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INSIDE *NIR*

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HDL CEO Resigns Post as Lab Faces Federal Investigation

Tonya Mallory, the president and chief executive officer of Richmond, Va.-based Health Diagnostic Laboratory (HDL), resigned Sept. 23. Although HDL was the subject of a recent *Wall Street Journal* article and is under investigation by the federal government, the company says that Mallory's resignation is unrelated and is for personal family reasons.

Joseph McConnell, M.D., co-founder of the company and its chief laboratory officer, will take over as president and CEO. Mallory will continue to serve as a company board member and an adviser to McConnell.

Mallory said she is leaving HDL to help her brother run a new business. In a letter to employees posted on the company's Web site, Mallory wrote, "Many of you know that my brother lost his wife a little over two years ago. He has recently started a new business close to home to avoid what was a two-hour round trip commute each day. The new venture will permit him to keep his young kids in their supportive community. I am leaving HDL, Inc. to help him get his new company off the ground in an effort that we hope will give his family financial security in addition to allowing him more time with his children."

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Congress Passes Continuing Resolution, Heads Home Until November

Congress adjourned Sept. 18 for an eight-week break, but not before passing a stopgap spending bill along with an authorization to arm and train Syrian rebels to fight the Islamic State. Both the House and Senate leave much work to do when they return following the November midterm elections.

The continuing resolution (H.J. Res. 124) will fund government programs and services at current levels until Dec. 11, 2014.

After the Nov. 4 elections, the length of the so-called lame-duck session will depend on which party controls the Senate. If Republicans take control of the Senate, there won't be much incentive for them to take up major legislation until next year.

If Democrats can retain the majority and maintain the current status quo, there may be a busier, and longer, lame-duck session with possible action by the end of the year on fixing the way Medicare pays physicians under the Sustainable Growth Rate (SGR) formula.

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Congress Passes Continuing Resolution, Heads Home Until November, *from p. 1*
Each year, the SGR formula calls for deep cuts in Medicare physician pay rates that are routinely canceled by Congress with a temporary patch known as the "doc fix." The most recent patch will expire March 31, and most experts and government agencies, including the Congressional Budget Office, assume Congress will pass another patch this year that will maintain current payment levels.

There was bipartisan, bicameral support for a permanent fix earlier this year, but lawmakers couldn't agree on how to offset the cost. President Barack Obama signed the current doc fix law April 1.

For Republicans, the Affordable Care Act will continue to be a target for legislative action, but sources said not to expect a full-on repeal vote in the House.

In 2014, 33 of the 100 seats in the Senate are being contested in regular elections whose winners will serve six-year terms from Jan. 3, 2015, to Jan. 3, 2021. There will also be elections to fill three midterm vacancies. In the House, all 435 seats are up for grabs, with 218 seats needed for a majority. Elections will be held Nov. 4.

FDA Lowers Risk Classifications For Bone Marrow, Diabetes Diagnostic Tests

In separate actions, the FDA recently lowered the risk classifications for a laboratory test designed to diagnose diabetes mellitus and a genetic bone marrow test for patients with leukemia or myelodysplastic syndrome.

In an Aug. 25 *Federal Register* notice (*79 Fed. Reg. 50,549*), the Food and Drug Administration (FDA) issued a final order to reclassify the COBAS INTEGRA 800 Tina-quant HbA1cDx Gen.2 assay, a class III (highest risk) device into class II (special controls) to provide a reasonable assurance of the device's safety and effectiveness. The order is effective Sept. 24. The FDA issued an order to the manufacturer classifying the device into class II on May 23, 2013.

According to the final order, the device is assigned the generic name hemoglobin A1c test system. It is indicated to measure the percentage concentration of hemoglobin A1c in blood. The order said the measurement of hemoglobin A1c is used as an aid in the diagnosis of diabetes mellitus and as an aid in the identification of patients at risk for developing diabetes mellitus.

Three potential risks associated with using the device are identified in the final order, which also includes steps to mitigate the risks.

Roche Diagnostics Corp., based in Basel, Switzerland, requested the reclassification. Its main U.S. office is in Indianapolis. Hoffmann-La Roche, also of Basel, owns Roche Diagnostics Corp.

Leukemia Test Reclassified

In a Sept. 3 *Federal Register* notice (*79 Fed. Reg. 52,195*), the FDA issued a final order to reclassify the early growth response 1 (EGR1) gene fluorescence in situ hybridization test system for specimen characterization, a class III (highest risk) device into class II (special controls) to provide a reasonable assurance of the device's safety and effectiveness. The order is effective Oct. 3. The FDA issued an order to the manufacturer classifying the device into class II on July 29, 2013.

