LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UNITEDHEALTHCARE MOVING AHEAD WITH FULL IMPLEMENTATION OF BeaconLBS

Despite protests from CAP and the Florida Medical Assn., UnitedHealthcare is moving ahead with full implementation of its lab benefit management program (LBMP) in Florida effective January 1, 2015. The program is being managed by BeaconLBS, a wholly-owned subsidiary of LabCorp, and will affect some 500,000 commercial members in Florida.

UnitedHealthcare's LBMP requires referring physicians to notify Beacon if they intend to order any tests that appear on an 81-test list that includes fast-growing high-volume clinical lab tests like Vitamin D and allergy panels as well as Pap tests and nearly all anatomic pathology services.

UnitedHealthcare's started a "soft launch" of the program in October (see *LE*, October 2014) that delayed enforcement of its claims rejection component. However, starting January 1, UnitedHealthcare says it will reject lab test claims that have not been "pre-notified" through the BeaconLBS system at the time the physician orders the test. *Cont'd on pages 7-9.*

OUTPATIENT BUNDLING MEANS LOWER VOLUME

As everyone now knows, starting next year pathology technical services provided to hospital outpatients covered by Medicare will no longer be billed separately and will instead operate within a DRG-type budget. Every pathology lab service provided to hospital outpatients will now be viewed by hospital administrators as an expense rather than added revenue. As a result, pathology service volume in hospital outpatient departments (HOPDs) is expected to decline. That means fewer 88305s and special stains for each outpatient biopsy operation.

CMS says that bundled payments encourage hospitals to "scrutinize the services ordered by practitioners" and "to use the most cost-efficient item that meets the patient's needs."

The change to bundled payments could also bring big changes to independent pathology labs that are contracted to provide technical services to HOPDs. *Continued on page 4.*

PALMETTO SEEKS TO ELIMINATE CODE STACKING FOR MolDx TEST PANELS

Starting January 1, Medicare contractor Palmetto GBA says that labs that perform molecular test panels (*i.e.*, tests with multiple molecular markers performed on a single sample) can no longer bill for each marker individually. Instead labs must now register each panel under Palmetto's MolDx program, obtain a unique MolDx identifier for each panel and bill using a single CPT code. *Continued on page 2.*

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HAPPY HOLIDAYS!

PALMETTO SEEKS TO ELIMINATE CODE STACKING (*cont'd from p. 1*)
Palmetto, which is owned by BCBS of South Carolina, processes Part B Medicare claims in North Carolina, South Carolina, Virginia and West Virginia. Its MolDx program, which determines coverage and reimbursement for molecular tests, is also followed by the Medicare contractor Noridian in California, Nevada and Hawaii.

Palmetto began notifying affected labs on November 17, 2014, and they have been given 30 days to obtain unique MolDx identifiers for their molecular test panels. Beginning January 1, 2015, Palmetto says its MolDx program will set edits to reject panel test claims that bill for multiple CPT codes rather than with a single CPT code and a unique MolDx identifier.

The new policy has enraged labs who believe that Palmetto's MolDx program is sidestepping the current CPT code system in an effort to reduce reimbursement for molecular test panels. The California Clinical Lab Assn. has requested a meeting with Tamara Syrek Jensen, acting director for the Coverage and Analysis Group at CMS, to protest the new policy. The new MolDx policy follows CMS's movement away from the "code stacking" method of billing that molecular testing labs used prior to the introduction of more than 100 specific CPT codes for molecular tests in 2013.

For example, Palmetto says that labs that currently perform a blood clotting panel that assesses three markers, CYPC19 (CPT 81225), Factor II (CPT 81240) and Factor V (CPT 81241), are billing for all three CPT codes at a total of $442.

Another example would be the pharmacogenetic testing panels that some labs are marketing to guide prescription drug decisions. One such test panel includes nine different markers with combined CPT code reimbursement of approximately $1,500.

Under the new MolDx policy, each test panel would receive a unique z-code identifier and then be billed using a single code for an unlisted molecular pathology procedure (CPT 81479).
The new MolDx system gives Palmetto the opportunity to: 1) decline coverage for test panels it deems unnecessary; or 2) set new reimbursement levels for test panels at rates less than the sum of their component CPT codes. The rationale is that there are economies of scale for panel tests performed with the same extraction and testing platform and these savings should be shared with the Medicare program.

However, *Laboratory Economics* notes that the economies-of scale argument is diminished when panels are created with tests that are run on different platforms such as those provided in Palmetto's blood clotting panel example. Palmetto's assumption is that panel tests are all next-generation-sequencing (NGS) services, but that is not always the case.

