CellNetix was formed in 2005 by the merger of three independent pathology groups in Washington—Black Hills Pathology (Olympia), Associated Pathology (Everett) and Washington Pathology Consultants (Seattle). CellNetix added Northwest Pathology Group in 2008 and then acquired the pathology groups at Deaconess Hospital in Spokane and at Mat-Su Regional Medical Center in 2012. Highline Pathology Associates (South Seattle) was acquired in 2014.

Pathologists at CellNetix own 100% of the professional corporation (CellNetix Pathology PLLC) and have majority ownership of the technical lab (CellNetix Labs LLC). The national reference lab PAML (Spokane, WA) bought a 22% stake in CellNetix Labs in 2013.

CellNetix and PSIP at a Glance

	CellNetix	PSIP	Combined
# Pathologists	53	17	70
# Hospital medical directorships	36	11	47
Annual volume of surgical cases	130,000	70,000	200,000
Annual volume of Pap cases	150,000	50,000	200,000
Total number of employees	300	90	390

Source: CellNetix

"In an ever-evolving healthcare market it has become clear that if we are not moving forward, innovating, investing and growing, we will lose ground," according to CellNetix CEO Kathleen Fondren. "It is less about necessity and more about investing in the future."

Fondren will continue to be the CEO of the merged company. She became CEO of CellNetix after the previous CEO, Don Howard, MD, PhD, resigned earlier this year. Fondren had previously been the Chief Operating Officer of the company since September 2014.

Ken Meckler, MD, President and Chairman of PSIP, Chief Executive Stewart Adelman, as well as the entire PSIP management team, are expected to continue work at the merged company, according to a CellNetix spokesman. He says the companies are in the due diligence phase to determine what the combined organization will look like, including the new management structure.

Recent Pathology Group/Lab Transactions

Date	Buyer	Target	Purchase Price	Acquired Revenue	Price/ Revenue
Pending	CellNetix	Puget Sound Institute of Pathology	NA	NA	NA
Oct-16	LabCorp	ClearPath Diagnostics	NA	NA	NA
Aug-16	Pritzker Group Private Capital	PathGroup	NA	~$240M	NA
May-14	Advanced Dermatology	Skin Pathology Associates	NA	NA	NA
Apr-16	Aurora Diagnostics	Pathology Associates of Sebring	$250K	NA	NA
Mar-16	Aurora Diagnostics	Pacific Pathology Associates	$7M	NA	NA
Jan-16	LabCorp	Pathology Inc.	NA	NA	NA
Dec-15	NeoGenomics	Clarient Inc.	$310M	$124M	2.5
Oct-15	Aurora Diagnostics	Consultants in Laboratory Medicine	$7M	NA	NA

Source: *Laboratory Economics*

FINAL MEDICARE PFS CUTS 88305-TC (*cont'd from page 1*)

CMS says the 13% reduction to CPT 88305-TC relates to an update that reflects reduced costs for eosin stain supplies. For similar reasons, CMS finalized significant TC rate reductions for several other key pathology codes, including CPT 88302-TC (-7%), 88304-TC (-14%), 88307-TC (-19%) and 88309-TC (-19%).

Prostate Biopsies

The professional component of the prostate-biopsy G-code (G0416) reported for all prostate biopsy services was increased by 18% to $186.26. However, the technical component was cut by 19% to $304.70. As a result, global reimbursement for G0416 declined by 8% to $490.96.

Immunohistochemistry

The professional component of CPT 88341 (immunohistochemistry, each additional stain) was increased by a substantial 7% to $29.79, while the technical component was unchanged, resulting in a global increase of 2% to $92.23. Meanwhile the professional rate for CPT 88342 (immunohistochemistry, initial stain) was unchanged at $37.32 and the technical rate was up 1% to $71.06, resulting in a global increase of 1% to $108.38.

Flow Cytometry

In the final fee schedule, the CMS finalized significant cuts to both professional and technical fees for flow cytometry as part of its misvalued code initiative. For example, CPT 88185 (flow cytometry, tech-only, add on) was cut by 19% to $37.68. And CPT 88189 (flow cytometry, read 16+ markers) was also cut by 19% to $92.59.