According to the final order, the device is intended to detect the EGR1 probe target on chromosome 5q in bone marrow specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The order said the assay results are intended to be interpreted only by a qualified pathologist or cytogeneticist.

Two potential risks (false negatives, false positives) associated with using the device are identified in the final order, which also includes steps to mitigate the risks.

The device reclassification request was made by Abbott Molecular Inc., based in Des Plaines, Ill., a subsidiary of Abbott Park, Ill.-based Abbott Laboratories.

Takeaway: The FDA has modified risk classifications for certain tests to reflect a lower risk.

CMS Adjusts Specimen Collection Fee in Limited Circumstances

Laboratories that collect blood samples from people in nursing homes or on behalf of a home health agency are having their collection fee increased from $3 to $5, effective April 1, 2014.

The change, announced by the Centers for Medicare and Medicaid Services in Transmittal 3056 (Change Request 8837), was mandated by the Protecting Access to Medicare Act.

For this situation, a new code will be used: G0471, Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA).

The fee is raised from $3 to $5 only when the following statements apply:

1. The sample is being collected by a laboratory technician who is employed by the laboratory that is performing the test; and

2. The sample is from an individual in either an SNF or an HHA.

The change in payment is retroactive to April 1, 2014, but Medicare administrative contractors (MAC) will not search their files to adjust claims already processed. Therefore, labs should bring such claims to the attention of their MAC.

Takeaway: Labs that serve nursing homes and home health agencies will get a bump in their specimen collection fees.

Appeals Court Dismisses Case Against Quest

The U.S. Court of Appeals for the Third Circuit Sept. 11 dismissed a lawsuit filed against Quest Diagnostics, agreeing with the trial court that the proposed class of former Quest patients didn't meet the requirements of class certification (*Grandalski v. Quest Diagnostics Inc.*).

Plaintiffs Richard Grandalski, Janet Grandalski, and Denise Cassese alleged that Quest overbilled patients for services by requesting payment from patients in excess of the amount allowed by insurers in the explanation of benefits. They sought damages for violations of state consumer fraud laws and for unjust enrichment. The U.S. District Court denied class certification, and the plaintiffs appealed.

Consumer Fraud Claims

The plaintiffs sought to certify a nationwide class based on allegations that Quest violated state consumer fraud laws. The trial court engaged in a choice-of-laws analysis and determined that the laws of each class member's home state would determine whether he or she could recover damages from Quest. This would pose an "intractable" problem for trial management and, thus, the trial court said, made class certification inappropriate.

On appeal, the plaintiffs argued that the trial court shouldn't have engaged in a choice-of-law analysis at this stage of the proceedings. The appeals court disagreed, saying it was appropriate for the trial court to determine whether there were variations in state law that would "swamp" any common issues.

The appeals court also said the trial court didn't err in concluding that the laws of the class members' home states controlled the state law claims. The place where the class members received Quest's bills and relied upon them in settling the accounts—that is, their home states—weighed in favor of applying the law of the members' home states, the Third Circuit said.

The place where Quest made the misrepresentations, its home state of New Jersey, weighed in favor of applying New Jersey law, the court said. But nothing else about the parties' relationship took place in that state, it said.

The place where the consumer received and relied on the defendant's alleged fraud, the consumer's home state, had the most significant relationship to the action, the court said. Due to the number of state laws that would apply here, this wasn't a proper case for class certification, it concluded.

Unjust Enrichment Claims

The Third Circuit came to a similar conclusion with respect to the purported class's unjust enrichment claims. Because Quest may have had reasons for mistakenly overbilling certain patients, the trial court would have to look at each member's case individually to determine whether Quest was unjustly enriched by an overpayment.

That there were individualized questions of fact regarding each member counted against class certification, the court said.

Takeaway: Quest Diagnostics escaped a challenge to its billing practice due to lack of class certification.

HDL CEO Resigns Post as Lab Faces Federal Investigation, *from p. 1*

Mallory's resignation comes as HDL cooperates with an ongoing U.S. Department of Justice investigation into its reimbursement practices. The government is investigating a practice by HDL and some other laboratories of paying fees to health care providers to collect patients' blood samples and send them to the labs for testing. Regulators have warned that such fees could amount to an illegal financial inducement.

HDL in late June discontinued its "process and handling (P&H) payments" following a special fraud alert issued June 25 by the Department of Health and Human Services Office of Inspector General. That alert warned clinical laboratories that providing remuneration to physicians to collect, process, and package patient specimens could violate the anti-kickback law. HDL said the fraud alert was the first clear guidance it received from regulators about P&H payments (*NIR*, July 24, 2014, p. 1)

An article on *Forbes.com* recently suggested that the federal probe may go beyond investigating the practice of paying fees to health care providers and also may look at other billing practices, such as deferring or covering patient copays that are not covered by insurance.