Palmetto announced the policy for its jurisdiction (NC, SC, VA and WV) in mid-November leaving no time for stakeholder comment. Noridian is expected to follow the same policy.
That's important because Noridian processes claims in California where a large number of the nation's molecular testing labs are located.

Furthermore, *Laboratory Economics* notes that there is the potential for Palmetto's MolDx policies to become the national standards, if CMS uses its new authority to consolidate the MAC jurisdictions that process laboratory claims.

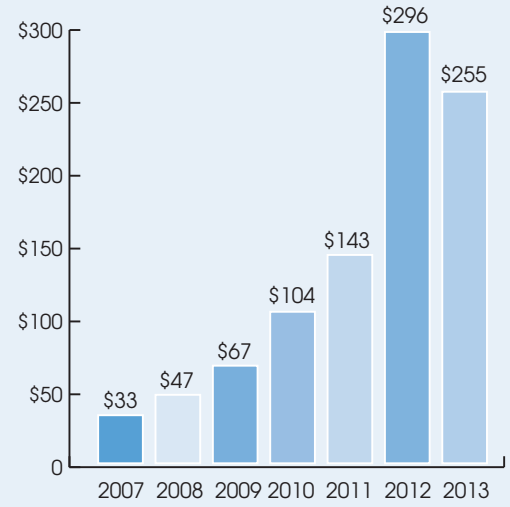
On April 1, 2014, new Section 1834A, "Improving Policies for Clinical Diagnostic Laboratory Tests," was added to the Social Security Law (the Act) by the Protecting Access to Medicare Act of 2014 (PAMA). The section states: "The Secretary may designate one or more (not to exceed 4) medicare administrative contractors to either establish coverage policies or establish coverage poli-

cies and process claims for payment for clinical diagnostic laboratory tests, as determined appropriate by the Secretary." To date, CMS has not made any announcements regarding any potential process or criteria to consolidate the MAC jurisdictions that process laboratory claims.

Meanwhile, *Laboratory Economics* notes that molecular testing labs are already struggling with the lower reimbursement rates and higher denial rates that resulted from the introduction of 100+ new molecular CPT codes in 2013. The switch from code-stacking with generic codes to more specific codes resulted in about a 15% decline in Medicare reimbursement for molecular tests. But the rise in claim denials has been even more problematic. An average of 42.6% of Part B claims for high-volume molecular tests were denied in 2013. In comparison, an average of only 5% to 10% of Part B claims for routine lab tests are denied each year.

"2014 has been better than 2013 since we have seen some stabilization in policies for some of the covered genetic services," according to Lale White, President of the billing firm XIFIN Inc. (San Diego, CA). However, White says that there is still roughly a 40% denial rate because current policies often don't align with the standard of care for a large number of patient indications. "The predominant problem is with getting genetic services reimbursed for cancer patients and patients with cardiovascular disease."

Medicare Part B Spending on Molecular Tests ($ millions)



Source: CMS (for 2007-2012 sum of allowed charges for CPT codes 83890-83914, 88381 and 88384-88386; for 2013 sum of allowed charges for CPT codes 81200-81407, 81479, 88381 and G0452)

Medicare Part B spending on molecular testing had grown at an average annual rate of 42% between 2007 and 2012. Reduced reimbursement and increased denials led to a drop of 14% in 2013.

Denied Claims for High Volume Molecular Tests in 2013

CPT Code	Short Description	Submitted Claims	Denied Claims	% Denied	Allowed Charges
81225	CYP2C19 genotype	245,078	46,171	18.8%	$58,801,541
81226	CYP2D6 genotype	166,028	36,805	22.2%	53,073,157
81211	BRCA1, BRCA2 gene analysis	21,933	4,505	20.5%	48,565,179
81227	CYP2D9 genotype	143,567	59,424	41.4%	13,571,855
81241	Factor V gene analysis	196,803	29,273	14.9%	12,820,651
81291	MTHFR gene analysis	186,332	34,746	18.6%	12,799,131
81213	BART testing	19,587	3,848	19.6%	9,239,682
81240	Factor II gene analysis	188,447	28,302	15.0%	7,484,912
81479	Unlisted molecular pathology procedure	219,824	206,703	94.0%	4,158,826
81235	EGFR mutation analysis	15,153	4,539	30.0%	2,480,170
81404	Molecular pathology procedure, level 5	19,613	10,140	51.7%	2,360,776
81401	Molecular pathology procedure, level 2	272,576	254,783	93.5%	2,208,629
81275	KRAS mutation analysis	13,950	5,851	41.9%	1,852,837
81206	BCR/ABL1	19,988	3,935	19.7%	1,693,869
G0452	Molecular pathology interpretation	144,475	69,448	48.1%	1,422,489
Totals		1,873,354	798,473	42.6%	$232,533,704