Estimated Revenue Impact for 2017

Reductions in Medicare rates for the top 10 pathology codes, based on annual Medicare Part B allowed charges, will result in an estimated revenue loss of $93 million for pathology groups and labs next year. This estimate is based on $1.7 billion of annual Medicare Part B allowed charges for the top 10 pathology codes multiplied by reimbursement reductions that average -5.6% on a weighted basis.

In addition, the Medicare rate changes will also influence rates paid by commercial third-party payers and Medicaid plans. Many, if not most, payers base their rates on a percentage of the Medicare PFS and will adjust their rates proportionately as contracts come up for renewal.

Medicare Reimbursement Estimates for Top 10 Pathology Codes

Code (Description)	Annual Allowed Charges ($MM)*	2017 Global Rate Change	2017 Revenue Impact ($MM)
88305 (Tissue exam by pathologist)	$968.7	-6%	-$58.1
88185 (Flow cytometry, each add'l marker)	108.0	-19%	-20.5
88342 (Immunohistochemistry, first stain)	103.0	1%	1.0
88312 (Special stains)	98.9	1%	1.0
88307 (Level V, tissue exam by pathologist)	86.6	-14%	-12.1
88341 (Immunohistochemistry, each add'l stain)	83.4	2%	1.7
88313 (Special stains, group 2)	64.2	2%	1.3
G0416 (Prostate biopsy, any method)	58.5	-8%	-4.7
88120 (Cytopath-manual for urine specimen)	47.4	0%	0.0
88112 (Cytopath cell enhance tech)	44.5	-5%	-2.2
Totals	$1,663.3	-5.6%	-$92.7

*Allowed charges are national data for Part B spending for 2015 (the latest available data from CMS)
Source: CMS and *Laboratory Economics*

Final Medicare Rate Changes for Key Pathology Codes

CPT Code	Description	2017*	2016**	% Change
88112-Global	Cytopath cell enhance tech	$68.91	$72.32	-5%
88112-26	Cytopath cell enhance tech	29.07	29.00	0%
88112-TC	Cytopath cell enhance tech	39.84	43.32	-8%
88184-TC only	Flow cytometry/1st marker	61.73	76.26	-19%
88185-TC only	Flow cytometry/each add'l marker	37.68	46.55	-19%
88189-PC only	Flow cytometry, read 16+	92.59	114.22	-19%
88304-Global	Level III, tissue exam by pathologist	41.63	46.19	-10%
88304-26	Level III, tissue exam by pathologist	12.20	11.82	3%
88304-TC	Level III, tissue exam by pathologist	29.43	34.37	-14%
88305-Global	Tissue exam by pathologist	69.62	74.11	-6%
88305-26	Tissue exam by pathologist	39.84	39.74	0%
88305-TC	Tissue exam by pathologist	29.79	34.37	-13%
88307-Global	Level V, tissue exam by pathologist	269.88	312.21	-14%
88307-26	Level V, tissue exam by pathologist	87.93	87.36	1%
88307-TC	Level V, tissue exam by pathologist	181.96	224.85	-19%
88312-Global	Special stains, group 1	99.77	98.82	1%
88312-26	Special stains, group 1	28.35	28.29	0%
88312-TC	Special stains, group 1	71.42	70.53	1%
88313-Global	Special stains; group 2	70.70	69.10	2%
88313-26	Special stains; group 2	12.56	12.53	0%
88313-TC	Special stains; group 2	58.14	56.57	3%
88331-Global	Pathology consult during surgery	98.69	97.03	2%
88331-26	Pathology consult during surgery	66.04	65.52	1%
88331-TC	Pathology consult during surgery	32.66	31.51	4%
88341-Global	Immunohistochemistry (Add'l stain)	92.23	90.23	2%
88341-26	Immunohistochemistry (Add'l stain)	29.79	27.93	7%
88341-TC	Immunohistochemistry (Add'l stain)	62.45	62.30	0%
88342-Global	Immunohistochemistry (1st stain)	108.38	107.41	1%
88342-26	Immunohistochemistry (1st stain)	37.32	37.24	0%
88342-TC	Immunohistochemistry (1st stain)	71.06	70.18	1%
88360-Global	Tumor immunohistochem/manual	142.12	121.73	17%
88360-26	Tumor immunohistochem/manual	57.42	56.57	2%
88360-TC	Tumor immunohistochem/manual	84.7	65.16	30%
88361-Global	Tumor immunohistochem/computer	156.83	149.66	5%
88361-26	Tumor immunohistochem/computer	61.01	60.87	0%
88361-TC	Tumor immunohistochem/computer	95.82	88.79	8%
G0416-Global	Prostate Biopsy, any method	490.96	534.20	-8%
G0416-26	Prostate Biopsy, any method	186.26	157.90	18%
G0416-TC	Prostate Biopsy, any method	304.70	376.30	-19%