HDL also said that it eliminated 30 jobs in August, which is less than 3.5 percent of its total workforce. The company previously reported having about 860 employees.

Takeaway: Health Diagnostic Laboratory is under the gun as federal authorities investigate billing practices and its president and chief executive officer announces her resignation.

More Docs Implicated in Biodiagnostic Scheme

Two more New Jersey doctors have admitted to federal charges of accepting bribes in exchange for test referrals, as part of a long-running scheme operated by Biodiagnostic Laboratory Services LLC (BLS), its president, and numerous associates, U.S. Attorney Paul J. Fishman announced Sept. 16.

Eugene DeSimone, who practiced in Secaucus, N.J., and Douglas Bienstock, whose practice was in Hawthorne, N.J., each pleaded guilty to one count of accepting bribes before Judge Stanley R. Chesler of the U.S. District Court for the District of New Jersey in Newark.

DeSimone admitted accepting $1,500 in cash payments monthly between August 2010 and March 2013, in return for referring patient blood specimens to BLS, which is based in Parsippany, N.J., according to documents filed in this and related cases and statements made in court. The laboratory received a total of $980,000 in reimbursement from Medicare and private payers for the tests DeSimone referred, the government alleged.

Bienstock admitted that in return for referrals of patient blood specimens to BLS, he was paid $2,560 per month under a sham service contract with BLS that ostensibly reimbursed him for basic blood drawing services.

Cash Paid for Each Test Referred

The payments far exceeded fair market value for such services, according to federal prosecutors.

BLS also paid Bienstock $100 in cash for each of a certain type of blood test that he ordered. His referrals generated a total of $51,600 in lab business for BLS, the government alleged.

As part of their guilty pleas, DeSimone agreed to forfeit $260,500 and Bienstock $79,695. Both men are scheduled for sentencing Dec. 16. A total of 31 people, including 20 doctors, have pleaded guilty so far in connection with the BLS bribery scheme. Its organizers have admitted the scheme involved payment of millions in bribes and resulted in more than $100 million in payments to BLS from Medicare and private insurance companies.

The investigation has recovered more than $10.2 million through forfeiture.

BLS president and part owner David Nicoll; his brother Scott Nicoll, a senior BLS employee; and their cousin Craig Nordman, a BLS employee and the chief executive officer of Advantech Sales LLC, which was an entity used by BLS to make illegal payments to doctors, pleaded guilty to charges related to their involvement in the scheme in June 2013.

Takeaway: In a case that seems to never end, more physicians have pleaded guilty to accepting bribes in exchange for referring laboratory testing to Biodiagnostic Laboratory Services. G2

Accountable Care Organizations Meeting Goals, Says CMS

Accountable care organizations (ACOs) created under the Affordable Care Act (ACA) are meeting their goals of improving patient care while saving Medicare money, the Centers for Medicare and Medicaid Services (CMS) said Sept. 16.

ACOs in the Pioneer ACO Model and Medicare Shared Savings Program (MSSP) generated more than $372 million in total program savings for Medicare ACOs, the agency said in a fact sheet. ACOs also qualified for shared savings payments of $445 million.

The results come from preliminary quality and financial results from the second year of performance for 23 Pioneer ACOs (which have more experience with coordinating care) and final results from the first year of performance for 220 Shared Savings Program ACOs, CMS said.

More than 360 Medicare ACOs have been established in 47 states, serving over 5.6 million Americans with Medicare, according to CMS. Medicare ACOs are groups of providers and suppliers of services that work together to coordinate care for Medicare fee-for-service beneficiaries.

In its first report on the operation of Medicare's ACO program, CMS in January said the entities shared in $273 million of savings in 2012 and funneled an additional $128 million to the Medicare trust fund.

The Pioneer program is administered under CMS's Center for Medicare and Medicaid Innovation and is designed for health-care organizations and providers that have experience coordinating care for patients across care settings. The program allows those provider groups to move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the MSSP.

Spending Money Wisely

"We all have a stake in improving the quality of care we receive, while spending our dollars more wisely," Health and Human Services (HHS) Secretary Sylvia Mathews Burwell said in a press release. "It's good for businesses, for our middle class, and

for our country's global competitiveness. That's why at HHS we are committed to partnering across sectors to make progress."

Some providers have been critical of the program. In an April letter to CMS, for the example, the American Hospital Association said current models for ACOs won't be sustainable in the long run unless CMS makes significant changes to encourage more provider participation. The hospital group said the ACO programs "place too much risk and burden on providers with too little opportunity for reward in the form of shared savings."