Source: *Laboratory Economics* from CMS

OUTPATIENT BUNDLING MEANS LOWER VOLUME (*cont'd from page 1*)

"I think CMS would say that lower utilization in some cases would be the right choice — this is part of the efficiency incentives the agency believes it is creating with packaging," observes Jugna Shah, President of Nimitt Consulting (Washington, DC), which specializes in hospital outpatient reimbursement issues.

"Hopefully, patients will continue to receive all of the services they need, during the same visit... without any fragmentation of care...but that any 'unnecessary/extra testing/imaging' will be eliminated," adds Shah.

Shah believes it's just a matter of time before private payers like Aetna and UnitedHealth follow Medicare and start making more bundled payments for outpatient surgery procedures.

Meanwhile, Shah says that there is no easy way to determine if the 2015 bundled payment rates have been appropriately priced to cover all bundled services that they are supposed to cover. She suggests that hospitals take a handful of claims and calculate their current payment rates versus the bundled payments they will receive next year.

Medicare's new packaging policy only applies to surgical procedures performed in hospital outpatient departments and not those performed in free-standing ambulatory surgery centers (ASCs).

For example, *Laboratory Economics* calculates that a colonoscopy (CPT 45380/APC 0143) with two biopsy specimens (CPT 88305/APC 0433 x 2) and one special stain (88312/APC 0342) is currently reimbursed by Medicare through the OPPS fee schedule at total reimbursement of $830. Next year, this same example will be reimbursed with a single bundled payment of $790 with a single code (CPT 45380/APC 0143). Keep in mind that professional pathology services are not being bundled and will continue to be billed separately through Medicare's Physician Fee Schedule in 2015.

Common Hospital Outpatient Surgery Procedures

APC	CPT	Description	2015	2014	% Chg.
0143	45380	Colonoscopy with biopsy	789.55	736.84	7.15%
0015	11100	Biopsy skin lesion	146.08	147.39	-0.89%
0141	43239	Egd biopsy single/multiple	745.31	670.47	11.16%
0184	55700	Biopsy of prostate	1,461.73	1,061.99	37.64%
0113	38525	Biopsy of lymph node	2,343.59	2,026.95	15.62%

Source: *Laboratory Economics* from CMS

The table above lists some common biopsy procedures and the final OPPS rates for 2015. Most are going up to help pay for the pathology tests and imaging services that are being bundled into them.

But is it enough? Dennis Padget, Lead Consultant at APF Consulting Services (Laguna Beach, CA), is skeptical. Padget says his review of common biopsy procedures showed the increased rates for 2015 are not sufficient to cover the associated bundled pathology services let alone all the other services that are being bundled.

What Should Independent Pathology Labs Do?

Mick Raich, President of Vachette Pathology (Blissfield, MI), says that hospital outpatients can represent 25% to 30% of overall revenue for some independent pathology labs. Most current contracts to provide TC services to hospital outpatients are set at an average of 75% of OPPS rates, but can range anywhere from 50% of OPPS to upwards of 120%, according to Raich. "Begin negotiations with hospitals now. If you wait, you run the risk of having to go back to try and recoup monies, or worse yet, not getting paid."

Jane Pine Wood, attorney at McDonald Hopkins (Chicago, IL), suggests that independent pathology labs check the term and termination provisions of their agreements with hospitals. "I would not necessarily expect many hospitals to exercise early termination rights. However, I would expect most hospitals to more aggressively negotiate pricing when the agreements come up for renewal, or even put the hospital laboratory services out to bid." It will be important for laboratories to determine their cost of providing testing, to ensure that they don't negotiate below cost, and to have an idea of comparable pricing in the marketplace, according to Pine Wood. For many hospitals (and particularly their medical staffs), customer service can be very important, and laboratories who believe that either their pricing or their contracts may be in jeopardy should focus upon customer service and winning the allegiance of both top ordering clinicians as well as the laboratory administrator, she advises.

Dennis Padget says that the switch to bundling is an opportunity for independent labs to proactively reach out to their hospital clients. For example, he says that those independent labs that are currently billing hospitals directly for pathology professional services should switch to billing Medicare directly. The savings to the hospital can be used by independent labs as negotiating leverage to maintain their technical fees from the hospital under the new bundled payment system.