*Conversion factor for 2017 is 35.8887

**Conversion factor for 2016 is 35.8043

Source: Final Medicare Physician Fee Schedule 2017

PATHOLOGISTS HAVE OPTIONS FOR AVOIDING PENALTIES (*cont'd from page 1*)

CMS on October 14 published a final rule implementing provisions of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA repealed the sustainable growth rate formula (SGR) previously used to establish Medicare payment for physicians and replaced it with new payment pathways called the Quality Payment Program (QPP).

Under this program, physicians may choose to participate in the Merit-based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (APMs). Medicare payment adjustments to physicians in the program range from +/-4% starting in 2019 to +/-9% in 2022 and beyond.

The final rule also provides a new definition of non-patient-facing physicians. CMS will now define this category as those physicians with 100 or fewer patient-facing encounters (up from 25 patient encounters in the proposed rule). If 75% of the members in a group are considered non-patient-facing, then the entire group is considered to be non-patient-facing. CMS will notify pathologists about whether they meet this definition before the beginning of the MIPS performance period. CMS also is expected to issue sub-guidance on MACRA and MIPS by the end of the year that will provide additional information on exactly which services and codes will be considered non-patient-facing.

MIPS Reporting


Jon Myles, MD

Pathologists are required to participate in the MIPS program. However, they may avoid Medicare penalties by reporting just one quality measure and may actually get a bonus if they report more, according to Jon Myles, MD, FCAP, Chair of the Economic Affairs Committee for the College of American Pathologists (CAP). Those who report on six applicable measures in 2017 and participate in a high-impact clinical practice improvement activity will be eligible for a bonus of up to 4% in 2019. Those who report for just 90 days may receive a partial bonus.

Under the final rule, physicians have four MIPS tracks to choose from:

1. **Don't Participate.** If you don't send in any 2017 data, then you receive a negative 4% payment adjustment.
2. **Test MIPS.** If you submit a minimum amount of 2017 data to Medicare (one quality measure or one improvement activity, for example), you can avoid a downward payment adjustment.
3. **Partial Year Reporting.** If you submit quality data to Medicare for 90 days in 2017, you may earn a neutral or small positive payment adjustment.
4. **Full Year Reporting.** If you submit a full year of 2017 data to Medicare, you may earn a moderate positive payment adjustment.

There are four performance categories used to determine payment adjustments under MIPS: quality, advancing care information, clinical practice improvement activities and resource use.

The quality category replaces the Physician Quality Reporting System (PQRS); clinicians may report up to six quality measures. Advancing care information replaces the EHR incentive program, but non-patient-facing clinicians do not need to report on this category. Clinical practice improvement activities is a new category; clinicians must attest that they completed up to four im-

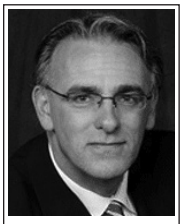
provement activities (such as timely communication of test results and improving communication among healthcare team members). The resource use category replaces the value-based modifier.

