G2 INTELLIGENCE
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NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 35th Year of Publication

Vol. 14, Iss. 21, November 25, 2014

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Medicare Outpatient Packaging Policy Will Not Apply to ASCs

To the relief of pathologists across the country, the Centers for Medicare and Medicaid Services (CMS) has confirmed that its new policy under which it will package the technical component of many anatomic pathology (AP) services into a single hospital outpatient payment will not apply to services provided in ambulatory surgical centers (ASCs).

The final hospital Outpatient Prospective Payment System (OPPS) rule, published in the Nov. 10 *Federal Register*, seemed to give conflicting statements about whether the new packaging policy would apply both to AP services provided in hospital outpatient departments and AP services provided in freestanding ambulatory surgical centers.

However, Jane Pine Wood, an attorney with McDonald Hopkins, tells *National Intelligence Report* that she has confirmed with CMS that the technical component of AP codes is not bundled into ASC payments when performed by an outside laboratory.

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Lab Sector Goes to Big Legal Guns in Grapple With FDA Over Test Regulation

The American Clinical Laboratory Association (ACLA) has officially loaded up its legal howitzers in a likely path toward litigation over the U.S. Food and Drug Administration's (FDA's) intent to regulate laboratory-developed tests (LDTs).

ACLA recently retained the services of renowned attorneys Laurence H. Tribe and Paul D. Clement, both of whom have voluminous experience litigating and appealing cases in the federal courts.

Tribe, 71, a professor of constitutional law at Harvard University, is perhaps the foremost legal scholar in the United States. He has argued nearly three dozen cases in front of the U.S. Supreme Court since the early 1980s, winning about 60 percent of them.

Clement, 48, is a partner in the Washington, D.C., law firm of Bancroft PLLC, which specializes in Supreme Court and federal appellate litigation. He was a solicitor general in the George W. Bush administration, arguing cases on its behalf in front of the Supreme Court. In private practice, Clement argued in front of the high court in 2012 against the constitutionality of the Affordable Care Act.

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Medicare Outpatient Packaging Policy Will Not Apply to ASCs, *from p. 1*
Agency officials referred Wood to certain pages of the *Federal Register*, which offer some clarification of this issue. Page 66806, for example, states:

> The commenters are correct that the comprehensive APC [Ambulatory Payment Classification] payment policy methodology is not being adopted under the ASC payment system. . . . This continuation of separate payment for covered procedures and covered ancillary services performed in the ASC . . . should help mitigate any incentive to perform procedures assigned to C-APCs in the [hospital outpatient department].

And on page 66925, CMS states:

> Given the final OPPS comprehensive APC policy and after consideration of the public comments we received, we are finalizing our proposal that all separately paid covered ancillary services that are provided integral to covered surgical procedures that would map to comprehensive APCs will continue to be paid separately under the ASC payment system instead of being packaged into the payment for the comprehensive APC as under the OPPS.

In fact, CMS has indicated that it will be very difficult for the agency to package ancillary services provided in the ASC setting into a single payment, noting that "Unlike the OPPS claims processing system that can be configured to make a single payment for the encounter-based comprehensive service whenever a[n] HCPCS code that is assigned to a comprehensive APC appears on the claim, the ASC claims processing does not allow for this type of conditional packaging."

While this is good news for pathologists who provide services for patients receiving care at ASCs, the news is not so good for pathologists who provide services for patients receiving care in hospital outpatient settings. Effective Jan. 1, 2015, CMS will package services assigned to APC 352 (Level I Pathology) and APC 433 (Level II Pathology), as well as APC 0345 (Transfusion Laboratory Procedures). A partial list of services affected by this policy can be found in the Nov. 13, 2014, issue of *NIR*.

Pathologists in this situation will need to renegotiate their contracts with hospitals to ensure they are paid for the services they provide under these APCs.

Takeaway: Payment for pathology services provided to patients receiving care in ambulatory surgical centers will not be packaged into a single payment as they will be for patients in hospital outpatient settings. G2

Closely Scrutinized Health Diagnostic Laboratory Cuts 15 Percent of Its Workforce

Exactly a year ago, Health Diagnostic Laboratory (HDL) founder and Chief Executive Officer Tonya Mallory talked at length to G2 Intelligence about the remarkable success of her company, which grew from virtually no sales in 2009 to $420 million in three years.