And finally, **Robert Mazer,** attorney at Ober Kaler (Baltimore, MD), says that regardless of the approach taken by the hospital, it will be required to pay independent labs the fair market value of their services, without regard to one party's referrals of Federal healthcare business to the other or its ability to otherwise generate such business for the other party. Mazer notes that these types of fair market value determinations can be complicated because of the scarcity of available market data reflecting pricing arrangements for such services between independent parties who are unable to generate business for each other.

LAB INDUSTRY AWAITS MORE INFO ON CLFS REPRICING

The Protecting Access to Medicare Act of 2014 (PAMA) gave CMS the authority to use private payer rates to reprice nearly all lab tests on the Part B Clinical Lab Fee Schedule effective in 2017.

This initiative has the potential to dramatically change the landscape of the entire U.S. clinical lab market. That's because it allows for maximum annual rate cuts of 10% per test from 2017-2019, followed by cuts of up to 15% per year from 2020-2022. After six years, for example, the cumulative effect of maximum annual cuts would lower the Medicare rate on a $15 lab test down to $6.72.

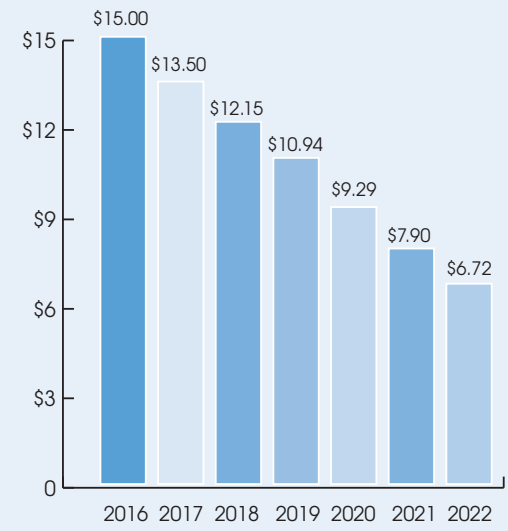
CMS had been expected to release crucial details for the repricing initiative through a Proposed Rule by December 31. But it now looks like the Proposed Rule won't be released until early next year. The mandated deadline for issuing the Proposed Rule is June 30, 2015.

The Proposed Rule is expected to detail exactly which types of labs fall under the category of "applicable laboratory" and will be required to report private payer data to CMS. The Proposed Rule is also expected to set low-volume or low-revenue thresholds that excuse smaller labs from reporting.

The hope is that, along with commercial labs, hospital outreach labs and large POLs will be required to report their pricing data. Without the inclusion of hospitals and POLs, the "weighted median" prices calculated by CMS will be dominated by the low prices offered by the national lab companies.

CMS has noted on several occasions that when a hospital furnishes testing services for non-hospital patients, it is "functioning as an independent lab," notes Alan Mertz, President of the American Clinical Laboratory Assn. "Thus, it seems reasonable, and justified by the terms of the statute, to determine that a hospital laboratory performing outreach testing is an "applicable laboratory,"" he adds.

Maximum Potential Rate Reductions for a $15 Lab Test



Source: *Laboratory Economics*

In addition, as part of the reforms, CMS is required to establish an independent advisory panel of up to 15 individuals with expertise in clinical lab tests, which may include representatives of clinical labs, molecular pathologists and experts in laboratory economics. The panel will be headed by a Chair who is a federal official designated by the Secretary of Health and Human Services or the Administrator of CMS. The deadline for submitting nominations was November 26, 2014.

The panel will provide CMS with input on the calculation of weighted median lab test prices using private payer rates. It will also provide recommendations to CMS on the factors to be used in determining coverage and payment processes for new clinical lab tests. CMS has until July 1, 2015 to select and finalize the panel.

Timetable for CLFS Reform

- Proposed rule to be issued on the process by June 2015
- January 1, 2016: "Applicable laboratories" must report data on private payer payment rates and test volumes
- January 1, 2017: New CLFS rates will apply; based on weighted median of private payment rates

Source: *Laboratory Economics* from CMS

On an October 28 conference call with investors, Dave King, Chairman of LabCorp, noted that ACLA representatives had recently met with CMS to discuss how the pricing survey is going to be formulated and evaluated. "I think the good news coming away from that discussion is that CMS recognizes it's a complex task…but it has to be representative of the true market for laboratory services, including all competitors in the marketplace… not just the independent lab market," said King. "And the true market has to include commercial payer pricing to hospital laboratories that are paid on an average basis or paid off a commercial lab fee schedule," he added.