Quality Reporting Measures

Pathologists, who are considered non-patient-facing physicians, only need to concern themselves with the quality category, which will count for 85% of the score used to determine payment adjustments, and clinical practice improvement activities, which will account for 15% of their score.

In the quality performance category, pathologists may choose from the following quality reporting measures:

- Breast cancer resection pathology
- Colorectal cancer resection pathology
- Barrett's esophagus pathology
- Radical prostatectomy
- Evaluation of HER2 for breast cancer patients
- Lung cancer reporting (biopsy/cytology specimens)
- Lung cancer reporting (resection specimens)
- Melanoma reporting



Mick Raich

To avoid a penalty in 2019, pathologists need to report just one of the above items during the 2017 performance year. However, Mick Raich, President of Vachette Pathology (Blissfield, MI), advises that pathologists "hit the ground running" if you're already confident in your quality reporting since clinicians can receive a bonus. "In 2017, CMS expects non-patient facing specialists who are seeking a bonus to report at least six quality measures for 50% of their Medicare patients if reporting via claim and to report on at least one high-weighted or two medium-weighted practice improvement activities," he says.

Ongoing Concerns

While the CAP is pleased that CMS made changes to its proposals on non-patient-facing physicians in the final rule, the organization does still have some concerns about how the performance categories are weighted for pathologists, says Dr. Myles. If a category does not apply to pathologists, such as advancing care information, CMS would apply a zero weight rather than an average or median score, he explains. This results in other categories, such as quality performance, being weighted more heavily.

"We think that's bad because it doesn't spread out the risk," says Dr. Myles. "So one of the things the CAP is advocating for is a neutral score for the category that doesn't apply to you, and we are exploring the development of measures for advancing care information that pathologists could participate in. The CAP is also working to expand the clinical practice improvement activities to encompass more activities that pathologists do to improve patient care, such as participating on tumor boards and being involved with blood banking."

SPOTLIGHT INTERVIEW WITH NORTHWELL'S JAMES CRAWFORD

Northwell Health, formerly North Shore-Long Island Jewish Health System, is a New York-based integrated health system consisting of 21 hospitals and more than 450 ambulatory and physician practices. *Laboratory Economics* recently spoke with James Crawford, MD, PhD, Executive Director and Senior Vice President for Laboratory Services at Northwell Health (Great Neck, NY).


James Crawford, MD, PhD

Why did North Shore-Long Island Jewish Health System change its name to Northwell Health?

The health system is now supra-regional. We extend into Westchester County, and we are affiliated with other entities across the United States and those affiliations are likely to grow. "North Shore-Long Island Jewish" is very geographically anchored. Northwell Health captures the essence of our goal of being a provider of "health" services with an eye on wellness, not just sickness.

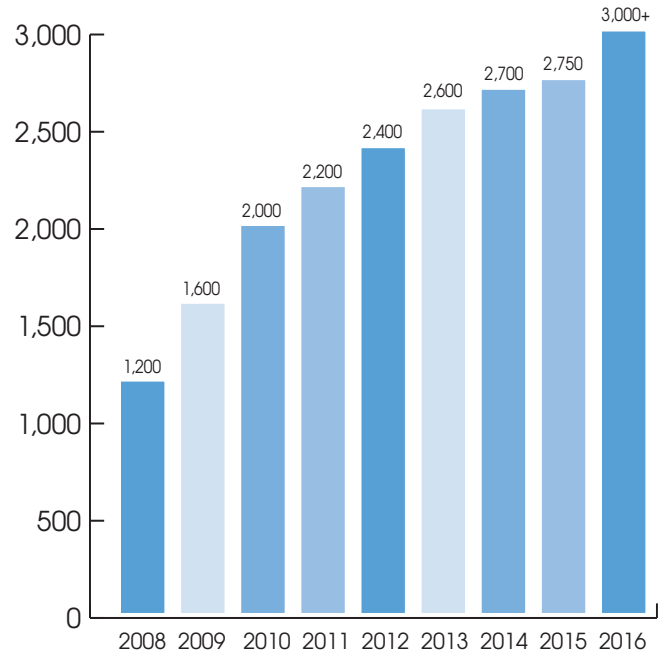
What are the biggest changes that have occurred in the laboratory since NorthShore became Northwell?