Mallory also discussed helping employees with issues such as fitness and childcare and helping to fund their own startup businesses. Ten months later, Mallory stepped down, ostensibly to help her brother with a startup of his own. However, her exit came under a cloud of allegations of illegal kickbacks paid to physicians in the guise of specimen collection fees, a federal investigation into the lab's pay-

ment practices, and more recently, a fraud lawsuit filed against the Virginia-based company by one of the nation's largest health insurers.

Now, the employees Mallory had spoken of in glowing terms are being shown the door themselves.

HDL confirmed it has laid off 132 employees this month, representing about 15 percent of its total workforce. The job cuts were throughout the organization and did not impact a specific department or operation, according to spokesperson Jeff Kelley.

HDL Chief Executive Officer Joe McConnell—the company's former chief laboratory officer who replaced Mallory—cast the job cuts as part of a plan to refocus on the company's strengths.

"HDL . . . has made the strategic decision to return to its core mission: Fighting cardiovascular disease and diabetes with innovative cutting-edge, advanced laboratory testing that can lead to earlier diagnosis and treatment," McConnell said in a statement. "In recent years, HDL had become involved in a number of noncore business interests that required significant time, attention and resources. The need to reallocate our resources to return to our core mission is what led to the reduction in force."

Kelley declined to say what noncore resources that company had been focusing on.

The company no doubt has some stormy times ahead. Mallory indicated last year that its 2013 revenues were flat compared to 2012, suggesting the company abruptly hit a wall after a relatively brief period of dramatically explosive growth. The federal investigation and the probe are likely to impact its bottom line even further.

And in late October, the Connecticut-based insurer Cigna sued HDL for $84 million. It claims in its suit that a combination of the large panels HDL offers to providers, along with its systematic forgiveness of patient copayments, deductibles, and other charges, allows it to engage in unnecessary testing and to bill the insurer excessively.

But McConnell indicated he expects the layoffs will help spur a turnaround. "We deeply regret the business necessity that made this reduction in force necessary and we are all mindful that this will pose difficulties and challenges for our former colleagues and their families. At the same time, these necessary changes provide us with the opportunity to re-energize our company," he said.

Takeaway: Health Diagnostic Laboratory is facing numerous obstacles in continuing on the path of the dramatic growth it enjoyed during the first four years of its operation.

Government Collects $2.3 Billion From Health Care FCA Cases

The federal government collected $2.3 billion in fiscal year 2014 from health care-related False Claims Act (FCA) actions, the Department of Justice (DOJ) announced Nov. 20.

Health care recoveries accounted for a substantial portion of a total $5.69 billion recovered by the DOJ in FCA actions for FY 2014. The DOJ attributed the recovery, which marked the fifth consecutive year FCA recoveries from health care fraud exceeded $2 billion, to "the high priority the Obama Administration has placed on fighting health care fraud."

The DOJ reported in December 2013 that FCA health care actions accounted for $2.6 billion in federal recoveries for FY 2013.

The $2.3 billion in health care FCA judgments and settlements only accounted for recoveries to the federal government; additional recoveries totaling "billions of dollars for consumers and state treasuries" also were achieved, the DOJ said. Acting Assistant Attorney General Joyce R. Branda said the "true significance" of the recoveries "is in the billions of dollars restored to the federal treasury."

The DOJ reported that 713 qui tam FCA actions were filed in FY 2014, just below FY 2013 when 752 were filed. Qui tam actions represented almost $3 billion of total FCA recoveries in FY 2014 and included $435 million in relator awards—up from $345 million in FY 2013.

Of those FCA actions filed in FY 2014, there were 469 qui tam and 31 non-qui tam actions related to federal health care programs, according to the DOJ.

The vast majority of the $2.3 billion in FCA health care recoveries were the result of qui tam actions, accounting for $2.22 billion of the total. Health care relators in FY 2014 also recovered far more in qui tam actions where the government intervened, representing $332 million of the total health care relator awards of $342 million.

