



NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 35th Year of Publication

Vol. 14, Iss. 11, June 5, 2014

INSIDE NIR

- Combination product group calls for new FDA policy on IVDs, LDTs.....1
- CMS to cover hepatitis C screening in eligible adults1
- Stakeholder group calls for reform of CLIA waiver process2
- Pathologists exempt from 2015 meaningful use penalty3
- Court allows some claims against Quest to go forward.....4
- CMS to hold public meeting on lab fee schedule updates6
- Callaway Laboratories to pay \$4.7M to settle fraud allegations.....7
- Burwell expected to be confirmed as HHS secretary..8

www.G2Intelligence.com



Upcoming G2 Conferences

June 11-13, 2014
MDx NEXT: Molecular Diagnostics at the Crossroads: Innovation in the Face of a Reimbursement Crunch

Royal Sonesta Harbor Court Baltimore
www.MDxconference.com

Oct. 15-17, 2014
Lab Institute: Inflection Point for Labs
Hyatt Regency Washington, D.C.
www.LabInstitute.com

Combination Product Groups Calls For New FDA Policy on IVDs, LDTs

The Food and Drug Administration (FDA) needs to take action and make a decision on whether it has the authority to regulate laboratory-developed tests (LDTs) as medical devices, a group representing manufacturers of combination products said in a recent letter to the agency.

The Combination Products Coalition (CPC) May 15 told the FDA it needs to make a decision about regulating LDTs and in vitro diagnostics (IVDs). According to the letter, the FDA’s approach to lab-developed tests and the FDA’s approach to IVDs can’t both be correct. Either the federal government is dramatically overregulating IVDs or underregulating lab-developed tests, or both, the group said.

The group called on the FDA to create a single regulatory system for both IVDs and LDTs.

LDTs are in vitro assays that clinical laboratories develop as testing services according to their own procedures. These tests are often created in response to unmet clinical needs and are commonly used for early and precise diagnosis, monitoring, and guiding patient treatment.

Continued on p. 5

CMS to Cover Hepatitis C Screening In Eligible Adults

The Centers for Medicare and Medicaid Services (CMS) will cover screenings for the hepatitis C virus (HCV) in adults eligible for Medicare Part A or enrolled in Part B.

In a June 2 decision memo (CAG-00436N), CMS says the evidence is adequate to conclude that screening for HCV, consistent with the grade B recommendations by the U.S. Preventive Services Task Force, is reasonable and necessary for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

The agency will cover a screening in two circumstances for Medicare-covered adults: those adults who are at “high risk” of infection and those born between 1945 and 1965 who are not at high risk. Screenings must be conducted with the appropriate Food and Drug Administration approved or cleared laboratory tests, “used consistent with FDA approved labeling” and in compliance with the Clinical Laboratory Improvement Amendments regulations.

Continued on p. 2

CMS to Cover Hepatitis C Screening in Eligible Adults, from p. 1

The determination of “high risk for HCV” is identified by the primary care physician or practitioner who assesses the patient’s history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan.

There are likely more than 3 million people chronically infected with HCV in the United States, though more than half are unaware that they are infected, according to national estimates.

Takeaway: Given the latest coverage policy and expanded guidelines, clinical laboratories can expect to see a surge in HCV testing. Experts size the HCV testing market at about \$300 million annually. 

Stakeholder Group Calls for Reform of CLIA Waiver Process

A newly formed stakeholder group wants the Food and Drug Administration (FDA) to ease restrictions on where diagnostic tests can be performed.

James Boiani, head of the Coalition for CLIA Waiver Reform and an attorney with Epstein Becker & Green PC in Washington, D.C., told Bloomberg BNA May 28 the group wants the FDA to ease its regulations and ensure patients have easy access to important diagnostic tests.

All facilities in the country that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Boiani said the coalition wants the FDA to change the way it interprets the CLIA law. The agency’s current requirements for CLIA-waived labs put the emphasis on how accurate the tests are, rather than how effective they are.

According to the coalition, all laboratory tests must be reviewed by the FDA and assigned a complexity level (low/waived, moderate, or high). The complexity level dictates where the test can be performed. Moderate- and high-complexity tests may be performed only in sophisticated laboratories that satisfy the strict requirements

of CLIA (including personnel training, quality standards, proficiency testing, and recordkeeping requirements, among others).