The trajectory was already there. 2016 has seen alignment of the expansive health system vision and laboratory vision. This is partly by circumstance because we have been asked to provide leadership and assistance to other hospital-based clinical laboratories in our region, specifically in Brooklyn. For example, in June 2016, Coney Island Hospital of New York City Health and Hospitals asked us to provide management oversight to ensure that their clinical laboratory performs at a high level. This moves us beyond the comfort zone of our own health system's footprint. In so doing, we believe we can be a model for best laboratory practices in a broader geographic setting.

Northwell has purchased a number of physician practices – how is this benefitting the health system?

Northwell has grown from 1,200 employed physicians to over 3,000 in the past eight years. In many cases, acquired physician practices already knew Northwell through the laboratory, since we often were already their laboratory service provider. Now with an extensive ambulatory network, Northwell can truly provide coordinated care for our patients across all healthcare settings.

Number of Employed Physicians at Northwell Health



Source: Northwell Health

The acquisition of physician practices has brought more test volume to Northwell's core laboratory. On August 1, 2016, for example, Northwell acquired University Physicians Group, which is Staten Island's largest group of internal medicine physicians with 50 doctors at 25 offices on Staten Island and in Brooklyn.

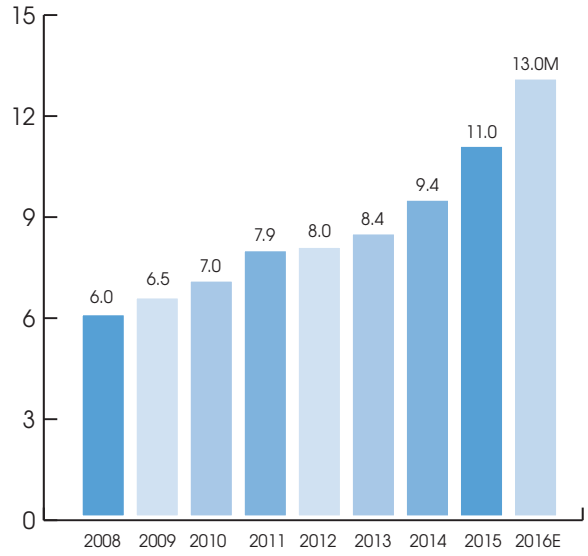
Which areas of testing are growing the fastest?
With each new hospital that comes in, there is an incremental uptick in reference testing, but the annualized steady growth has been in the ambulatory outreach arena. In 2008, our reference laboratory performed approximately six million billable tests. For 2016, we are targeting 13 million billable tests. In addition, we have been specifically growing anatomic pathology and esoteric testing. In December 2015 we formed an alliance with OPKO/BioReference Labs to bring precision medicine to our health system. Our health system is responsible for 40,000 live births per year and 19,000 new cancer diagnoses. That's a lot of need for carrier screening, non-invasive prenatal testing, and cancer testing.

Tell me about the joint venture cooperative with the New York City Health and Hospitals network of laboratories.
We were approached in 2011 by Health and Hospitals about working together. Our respective health systems are very well matched in terms of our mission and our demographics. In 2014 we formed an alliance, starting with our doing all of their reference work. We are a third of the way to getting on the same LIS platforms and are working to standardize testing across both health systems.

What is Northwell's strategy going forward to remain competitive in today's challenging market?
Northwell Health Laboratories are aiming to be a best-practice, supra-regional laboratory network. A theme is local and regional integration based on the premise that in-house laboratory services are a core competency of a highly-functioning health system.

We also are a founding member of Project Santa Fe, which includes TriCore, Henry Ford, Geisinger and Kaiser Permanente. The goal is to provide thought leadership to laboratories during the next era of American healthcare. The first deliverable is a white paper articulating what integrated laboratory services can mean to patients and health systems. The second is a portfolio of demonstration projects that can show the value of laboratory leadership programs across multiple health systems.