Pharmaceuticals, Hospitals Heavily Represented

Settlements involving pharmaceuticals constituted a large portion of the health care FCA recoveries. Notable actions included a $1.1 billion settlement with Johnson & Johnson in November 2013 for alleged illegal drug promotions and kickbacks involving the drugs Risperdal, Invega, and Natrecor. The $1.1 billion recovery was part of a larger $2.2 billion global settlement with Johnson & Johnson that also included settlement of $600 million in Medicaid claims from states and $485 million in criminal penalties.

Another notable recovery included a $116 million settlement with pharmacy supplier Omnicare announced June 25 for allegedly paying kickbacks to nursing homes as incentive to choose Omnicare as a pharmaceutical supplier. The Omnicare settlement also included an additional $8.2 million in state Medicaid recoveries.

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Hospital settlements figured prominently in FCA recoveries in FY 2014 as well, with the largest being a $98 million settlement with Community Health Systems Inc. in August for alleged unnecessary inpatient admissions of federal health care beneficiaries.

Halifax Hospital Medical Center settled a prominent FCA action March 10 alleging Stark law violations from an employee whistle-blower for $85 million. Halifax allegedly violated the Stark law in its compensation packages to certain oncologists and neurologists by incorporating their referrals into their bonuses.

Two hospitals also were involved in settlements amid allegations of performing medically unnecessary coronary procedures on Medicare and Medicaid beneficiaries. King's Daughters Medical Center paid $39 million to the federal government and $2 million to state Medicaid agencies in a settlement announced May 28. The DOJ announced a settlement with Saint Joseph Health System on Jan. 28 for $16.5 million.

Takeaway: The Department of Justice is continuing its aggressive pursuit of health care fraud, recovering $2.3 billion in 2014.

Lab Sector Goes to Big Legal Guns in Grapple With FDA, *from p. 1*

Although ACLA trumpeted its hiring of Tribe and Clement in a press release issued last week, ACLA President Alan Mertz would not say specifically whether the organization plans to sue the FDA, perhaps with the intent of establishing in federal court that agency's authority—or lack thereof—to regulate the laboratory sector.

Instead, Mertz has stuck to the argument that the FDA's regulation of LDTs would duplicate the regulatory oversight already provided by the Clinical Laboratory Improvement Amendments (CLIA), the College of American Pathologists, and regulators in states such as New York and Florida.

The FDA announced last July that it intended to regulate LDTs much in the way it currently regulates medical devices, with a vetting process based on the risk of each test to patients. It issued a 43-page framework last month, which is currently open for public comment until February.

"We're not against oversight—just the way they're doing it," said Mertz, who added that the ACLA wants a withdrawal of the FDA's draft regulations of LDTs.

The FDA has countered that the current system under CLIA is unsatisfactory and has created a market full of complex assays, some of which have been vetted by the agency and others that have not.

"For a long time, we have supported making some modifications to CLIA, and we can add on to [its] process of authority," Mertz said. "You can make some additions to that that would be far less destructive to innovation, and not just re-create the wheel."

The hiring of Tribe and Clement appears to be timed with increasing pressure on the FDA from outside organizations. On the same day as ACLA's announcement, the American Association for Clinical Chemistry, the American Medical Association, the American Hospital Association, and a variety of other health care trade organizations called on the FDA to withdraw its proposed regulatory framework.

FDA spokesperson Jenny Haliski declined to comment specifically on the possibility of litigation from the lab sector. "The agency looks forward to receiving feedback from all stakeholders on the draft guidance and intends to hold a public meeting early next year to get further input from all interested parties," she said.

Takeaway: With the hiring of perhaps the two best-known appellate lawyers in the United States, ACLA appears poised to sue the Food and Drug Administration over its intent to regulate laboratory-developed tests.

FDA to Hold Workshop on LDTs

The Food and Drug Administration (FDA) will hold a two-day public workshop in early January to discuss its framework for regulatory oversight of lab-developed tests (LDTs).

The workshop will be Jan. 8-9 at the National Institutes of Health campus in Bethesda, Md., and via webcast.

Stakeholders have until Dec. 12 to register to attend the workshop. In addition, the agency said stakeholders may indicate if they want to present at the workshop's public comment sessions during registration. The agency will begin notifying presenters with information about the time they are allotted to speak by Dec. 17. Those selected to present must submit their presentation materials by Jan. 6. According to the FDA, the deadline for submitting comments related to the workshop is Feb. 2.