Boiani said tests performed in CLIA-waived labs are simple and are often performed at the point of care, such as a physician’s office. Such testing can save time, lives, and health care dollars, he said, because the results get to patients much faster than if the tests were sent away.

If a user needs special laboratory expertise and training to run a test, its use needs to be restricted to nonwaived labs. But if the tests can be performed in the hands of untrained users the same as trained users, then it should be allowed in a CLIA-waived lab. According to the coalition, the majority of point-of-care testing in the United States is done at CLIA-waived laboratories, which represent nearly 70 percent of all laboratories in the country.

Interpretation Issue

Boiani said the coalition wants the FDA to change the way it interprets the CLIA law. The agency’s current requirements for CLIA-waived labs put the emphasis on how accurate the tests are, rather than how effective they are.

“The only issue is whether the tests perform the same way” in a CLIA-waived lab, Boiani said. If they do, “there’s no reason to restrict access to only complex labs. The results are being used the same way.”

In 2001, the agency first issued a draft guidance document explaining the CLIA application process for manufacturers, which focused mainly on performance in a waived lab versus a nonwaived lab.

The agency issued two other guidance documents on CLIA waivers since, most recently in 2008, but each has deviated from the 2001 guidance, Boiani said. He said the coalition is pushing for the FDA to issue a new guidance document that is more in line with the 2001 version than the 2008 version.

“FDA got it right the first time,” Boiani said. “The current regulations don’t seem like they’re adding much.” He added the FDA isn’t focusing on the right question, which is, “Will the tests perform equally well?”

Takeaway: A new stakeholder group wants the FDA to reform the CLIA waiver process to focus on the user of the test, rather than the test itself. 

Pathologists Exempt From 2015 Meaningful Use Penalty

Pathologists will automatically be exempt from electronic health record (EHR) meaningful use (MU) adjustments in 2015, according to the Centers for Medicare and Medicaid Services (CMS).

The College of American Pathologists (CAP) has long advocated that pathologists should be exempt from MU penalties, arguing that pathologists have little control over whether there is certified EHR technology at their practice location and that the vast majority of objectives are outside the scope of pathology practice.

CMS recently released its 15-page application for physicians unable to meet federal requirements for demonstrating MU of an EHR by 2014 (http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/HardshipException_EP_Application.pdf). Starting in 2015, CMS penalizes eligible physicians for not using a certified EHR and achieving objectives such as reporting

clinical quality metrics electronically. The agency has granted the automatic hardship exception to five specialties, including pathology.

The College of American Pathologists (CAP) has long advocated that pathologists should be exempt from MU penalties, arguing that pathologists have little control over whether there is certified EHR technology at their practice location and that the vast majority of objectives are outside the scope of pathology practice.

While CAP supports the exemption for 2015, the college is seeking a longer-term exemption through 2019. “We urge CMS to continue the automatic granting of the significant hardship exception for pathologists for the full five years allowed under statute,” CAP said in comments to the Department of Health and Human Services Office of the National Coordinator for Health Information Technology.

The MU penalty for 2015 reduces Medicare payment by 1 percent. The penalty grows to 2 percent in 2016 and 3 percent in 2017 and each subsequent year.

Takeaway: Pathologists will be exempt from EHR meaningful use penalties in 2015, but the College of American Pathologists continues to push for a longer-term exemption. 

Court Allows Some Claims Against Quest to Go Forward

A federal court in New Jersey May 30 allowed certain claims in a whistleblower action to move forward against Quest Diagnostics Inc. (Madison, N.J.), including charges that the diagnostic testing company provided free testing supplies and discounted testing services to induce Medicare and Medicaid referrals (*United States ex rel. Judd v. Quest Diagnostics Inc.*, 2014 BL 151026, D.N.J., No. 2:10-cv-04914-KM-MAH).

In an unpublished opinion, the U.S. District Court for the District of New Jersey held that James J. Judd, a physician and managing partner of Hatboro Medical Associates PC (HMA), adequately pleaded that Quest's alleged provision of free testing supplies, office equipment, and discounts on testing services led to HMA's submission of false claims under the False Claims Act (FCA).