Northwell Health's Core Lab Test Volume*



*Includes hospital reference testing and outreach/ other testing

Source: Northwell Health

Northwell operates a fully automated, 60,000-square-foot core laboratory in Lake Success, NY, that currently performs approximately 13 million tests annually. The majority of the testing is esoteric, low-volume tests for Northwell's 21 hospitals. The core lab also performs about 1.9 million outreach tests per year for physician practices throughout the New York City area.

What do you see as the biggest challenge for the lab industry over the next five years?
The two concepts I use are middle game and end game. The end game is when a majority of health care is under risk contracting, whereby the providers themselves are responsible for the medical loss ratio and the cost of providing care for their patients. I believe the laboratory can be of tremendous value for the total cost of care and patient outcomes.

The middle game is alternative payment models. My concern in this middle period as we look at the decade between 2010 and 2020, is whether the lab industry is going to become commoditized beyond the point of recovery. My hope is that commoditization of laboratories will not outpace our ability to ultimately emerge as being of high value.

MORE ON BeaconLBS ROLLOUT IN TEXAS

As previously reported, UnitedHealthcare is expanding its use of BeaconLBS (Montvale, NJ), a lab benefit management program owned by LabCorp, to cover approximately 600,000 fully-insured UHC commercial members in Texas effective March 1, 2017 (see *LE*, October 2016, p. 1). UHC has used the system in Florida for the past two years and LabCorp expects it to be expanded into other states.

The program requires physicians to file advance notification using BeaconLBS's Physician Decision Support software when ordering certain high-value outpatient lab tests and most pathology services. UHC says that ordering physicians must use the program to make advance notification for these tests as a prerequisite for payment to the performing lab or pathologist.

Among the 79 tests that currently require advance notification are cystic fibrosis panels, Vitamin D, thyroid panels, allergy panels, Pap tests and DNA-based HPV tests, as well as essentially all anatomic pathology services, including biopsies and immunohistochemistry.

UHC has emphasized that its advance notification process will not deny or prevent physicians from ordering a test they deem necessary. Prenotification allows UHC through BeaconLBS to verify member benefits and share evidence-based clinical guidelines with ordering physicians, according to UHC. However, UHC says that if a member's diagnosis is not supported in its clinical policy, then the member will be liable for payment of the test.

In addition, UHC says all UHC-contracted labs located in Texas, as well as nationally-contracted labs that serve patients who live in Texas, must register at BeaconLBS.com. The registration process includes providing quality criteria, mapping test information and preparing to submit a laboratory test identifier on claims.

UHC Says BeaconLBS Improved Quality and Lowered Cost in Florida

UHC initially launched a BeaconLBS pilot program for 570,000 fully-insured commercial members in Florida in October 2014. According to UHC spokeswoman Kristie Hellmer, the program improved quality and lowered costs for lab tests ordered during the two-year pilot:

- Sixty-seven percent of lab orders processed through BeaconLBS met evidence-based guidelines, up from 46% prior to the pilot.
- Ninety-five percent of members now use in-network labs.
- UHC members saw an average out-of-pocket cost savings of 19% due to greater use of in-network labs and greater physician compliance with evidence-based guidelines.

Florida Rollout Upsets Doctors and Labs

UHC says that roughly 80% of Florida physicians now use BeaconLBS, which indicates increased familiarity and comfort using the system. However, the initial rollout was opposed by several large medical societies, including the Florida Medical Association, which said the program infringes on physicians' decision making and requires extensive data entry.

Labs have also been frustrated because they are penalized with non-payment if an ordering physician does not properly use the BeaconLBS system.

In addition, labs say that BeaconLBS directs lab work to a small network of labs (deemed "Labs-

of-Choice") that is dominated by LabCorp. Current Labs-of-Choice in Florida include all LabCorp-owned companies including Integrated Oncology, Integrated Genetics, Dianon and MedTox. There are also 15 other non-LabCorp labs that are Labs-of-Choice, including Bako Pathology Services, Bostwick Laboratories, Clarient Diagnostic Services (owned by NeoGenomics), and Ketchum, Wood & Burgert Pathology Associates.