Draft FDA guidance documents, announced in late September and published Oct. 3 in the *Federal Register*, outlined a proposed LDT oversight framework and addressed notification and medical device reporting for LDTs. Comments on both documents are due Feb. 2.

Details about the workshop and registration are available at *http://www.fda.gov/medicaldevices/newsevents/workshopsconferences/ucm423537.htm*.

Florida Health Care Execs Facing Charges Over Fake Lab Billings

Two Florida men were arrested earlier this month and are facing federal charges related to an alleged kickback scheme involving clinical laboratory testing.

David Brock Lovelace, 44, and Dale B. DuBois, 61, were arrested by federal agents and charged with conspiracy to defraud the Medicare program.

Lovelace was previously indicted on charges that he submitted $5.9 million in false radiology, audiology, neurology, and cardiology claims to Medicare in connection with his company, Summit Health, which operated health care clinics. Lovelace was one of 50 Floridian health care providers or executives caught up in a federal sting earlier this year.

According to the U.S. Justice Department, Lovelace and DuBois are accused of paying kickbacks to medical clinics in Miami in exchange for DNA samples and patient information. They would then sell the samples and patient data to medical laboratories, which would then use them as a pretext for billing Medicare. According to Justice, Lovelace has received at least $675,000 from just one lab over the past 14 months. The labs have not been named by investigators or prosecutors.

The case is being handled by the Federal Bureau of Investigation (FBI) and the Office of Inspector General of the U.S. Department of Health and Human Services (HHS). It is one of many Medicare fraud cases that have been brought in recent years, as the Obama administration has made Medicare fraud prevention a priority among its law enforcement policies.

According to the U.S. Justice Department, Lovelace and DuBois are accused of paying kickbacks to medical clinics in Miami in exchange for DNA samples and patient information.

HHS has created special media events throughout the country to discuss the issue and has set up special task forces in nine U.S. cities, although officials have indicated that the bulk of fraudulent activities have been occurring in Southern California and South Florida. A joint FBI-HHS strike force focused on Medicare and Medicaid fraud has charged some 2,000 defendants since 2007 and accused them of defrauding the program of more than $6 billion.

In an unrelated California case, state prosecutors earlier this month filed 31 charges of felony grand theft, conspiracy, false impersonation, and insurance fraud against Douglas J. Abeles, M.D., an orthopedic surgeon who practices in the Castro Valley, east of San Francisco. Abeles's office manager, Gabriela Cuevas, was also charged.

According to an indictment, Abeles operated several medical-related businesses, including one that performed urinlaysis tests for drug compliance purposes, primarily in workers' compensation cases. However, prosecutors say the work was never performed, even though insurance claims were routinely submitted by Abeles's businesses. Insurers Liberty Mutual, Travelers Insurance Co., Zenith Insurance Co., and Fireman's Fund Insurance Co. are among those payers to have alleged they received false claims.

"Large insurance fraud schemes are often highly sophisticated," said Alameda County District Attorney Nancy E. O'Malley in a statement issued by the California Department of Insurance. "This investigation required extensive and diligent investigative work, entailing the meticulous collection of evidence."

Takeaway: The federal crackdown on health care fraud in Florida is continuing, with laboratories likely to be targets in the not-too-distant future.

'Doc Fix' Legislation Estimated to Cost $144B Over 10 Years

The Congressional Budget Office (CBO) Nov. 14 said legislation (H.R. 4015, S. 2000) to replace the Medicare physician payment system would cost $144 billion from 2015 to 2024, a jump from the $138 billion 10-year estimate that CBO made in February when the identical bills were introduced.

The SGR Repeal and Medicare Provider Payment Modernization Act of 2014, introduced in February, made a number of changes to the current physician payment model, including creating a merit-based incentive payment system, and offered doctors a slight increase in payment.

Following on its February estimate, the CBO's latest document on the so-called doc fix estimated that freezing physician payment at the current rate through 2024 would cost $118.9 billion, while offering doctors an extra 0.5 percent hike for each of those years would raise the price to $140.2 billion.