UNITEDHEALTHCARE MOVING AHEAD WITH BeaconLBS (*cont'd from p. 1*)
The Florida Medical Assn., Florida Academy of Family Physicians and the Florida Chapter of the American Congress of Obstetricians and Gynecologists are all protesting UHC's requirement that physicians use BeaconLBS to order lab tests. These organizations say that BeaconLBS places a burdensome administrative layer to the ordering and billing functions for physicians without providing fair compensation for the additional work.

UHC says it will work with state medical societies to monitor any problems or concerns that arise during implementation. However, UHC will not reimburse providers for time spent using BeaconLBS. State medical societies are asking their members to provide information on how the required use of BeaconLBS is affecting their practice workflow and delivery of patient care.

Increased Likelihood of Claims Rejection
Meanwhile, the situation for clinical labs and pathologists is more dire because they risk not getting paid by UHC for many high-volume lab tests. UHC is requiring physicians to receive permission from BeaconLBS before ordering BRCA-1 and BRCA-2 testing. In addition, UHC is requiring physicians to provide "advance notification" by ordering 79 lab tests and pathology services through BeaconLBS. Tests requiring advance notification include allergy panels, cystic fibrosis screening, HCV and HIV genotyping, lipoprotein analysis, thyroid panels, Vitamin D testing, etc. Advanced notification is also required for the majority of biopsy tests, Pap tests, immunohistochemistry and special stains.

Effective January 1, UHC says that if there is no advance notification on file and the services are performed at either a physician office or independent lab, the claim will be denied as a provider liability. Network providers cannot balance bill the member for covered services, according to UHC.

UHC has stressed that its advanced notification process does not involve a clinical coverage review that authorizes test orders. Prenotification allows UHC through BeaconLBS to verify member benefits and share evidence-based clinical guidelines with ordering physicians, according to UHC.

Required Second Opinions for Maligninant Cases
The biggest concern from CAP and the Florida Society of Pathologists (FSP) has to do with the program's requirement that nearly all malignant and pre-malignant cancer diagnoses have a second review by a subspecialist in order for the claim to be paid. "We continue to have discussions with UnitedHealthcare regarding this and other concerns the CAP has with the Florida pilot program. The pilot's secondary pathology review requirement is overly broad and subspecialty certification requirements do not reflect current practice," according to Jonathan Myles, MD, Chair of CAP's Economics Affairs Committee.

Laboratories of Choice
UHC says that tests can be ordered from all of its existing network laboratories that register with BeaconLBS. In addition, BeaconLBS has created a separate small network of labs to serve the program which have been given the designation: Laboratory of Choice.

BeaconLBS currently lists 13 labs as being Labs of Choice, including five from LabCorp. Two other labs had been on the original list (The Meditrend Group and Precision Pathology) announced in August, but have since been dropped without explanation. UHC says that Laboratories of Choice "may see increased test volume and have access to performance-based compensation." However, it not clear exactly how order flow might be steered to the Labs of Choice. Importantly, UHC says that it will continue to pay network and non-network labs directly, but BeaconLBS will process payments for Labs of Choice.

BeaconLBS Laboratories of Choice

Laboratory	*Market*	*Services*
Bako Pathology	National	Pathology
Broward Health	South FL	Clinical Lab and Pathology
Clarient Diagnostic Services	National	Pathology
Dominion Diagnostics	National	Toxicology
Granite Diagnostic Labs	Florida	Clinical Lab
Gulf Coast Dermatopathology	Florida	Pathology
KWB Pathology	Florida	Pathology
LabCorp/Dianon	National	Pathology
LabCorp/Integrated Genetics	National	Genetic Testing
LabCorp/Integrated Oncology	National	Genetic Testing
LabCorp/Medtox	National	Toxicology
LabCorp	National	Comprehensive Testing
Millennium Laboratories	National	Toxicology

Source: LabCorp/BeaconLBS

LabCorp's Perspective

"We invested in BeaconLBS in 2011 because we understood that providers need assistance in selecting the right test for their patients and payers need help at appropriately managing the utilization of laboratory testing. After extensive market analysis and an enormous amount of hard work, we invented a tool that helps physicians choose the right test at the right time and helps payers improve quality of care and thoughtfully address concerns about unit cost and trend. UnitedHealthcare launched the innovative Laboratory Benefit Management Program with BeaconLBS in Florida on October 1, and we are pleased with the rollout thus far," Dave King, Chairman of LabCorp, told investors on an October 28 conference call.