Labs-of-Choice are featured on the first screen when physicians order tests through BeaconLBS. To choose another UHC network lab, physicians must select a search button to view a dropdown box with a list of network labs.

BeaconLBS administers payment for test orders made to Labs-of-Choice. Approximately $80 million per year of lab test revenue currently is being ordered through the Labs-of-Choice network in Florida and is being booked as revenue for LabCorp. BeaconLBS is now seeking to add Texas labs to its Labs-of-Choice network.

BeaconLBS's Labs-of-Choice

Laboratory Name	*Market*	*Services*
Aegis Sciences Corp.	Florida	Toxicology
Ambry Genetics	National	Genetic/Molecular
Bako Pathology Services	National	Pathology
Bostwick Laboratories	National	Pathology
Broward Health	South FL	Clinical Testing and Pathology
Clarient Diagnostic Services	National	Pathology
Dianon/LabCorp	National	Pathology
Diatherix Laboratories	Florida	Genetic Testing
Dominion Diagnostics	National	Toxicology
FirstPath, Inc.	Florida	Pathology
Granite Diagnostic Labs	Florida	Clinical Testing
Gulf Coast Dermatopathology	Florida	Pathology
Integrated Genetics/LabCorp	National	Genetic Testing
Integrated Oncology/LabCorp	National	Genetic Testing
Ketchum, Wood & Burgert Pathology	Florida	Pathology
LabCorp	National	Comprehensive Testing
Logan Laboratories	Florida	Toxicology
MedTox Labs/LabCorp	National	Toxicology
Millennium Health	National	Toxicology
RDL Reference Laboratory	Florida	Clinical Testing

Source: UnitedHealthcare Doc#: PCA19234_20151027

Will BeaconLBS Help LabCorp Keep its National UHC Contract?

Here's how LabCorp CEO Dave King answered on an October 26 conference call:

"Yes, I think BeaconLBS is an important component of our strategic relationship with United. It's a tool that we invented basically to address what we perceived to be a need in the marketplace for two things – better decision support around selection of high-value testing as well as better ability for payers to manage the trend in high-value testing, and so the fact that United has made the decision that they want to expand to another market. We're developing capabilities for molecular testing and want to develop capabilities that enhance not only test selection but also as a platform for HEDIS and Star ratings. I think these are all things that speak to the importance of this tool and the value that's placed on the relationship, and yes, obviously once we do the Texas implementation, we'll be looking to expand to other markets as well."

Note: LabCorp became the primary national lab for UnitedHealthcare in 2007. This contract will expire at the end of 2018.

FDA OVERSIGHT OF LDTS UNLIKELY UNDER TRUMP (*cont'd from page 1*)

Other changes to healthcare policy that Weissman believes are likely under a Trump administration:

- **Reform of the Affordable Care Act (ACA)**. While Trump campaigned on repeal of the ACA, he has since said there are parts of the law he would like to keep, such as preventing denial of coverage for people with pre-existing health conditions and letting young people stay on their parents' health plans until age 26. "It will be extremely difficult to keep the good stuff and get rid of everything else without the whole thing being thrown out of balance," says Weissman. Under ACA reform, health exchanges and subsidies are likely to be phased out over a period of time. Trump has said he wants to make individual mandate premiums tax deductible, support and expand Health Savings Accounts and allow insurers to sell policies across state lines.
- **End of Medicaid expansion**. Such expansion would likely be replaced with block grants to states. "The federal government would give each state a pot of money and say you can largely do what you want with it," says Weissman. "There would not be the type of robust minimum Medicaid requirements that we have now."
- **Move Medicare to a premium-support model**. Although Trump said during the campaign that he would not touch entitlements, Weissman believes he may ultimately support efforts by GOP leaders, particularly in the House, to phase out Medicare. Under the most likely approach, consumers of a certain age to be determined as Medicare eligible would receive some money or a credit to be applied toward purchase of a private insurance Medicare policy. "[Speaker of the House] Paul Ryan is wedded to that," says Weissman. "This would fundamentally change the nature of Medicare."