The freeze would override the Sustainable Growth Rate formula, which each year calls for deep cuts in physician payments.

The CBO made its predictions following release of the final 2015 Physician Fee Schedule, which said doctors and other Part B providers face a 21.2 percent cut in reimbursements from the time the current patch expires at the end of March 2015 until the end of the year unless Congress acts.

Temporary Patch

If Congress passes another temporary freeze that runs to the end of the year after the current one expires on March 31, it would cost $13.6 billion over 10 years. It also would result in a reimbursement cut of 17 percent in 2016, the CBO said.

Congress's budget analyst each year readjusts its estimates following the release of the upcoming year's fee schedule conversion factor, which converts units attached to doctors' services into a dollar amount.

"The revised reduction in payment rates for April to December of calendar year 2015, as well as other information provided in the final rule, change CBO's projections of Medicare payment rates for services provided on the [fee schedule] for 2015 and for future years," the Nov. 14 document said.

After H.R. 4015 and S. 2000 were introduced in February, leaders of the two parties reached an agreement to freeze pay rates for a year and to include "extenders," which continued funding for other health programs that were set to expire.

The measure—Pub. L. No. 113–93—was signed by President Barack Obama on April 1.

Takeaway: The Congressional Budget Office's estimates of the 10-year cost of repealing and replacing the Sustainable Growth Rate formula have increased from $138 billion to $144 billion.

Integrating Laboratories Into Patient-Centered Medical Homes

Clinical laboratories have numerous opportunities to play a role in patient-centered medical homes (PCMH), a new health care model intended to establish a foundation for primary care that achieves the Institute for Healthcare Improvement's threefold aim of better health, better care, and lower costs.

According to a new white paper from COLA, there are numerous opportunities to integrate labs into the PCMH model. Specifically, lab personnel can take the lead in establishing practices that align with PCMH standards in three key areas: Controlling utilization; identifying risks and controls for all phases of laboratory testing, including pre-analytic, analytic, and post-analytic; and coordinating lab results among primary care providers, other providers in the PCMH "neighborhood," and the patient.

Controlling Utilization

COLA notes that inappropriate testing can take two forms—overutilization and underutilization. Ramifications of overutilization go far beyond lab costs, unnecessary sample collection, and burden on health care resources. Downstream effects include increased likelihood of false results leading to incorrect diagnoses, unnecessary prescription drugs, longer hospital stays, and additional medical or surgical interventions. Lab utilization controls that could be implemented by physician office labs include physician education on lab test costs and evidence-based medicine, and restricting and auditing test ordering.

The COLA white paper on integrating clinical laboratories into the patient-centered medical home model is available at www.cola.org.

Identifying Risks and Controls

The total test process (TTP) is composed of three phases—preanalytical, analytical, and post-analytical. The preanalytic phase has the greatest estimated contribution to TTP errors (46 percent to 68 percent), followed by the post-analytical (18 percent to 47 percent), and the analytical (7 percent to 13 percent).

Labs operating in a patient-centered practice should follow the concepts of total quality management to ensure quality in the testing process. Accreditation agencies require POC labs to have a quality-management system and evidence that they are competently applying their quality system to the TTP.

Coordinating Lab Results

The increasing use of health information technology (HIT) is key to the success of a patient-centered medical home. HIT enables the practice of capturing and documenting the entire POC testing process in the patient records, including test and quality control results, billing, and the clinician's response to test results. Best practice quality system policies and procedures for reporting test results should, at a minimum, address receipt of results, review of results, backup reviewing, reporting and confirming receipt of results by the patient, handling of abnormal results, reporting time frame for critical as well as normal results, qualification and training requirements for results reporting, and quality plan for reporting process audits.

Takeaway: Given that laboratories perform work that impacts about three-quarters of diagnostic decisions affecting patients, the ultimate success of the PCMH depends upon successfully integrating labs into the model.

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 National Intelligence Report (ISSN 2332-1458) is published by G2 Intelligence, 24 Railroad Street, Keene NH 03431-3744 USA. Tel: 800-531-1026 or +1 603-357-8101. Fax: +1 603-357-8111. Web site: www.G2Intelligence.com.

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