An Out-of-Proportion Focus on Lab Test Spending

In 2012, UHC issued a report detailing its spending trends on molecular diagnostics and genetic tests ("Personalized Medicine: Trends and prospects for the new science of genetic testing and molecular diagnostics"). *Laboratory Economics* thinks this report has played a big role in UHC's out-of-proportion focus on lab test spending trends and the launch of BeaconLBS.

The report estimated that average annual spending per UHC member throughout the country on molecular and genetic tests increased by about 14% per year between 2008 and 2010. Of that amount, about 70% was due to increased utilization of test services; the balance was due to higher prices and intensity or complexity. Overall, UHC estimated that it spent $478 million on molecular diagnostics and genetic tests, or an average of $1.33 per member per month, nationally in 2010. To put things in perspective, *Laboratory Economics* notes that the $478 million represented less than 1% of UHC's total medical care spending of $69 billion in 2010.

UHC Molecular & Genetic Test Spending, 2010

Total Spend	$478 Mill
Cost PMPM	$1.33
Avg. Spend per Test Procedure	$63
Annual Growth in Spending, 2008-2010	14%
Volume Growth	10%
Price Growth	4%

Source: UnitedHealthcare

Where Next for BeaconLBS?
LabCorp won't say where BeaconLBS might be deployed next. However, we do know that network development executives at BeaconLBS are actively trying to build networks of clinical and specialty labs and pathology groups in seven additional states (Colorado, Florida, Maryland, New Jersey, New York, North Carolina, South Carolina and Texas).

Is Laboratory Benefit Management the Wave of the Future?
"I believe that the introduction of benefit management into the lab industry is inevitable," answers Michael Snyder, President of Clinical Lab Business Solutions LLC (Flemington, NJ).

Here are the reasons for his contention:

1. New reimbursement models will need to be managed. Using bundled payments as an example, "How will reimbursement for lab testing be meted out if the "bundle" is paid to a group practice or facility?" Under capitation, either the deal must be exclusive or there must be a mechanism in place (i.e., LBMPs) that "splits" or shares the capitated payment.
2. Need for evidence. The plans are and will only increase their demand for evidence that demonstrates the clinical utility of a diagnostic process to improve outcomes. The evidence will need to be based on independent evaluations (vs. solely based on the lab's research) to remove bias.
3. There is not a place for all labs. Health plans are seeking the "best" labs and will turn to management entities to select small networks of labs.

However, Snyder believes that LabCorp's BeaconLBS faces a huge hurdle in trying to convince other labs to join its network. "It's the classic fox in the henhouse issue," says Snyder.

In his opinion, a Lab Benefit Manager must possess the following characteristics:

1. Independent of any major lab entity (to avoid fox in the henhouse issue)
2. Affiliation with a panel of academically rooted experts that can/will determine the evidence base necessary for the regulation of testing
3. Sufficient IT capability to interface labs, health plans, providers (docs) and a source of evidence. Ordering lab testing by physicians cannot add to the burden of the practicing docs therefore automation is critical.
4. The managed network will need to include a network comprised of clinical pathologists and genetic counselors. GC's alone cannot (and should not) provide all of the consultation to ordering docs.
5. Ability to manage multiple reimbursement models.

UNITEDHEALTHCARE PILOTS BUNDLED PAYMENT FOR CANCER CARE

UnitedHealthcare has launched a pilot program that will pay the University of Texas MD Anderson Cancer Center a bundled payment for treating patients with head and neck cancers. The three-year pilot will be conducted in MD Anderson's Head and Neck Center for up to 150 patients newly diagnosed with cancers of the salivary glands, mouth, throat and larynx, and who are enrolled in certain employer-sponsored health plans insured or administered by UnitedHealthcare. The bundled payment is expected to cover nearly all of their cancer care for a year, including surgery, chemotherapy, radiation, imaging scans and pathology tests. The terms of the contract are confidential, but total care for these patients often reaches the six figures, according to UnitedHealthcare. UHC launched a similar pilot in 2010 involving 810 breast, colon and lung cancer patients who were treated at five medical oncology groups around the United States. The July 2014 issue of Journal of Oncology Practice featured the results of that study, which showed cancer costs were cut by a third and quality was improved.

OIG TO SCRUTINIZE MEDICARE PAYMENTS TO INDEPENDENT LABS

The Office of Inspector General (OIG) has released its Work Plan for Fiscal Year 2015 (2015 Work Plan) and independent clinical labs are in the crosshairs. The OIG's 2015 Work Plan provides insight into the focus areas for the OIG in its efforts to identify fraud and abuse in the Medicare and Medicaid programs.