However, Judge Dickinson R. Debevoise granted Quest's motion to dismiss Judd's claims that Quest's practices caused other medical providers to submit false claims because Judd had no independent knowledge of Quest's business arrangements with other providers. In addition, Debevoise said the FCA's public disclosure bar and heightened pleading standards under Federal Rule of Civil Procedure 9(b) barred Judd's claims that Quest itself submitted false claims to the government.

Allegations of Free Supplies

Judd said his FCA claims against Quest were the result of his own investigation into contracts between HMA and Quest, and Quest's provision of certain medical testing kits and supplies to HMA from 2005 through the present. Judd alleged that Quest also discounted certain testing services in order to induce referrals to Quest.

Judd alleged in his complaint that Quest's improper practices were duplicated with other providers similar to HMA, resulting in other providers filing false claims in the same manner as HMA. In addition, Judd said that Quest filed false claims for reimbursement for testing services as a result of its alleged kickbacks to providers like HMA. Judd provided claims for specific service dates, patient identification numbers, dates of reimbursements, and reimbursement amounts in his complaint.

Public Disclosure Bar Asserted

Quest moved to dismiss Judd's complaint on the grounds that Judd's claims were barred by the public disclosure bar and failed to allege false claims with particularity as required by Rule 9(b).

The court agreed that two prior FCA actions included similar claims regarding provision of free medical supplies (*United States ex rel. Urbanek v. Lab. Corp. of Am. Holdings, Inc.*, E.D. Pa., No. 00-cv-4863, filed 9/26/00) and discounted medical testing services (*Cal. ex rel. Hunter Lab., LLC v. Quest Diagnostics, Inc.*, Cal. Sup. Ct., No. 34-2009-48046, filed 12/14/09). However, the court said that Judd's own investigation was sufficient to establish himself as an original source of the allegations with respect to false claims made by HMA that were caused by Quest's improper provision of medical supplies and discounts.

But the court said Judd had no independent knowledge of what Quest's practices with other health care providers might be, despite Judd's claims that Quest used standard form contracts with all of its clients and likely was giving other providers free medical supplies as well.

Takeaway: A whistleblower lawsuit against Quest Diagnostics over inducement of referrals is being allowed to proceed in New Jersey. 

New Policy on IVDs, LDTs, from p. 1

LDTs are regulated under the Clinical Laboratory Improvement Amendments by the Centers for Medicare and Medicaid Services.

“FDA must act now because the ‘dual system’ of regulation for IVDs and LDTs does a disservice to patients. The IVD and LDT regulatory systems cannot both be right. There is no way that the two systems can provide equivalent benefits to the public health. If extensive FDA regulation is necessary to ensure the safety and effectiveness of IVDs, then FDA must regulate LDTs. On the other hand, if FDA regulation is unnecessary, the amount of waste caused by compliance with unnecessary FDA requirements is harming the public health by limiting resources for innovation,” the letter said.

The FDA regulates diagnostic tests only if they are developed and sold by device manufacturers as diagnostic kits, regardless of whether they were developed by clinical laboratory companies for in-house testing or by manufacturers for use in kits. The lab tests that companies develop internally generally aren’t subject to FDA review.

“FDA has not only the authority, but the obligation, to create a single regulatory framework for in vitro diagnostics, one where regulations depend on the risks and benefits of the test and not who makes them or where they are made,” the CPC letter said.

‘Frustration’ at Delay

Bradley Merrill Thompson, an attorney with Epstein Becker & Green PC in Washington and general counsel to the CPC, says the group decided to act because it appeared that all IVD- and LDT-related efforts at the FDA “have ground to a halt.”

According to the CPC, the current system doesn’t offer balance “but treats two indistinguishable products—LDTs and IVDs—completely differently, and imposes a number of extra requirements on IVDs beyond those for LDTs.”

Thompson said, “We’ve been waiting and waiting for a [final] guidance on companion diagnostics. Our understanding is that it’s being held up” at the White House Office of Management and Budget because of unresolved concerns about LDT regulation. The CPC letter calls on the guidance to be released and for other agencies to “step aside” if they are holding up its release.

Sending a letter “was the best approach we could think of. It’s pure and simple frustration. I don’t see how this gets resolved without FDA being more bold” about making a decision, Thompson said.

The CPC letter acknowledged the FDA isn’t alone in making LDT regulatory decisions.