WALGREENS SUES THERANOS FOR $140 MILLION

Walgreens has filed a $140 million breach of contract suit against Theranos Inc. (Palo Alto, CA), alleging that Theranos misled Walgreens about how far along its lab-testing technology was when the original partnership was made in 2010.

The most interesting point revealed in the lawsuit was that Theranos only served a total of about 275,000 Walgreens' customers during the three years it operated PSCs at Walgreens' stores in Arizona from March 2013 to June 2016. Furthermore, the lawsuit states that test results for 11.3% of these customers, or 31,000, had to be voided and/or corrected. This information contradicts Theranos' claim that its Walgreens' PSCs had served more than three million patients and is another indication of the lack of demand for direct-to-consumer testing services.

Theranos, which shut down all its lab operations in October (see *LE*, October 2016), is also facing a lawsuit from one of its major investors and numerous lawsuits filed by its former customer-patients.

PGXL LABORATORIES FILES FOR BANKRUPTCY

Pharmacogenetics Diagnostic Laboratory LLC (Louisville, KY), which does business as PGXL Laboratories, filed for Chapter 11 bankruptcy on November 8 in the U.S. Bankruptcy Court Western District of Kentucky. The company stated its primary reason for bankruptcy is a recent assessment against it by Medicare contractor CGS Administrators. Last month CGS Administrators—the Medicare contractor for the region—issued an overpayment demand to PGXL for more than $26 million due to the results of a recent audit performed by AdvancedMed, the Zone Program Integrity Contractor for Medicare Part B in Kentucky. The bankruptcy filings by PGXL stated that the company currently has 21 employees and anticipates gross revenues of approximately $8.8 million in 2016.

LAB STOCKS UP 7% YTD

Sixteen lab stocks have risen by an unweighted average of 7% year to date through November 15. In comparison, the S&P 500 Index is up 6%. The top-performing lab stocks so far this year are Psychemedics, up 134%, Exact Sciences, up 89%, and Enzo Biochem, up 52%. At the big two commercial labs, Quest Diagnostics is up 20% and LabCorp is up 4%.

Company (ticker)	Stock Price 11/15/16	Stock Price 12/31/15	2016 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$1.60	$3.30	-52%	$26	NA	1.1	0.9
CombiMatrix (CBMX)	2.35	10.95	-79%	6	NA	0.5	0.5
Enzo Biochem (ENZ)	6.83	4.50	52%	316	7.0	3.1	3.5
Exact Sciences (EXAS)	17.41	9.23	89%	1,890	NA	24.0	5.2
Foundation Medicine (FMI)	22.35	21.06	6%	784	NA	6.9	4.0
Genomic Health (GHDX)	33.13	35.20	-6%	1,110	NA	3.5	7.7
Invitae (NVTA)	8.53	8.21	4%	277	NA	14.6	3.9
LabCorp (LH)	128.03	123.64	4%	13,190	20.3	1.4	2.4
Myriad Genetics (MYGN)	16.98	43.16	-61%	1,160	13.1	1.6	1.6
NeoGenomics (NEO)	9.15	7.87	16%	718	NA	3.4	3.6
Opko Health (OPK)	10.23	10.05	2%	5,700	39.5	4.7	2.7
Psychemedics (PMD)	23.77	10.14	134%	130	29.0	3.8	9.3
Quest Diagnostics (DGX)	85.20	71.14	20%	11,810	18.1	1.6	2.5
Rosetta Genomics (ROSG)	0.68	1.23	-45%	14	NA	1.3	1.1
Sonic Healthcare (SHL.AX)	22.02	17.87	23%	9,160	20.2	1.8	2.5
Veracyte (VCYT)	7.25	7.20	1%	238	NA	3.9	6.8
Unweighted Averages			7%		21.0	4.8	3.6

Source: Capital IQ

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