Specifically, the 2015 Work Plan states:

> *We will review Medicare payments to independent clinical laboratories to determine laboratories' compliance with selected billing requirements. We will use the results of these reviews to identify clinical laboratories that routinely submit improper claims and recommend recovery of overpayments. Prior OIG audits, investigations, and inspections have identified independent clinical laboratory areas at risk for noncompliance with Medicare billing requirements. Payments to service providers are precluded unless the provider has and furnishes upon request the information necessary to determine the amounts due. (Social Security Act, §1833(e).) We will focus on independent clinical laboratories with claims that may be at risk for overpayments.*

The 2015 Work Plan did not name the particular methods it would use to identify independent labs that routinely submit improper claims. However, earlier this year the OIG issued a report (see *LE*, July 2014) that found that over 1,000 labs had unusually high billing for Medicare Part B lab tests in 2010.

Measures that the OIG used to identify labs with unusual billing activity included (1) average number of claims per beneficiary or ordering physician, (2) average allowed amount per beneficiary, and (3) percentage of claims with invalid or ineligible ordering-physician numbers. And *LE* thinks that another indicator that OIG is likely to use is the percentage of submitted claims that were denied.

FORMER MAYO EXEC RESIGNS FROM QUEST

Franklin R. Cockerill III, MD, has resigned from Quest Diagnostics as part of a settlement with his former employer, Mayo Medical Labs, over allegedly stolen trade secrets.

In the lawsuit filed in October (see *LE*, October 2014), Mayo alleged Cockerill was secretly hired by Quest but continued to work as President and CEO of Mayo Medical Labs so he could steal Mayo trade secrets.

Cockerill worked at Mayo for eight years up to September 30. Cockerill officially worked for Quest as its Chief Laboratory Officer only from October 1 to October 14. On October 14, Olmstead County Judge Robert Birnbaum granted a temporary restraining order requested by Mayo that prevented Cockerill from working for Quest. Mayo Medical Labs and Quest compete for reference testing contracts with hospitals.

Mayo is not pursuing any claims against Quest. But the clinic continues to pursue its lawsuit against Cockerill to protect confidential trade secrets.

Cockerill contends he was not subject to any non-compete agreements after leaving Mayo.

ROCHE BUYS ARIOSA DIAGNOSTICS

Roche (Basel, Switzerland) has acquired Ariosa Diagnostics Inc. (San Jose, CA) for an undisclosed amount. Ariosa markets a proprietary laboratory-developed test named Harmony at a list price of $795. The Harmony Prenatal Test evaluates fetal DNA found in maternal blood to assess the risk of Down syndrome and other genetic abnormalities. The test is performed at Ariosa's CLIA-certified lab in San Jose, California.

Ariosa markets the test through a direct sales force. LabCorp also markets the test through a non-exclusive agreement with Ariosa.

Competing tests include Sequenom's MaterniT21 PLUS Test, Natera's Panorama Test and Illumina's Verifi Prenatal Test (acquired through its $450 million buyout of Verinata Health in January 2013).

Ariosa reported a net loss of $2.4 million in 2013 on revenue of $53.3 million. In this year's first quarter compared to last year's, it more than doubled its revenue to about $19.5 million and swung from a loss of $2.5 million to a profit of $1 million.

Ariosa at a Glance

Chairman	John Stuelpnagel, DVM
Chief Executive	Ken Song, MD
Employees	157
Annual revenue	~$80 million
Owners	Venrock, Domain Associates

Ariosa had raised roughly $70 million in equity financing since its inception in 2008. Its largest shareholders were the private equity investors Venrock (39.1%) and Domain Associates (24%).

LABCORP ACQUIRES BODE TECHNOLOGY

LabCorp has made another acquisition outside of the traditional clinical lab testing business. LabCorp has purchased Bode Technology (Lorton, VA) from SolutionPoint International, Inc. for an undisclosed amount. This deal follows LabCorp's recently-announced plans to acquire contract research organization Covance Inc. (Princeton, NJ) for $6 billion (see *LE*, November 2014).

Bode Technology and its division Chromosomal Labs provide forensic DNA analysis and paternity testing services. LabCorp says Bode will be combined with its existing Cellmark Forensics business.

Under the new combined businesses, Cellmark Forensics and Bode Technology will provide DNA testing services to federal and state governments, crime labs, disaster management organizations, and the paternity testing market throughout the United States and worldwide.

Separately, LabCorp says it has completed its $85.3 million acquisition of LipoScience (Raleigh, NC), which markets a specialized cholesterol test under the brand name NMR LipoProfile. After adjusting for $22 million of cash held by LipoScience, the deal worked out to 1.5x its annual revenue of $42 million.