“Other agencies within the Executive Branch have been playing a significant role in the decision to maintain the status quo,” the letter said. “Therefore, we also ask that the rest of the Obama Administration—the Office of Management and Budget, the Centers for Medicare and Medicaid Services, the Department of Health and Human Services, and others—all offer their support for equal regulation either by endorsing this effort, or not standing in the way of addressing this problem. Unequal regulation has existed for far too long.”

According to the letter, “there is an optimal system for regulation that balances oversight of IVD manufacturing with flexibility that allows for innovation. Striking the right balance is crucial to the public health.”

According to the CPC, the current system doesn’t offer balance “but treats two indistinguishable products—LDTs and IVDs—completely differently, and imposes a number of extra requirements on IVDs beyond those for LDTs.”

The CPC's letter asks the FDA to respond to a citizen petition filed in June 2013 by the American Clinical Laboratory Association (ACLA) that challenged the FDA's authority to regulate LDTs as medical devices.

ACLA requested that the FDA refrain from issuing any guidance or rules (draft or final) that would regulate LDTs as devices. It also asked that the FDA confirm LDTs aren't medical devices.

According to the CPC, the FDA responded in November 2013 that it "has been unable to reach a decision on [the] petition because it raises issues requiring further review and analysis by agency officials" and to date hasn't provided a "fulsome response" to the petition.

Thompson said the CPC letter builds on the efforts of the citizen petition but is also different. According to the letter, ACLA's petition asks the FDA to refrain from regulating LDTs. According to the CPC, the FDA has "unquestionable" authority to regulate LDTs as devices. ACLA's request "misses the real issue, which is whether FDA should regulate LDTs and IVDs equally."

The combination products group in the letter said it is "understandable that laboratories would fight FDA regulation" because of the rising burden regulations have placed on manufacturers. None of the industry arguments, however, support dual regulatory systems, the letter said.

Call for Action

Thompson said nothing can be done about the regulations without Congress getting involved, but as a minimum first step, he said the agency needs to act and come out with a policy.

"Then we can have a discussion with Congress, get everyone talking," Thompson said. "I want to have a debate. I'm convinced that once the debate starts, we will get somewhere. It all starts with FDA. FDA can't walk around wringing its hands. Doing nothing can't be good for patients. There's no way the current system puts patients first."

The CPC in the letter said it understands that the FDA has drafted three guidance documents describing how it would propose to regulate LDTs, "so releasing those is the best way to quickly move the discussion forward."

Takeaway: Groups representing clinical laboratories and IVD manufacturers are at odds over whether the Food and Drug Administration should regulate lab-developed tests the same as IVDs. While lab groups would like the FDA to refrain from regulating LDTs, IVD groups believe LDTs should be regulated the same as IVDs. FDA action on this front appears to have stalled. 

CMS to Hold Public Meeting on Lab Fee Schedule Updates

The Centers for Medicare and Medicaid Services will hold a public meeting July 14, 2014, on new or revised codes on the Clinical Laboratory Fee Schedule for 2015. The meeting will be held in Baltimore.

All presenters for the meeting must register and submit their presentations electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov by July 3.

Attendees may register for the meeting beginning June 9. Registration may be completed online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/>.

For more information, see the March 25, 2014, *Federal Register*. 

Calloway Laboratories to Pay \$4.7M to Settle Fraud Allegations

Calloway Laboratories will pay nearly \$4.7 million to settle allegations that it fraudulently billed West Virginia Medicaid and the federal Medicare program.

Booth Goodwin, U.S. attorney for the Southern District of West Virginia, announced the settlement May 21, calling it “the largest-ever recovery in a health care fraud case” for his office.

The laboratory, based in Woburn, Mass., provided clinical laboratory services, including urine testing, for Medicare and West Virginia Medicaid, Goodwin said. But from March 2009 through April 2013, it routinely billed both using a code designated for pathology services, in addition to the code for urine drug testing, he said.

An investigation by the West Virginia Medicaid Fraud Control Unit and the Department of Health and Human Services Office of Inspector General established that treating health care providers didn’t deem pathology services necessary and didn’t knowingly order the service.

Goodwin said investigators determined Calloway didn’t provide pathology services, as billed, but performed a type of medical review with every urine drug screen. Medical review isn’t covered by Medicare or West Virginia Medicaid, he said.

The two programs paid the medical review claims, Goodwin said, because Calloway submitted them under a code reserved for covered pathology.