CMS said Pioneer ACOs in their second year showed improvements in three areas: financial, quality of care, and patient experience. Pioneer ACOs generated total model savings of more than $96 million and at the same time qualified for shared savings payments of $68 million, according to the agency. They also saved the Medicare Trust Fund about $41 million.

Pioneer ACOs also had lower per capita growth in spending for the Medicare program at 1.4 percent, which is about 0.45 percent lower than Medicare fee-for-service, the agency said. Eleven Pioneer ACOs earned shared savings, three generated shared losses, and three elected to defer reconciliation until after the completion of performance year three, it added.

The mean quality score among Pioneer ACOs increased by 19 percent, from 71.8 percent in 2012 to 85.2 percent in 2013. The organizations showed improvements in 28 of the 33 quality measures, CMS said. The Pioneer ACOs improved the average performance score for patient and caregiver experience in six out of seven measures, according to the agency.

Positive Caregiver Experience

"These results suggest that Medicare beneficiaries who obtain care from a provider participating in Pioneer ACOs report a positive patient and caregiver experience," it said.

CMS also reported results from year one of the Shared Savings Program ACOs, finding 53 ACOs held spending $652 million below their targets and earned performance payments of more than $300 million as their share of program savings.

The Medicare trust fund will save about $345 million, including repayment of losses for one ACO, CMS said. An additional 52 ACOs reduced health costs compared with their benchmark, but they didn't qualify for shared savings, as they didn't meet the minimum savings threshold, it added.

Shared Savings Program ACOs also improved on 30 of 33 quality measures, CMS said. Quality improvement was shown in such measures as patients' ratings of clinicians' communication, beneficiaries' rating of their doctor, health promotion and education, screening for tobacco use and cessation, and screening for high blood pressure, the fact sheet stated.

CMS said that in 2013, more than 125,000 eligible professionals who were ACO providers or suppliers qualified for incentive payments for reporting their quality of care through the Physician Quality Reporting System (PQRS). These providers will avoid the PQRS payment adjustment in 2015 because they demonstrated the ability to report quality measures through their ACO, the agency stated.

Takeaway: For laboratories that have been sitting on the sidelines waiting to see if ACOs actually work, this may be a sign that it's time to get involved with an ACO.

Inflection Point for Labs: This Year's Lab Institute Tackles Tough Issues Facing Lab Industry

Driven by ongoing reform and cost pressures, the U.S. health care system is undergoing multiple, simultaneous changes that are affecting the way providers, payers, and patients do business. What's more, the rapid changes give unprecedented opportunity for pathologists and laboratories alike to provide leadership in driving coordinated care.

This year's Lab Institute, "Inflection Point for Labs," will tackle the challenges facing clinical and anatomic pathology laboratories and provide solutions and strategies for labs to survive and thrive in these transformational times. Be sure to join more than 400 of your colleagues in Washington, D.C., Oct. 15-17 for this critical event.

In the opening keynote session, G2 founder Dennis Weissman and Marc Grodman, chairman, president, and CEO of BioReference Laboratories, will discuss the top market challenges Grodman sees for the lab sector, including continued reimbursement pressure by government and private payers, and the advent of new delivery and payment systems emerging around the country.

In the second keynote address, James Crawford, M.D., Ph.D., executive director and senior vice president for laboratory services at North Shore-LIJ Health System, will examine how the lab industry can leverage its massive data streams to drive improved patient outcomes and the delivery of cost-effective care, as well as why and how labs can lead programs in coordinated health care.

During the two-and-a-half-day conference, participants will identify critical market issues and trends affecting bottom-line performance of laboratory organizations, gain valuable insights into how innovative lab business models are positioned for future market success, and learn how lab business intelligence and analytics can improve financial performance.

Plus, participants will anticipate how the 2014 midterm elections will affect labs and pathologists; examine what Congress, Medicare, and private payers have in store for labs in 2015 and beyond; and keep on top of all key Medicare regulatory and policy initiatives for labs.

Among key conference sessions:

- ❑ The Acceleration of the ACA: How to Prepare for Health Reform 2.0
- ❑ Reimbursement and Policy Outlook for Labs and Pathologists
- ❑ Lab Pricing, Coverage and Transparency: Financial and Policy Implication for Labs
- ❑ From Big Data to Sensor Technology: The Future of Lab Testing
- ❑ The Power of Laboratory Data: Providing Added Value Through Real-Time Analytics

For more information about Lab Institute or to register, please visit *www.labinstitute.com*. See you in Washington!

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