LAB STOCKS DOWN 3% YTD

Fifteen lab stocks have declined an unweighted average of 3% year to date through December 15. In comparison, the S&P 500 Index is up 14%. The top-performing lab stock so far this year is Myriad Genetics, up 59%, followed by Enzo Biochem, up 42%. Quest Diagnostics is up by 18% and LabCorp is up 11%.

Company (ticker)	Stock Price 12/15/14	Stock Price 12/31/13	2014 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$27.83	$25.54	9%	$772	19.5	1.0	2.6
Cancer Genetics Inc. (CGIX)	6.17	13.78	-55%	64	NA	7.0	1.6
CombiMatrix (CBMX)	1.20	2.30	-48%	13	NA	0.9	1.5
Enzo Biochem (ENZ)	4.15	2.92	42%	186	NA	1.9	5.1
Foundation Medicine (FMI)	20.88	23.82	-12%	591	NA	11.2	6.1
Genomic Health (GHDX)	30.53	29.27	4%	968	NA	3.5	6.7
LabCorp (LH)	101.36	91.37	11%	8,565	16.4	1.5	3.1
LipoScience (LPDX)*	5.25	4.25	24%	85	NA	2.0	1.9
Myriad Genetics (MYGN)	33.43	20.98	59%	2,440	18.3	3.3	3.4
NeoGenomics (NEO)	4.09	3.62	13%	245	NA	2.6	4.2
Psychemedics (PMD)	13.71	14.69	-7%	74	21.8	2.5	5.7
Quest Diagnostics (DGX)	63.21	53.54	18%	9,136	15.6	1.3	2.2
Response Genetics (RGDX)	0.45	1.16	-62%	17	NA	1.0	8.6
Sonic Healthcare (SHL.AX)	17.44	16.58	5%	6,997	18.1	1.8	2.3
Veracyte (VCYT)	7.53	14.50	-48%	169	NA	4.4	3.5
Unweighted Averages			-3%		18.3	3.0	3.9

*LipoScience was acquired by LabCorp for $5.25 per share on November 20, 2014 Source: Bloomberg and Zacks

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor

LABORATORY ECONOMICS

SAVE THE DATE:
JANUARY 13TH, 2015

SPECIAL TELECONFERENCE

BUNDLING PAYMENT FOR HOSPITAL OUTPATIENT SERVICES:

DON'T LET YOUR LAB GET SQUEEZED OUT IN 2015 & BEYOND

Host: Jondavid Klipp, Publisher of *Laboratory Economics*

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Under a new policy implemented by Medicare effective January 1, 2015, payment for most pathology technical services performed for hospital Medicare outpatients is now being packaged into payment for the primary procedure.

Please join *Laboratory Economics* for a 75-minute conference call on **Tuesday, January 13, 2015 at 1:00 p.m. Eastern Time** with **Jane Pine Wood**, attorney at McDonald Hopkins and **Dennis Padget**, Lead Consultant at APF Consulting Services. Discussion will focus on specific strategies that independent pathology and clinical labs can use to avoid reimbursement reductions in their hospitals contracts.

This teleconference is an absolute essential for all independent pathology labs and clinical labs that contract with hospitals.

In just 75 minutes, you will:

- Get insight into Medicare's new bundling requirement for pathology technical services
- Understand which pathology services will be bundled with hospital outpatient primary procedures and which will still be billed separately
- Calculate the potential impact the new bundling policy will have on revenue that your pathology lab earns from hospital outpatient departments
- Find out how to minimize the bundling policy's potential negative impact on your hospital contracts
- Get straight answers from our two experts during a 30-minute Q&A

FEATURED SPEAKERS:

Mr. Padget is Lead Consultant for APF Consulting Services, Inc. as well as President and founder of DLPadget Enterprises, Inc. in The Villages, Florida. He is Senior Editor in Chief for Pathology Service Coding Handbook, the American Pathology Foundation's Internet-based electronic text. Mr. Padget is a Certified Public Accountant and a Fellow in the Healthcare Financial Management Association. He has an MBA degree from the University of Chicago and a BA degree from the University of Northern Iowa.

Jane Pine Wood is a member in the national Healthcare Practice Group at McDonald Hopkins law firm, where she also serves on the firm's Board of Directors. Wood joined McDonald Hopkins in 1988 and is a nationally respected healthcare attorney who has given hundreds of speeches throughout the country to various healthcare groups. She counsels more than 450 pathology groups and numerous clinical labs throughout the country.

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