In a statement released May 21, Calloway said it reached the agreement—without an admission of liability—“to conclude a government inquiry into a legacy issue dating back to the company’s previous management and involving a disagreement about services ordered and performed, but not covered.”

By resolving the allegations, the company said it has eliminated the financial uncertainty associated with litigation.

Change in Management Team

Goodwin said the fraudulent billing practices were initiated under Calloway’s former management team, which was replaced in late 2012.

Upon learning of the investigation, he said Calloway’s current management team voluntarily suspended the problematic billing practices nationwide.

Calloway Labs and two of its top executives were indicted in Massachusetts in 2010 on charges involving kickbacks and bribes to managers of group homes for recovering drug addicts, Goodwin said; in 2012, Calloway agreed to pay a \$20 million penalty to resolve the charges against the corporation. Two of the company’s executives later pleaded guilty, he said.

On its Web site, Calloway refers to itself as one of the fastest-growing clinical toxicology laboratories in the nation, specializing in tests that ensure patients aren’t abusing pain medications.

Takeaway: Calloway Laboratories, a toxicology lab based in Woburn, Mass., has agreed to settle allegations that it routinely billed using a code designated for pathology services, in addition to the code for urine drug testing. 

Burwell Expected to Be Confirmed as HHS Secretary

Sylvia Mathews Burwell is expected to be confirmed as secretary of the Department of Health and Human Services (HHS) the afternoon of June 5.

The Senate on June 4 cleared the way for a vote on Burwell's nomination. Senators voted 67-28 to approve a procedural measure limiting debate on Burwell's nomination to no more than 30 hours, allowing a final confirmation vote to move forward on June 5. If confirmed, Burwell would replace Kathleen Sebelius, who announced her resignation in April but agreed to stay on until a successor is confirmed.

Smooth Sailing in Senate

Burwell, director of the Office of Management and Budget, has sailed through Senate committee hearings and a committee vote. The Senate Finance Committee May 21 approved Burwell's nomination by a vote of 21-3. Committee Republicans Pat Roberts (Kan.), John Cornyn (Texas), and John Thune (S.D.) voted no.

On May 14, Burwell appeared at a confirmation hearing held by the Senate Finance Committee, where she received praise from Republicans and Democrats. On May 8, she appeared before the Senate Health, Education, Labor and Pensions Committee, which shares jurisdiction with the Finance Committee over the HHS but without voting authority on nominations.

During the hearings, Burwell demonstrated a mastery of the Affordable Care Act, including health spending issues, while deflecting efforts by Republican lawmakers to get her to commit to specific policy positions.

A Harvard graduate, Burwell is a veteran of the Clinton administration, where she served in a variety of positions, including as a deputy to Treasury Secretary Jacob Lew when he was President Bill Clinton's budget director. Before joining the Obama administration, Burwell was president of the Walmart Foundation, the charitable organization with ties to Walmart stores.

For much of the 2000s, she worked at the Bill & Melinda Gates Foundation, the \$40 billion fund that finances global health and poverty eradication programs. Burwell has a reputation for strong organizational skills and for navigating the bureaucracy of government. 

Note our change of address and phone numbers effective immediately.

To subscribe or renew *NIR*, call now +1-603-357-8101, 800-531-1026

(AAB or NILA members qualify for a special discount, Offer code: NIRNI1)

Online: www.G2Intelligence.com/NIR

Email: customerservice@G2Intelligence.com

Mail to: G2 Intelligence
24 Railroad Street
Keene, NH 03431-3744 USA

Fax: +1-603-357-8111

Multi-User/Multi-Location Pricing?

Please email jjping@G2Intelligence.com or call 603-357-8160.



Don't Miss This Upcoming Webinar

Doing More With Less: Understanding the Cost of Quality in the Laboratory

Thursday, June 19, 2014, 2 p.m.-3:30 p.m.

Featured Speaker:

Lucia Berte, MA, MT (ASCP) SBB, DLM; CQA (ASQ) CMQ/OE
President, Laboratories Made Better!

www.G2Intelligence.com/LabQuality

June 5, 2014 © 2014 Kennedy Information, LLC, A Bloomberg BNA Business, 800-531-1026. All Rights Reserved. Reproduction Prohibited by Law. www.G2Intelligence.com

Notice: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement. *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.

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 800-531-1026.