G2 INTELLIGENCE
A Bloomberg BNA Business

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 35th Year of Publication

Vol. 14, Iss. 15, August 2014

INSIDE *NIR*

www.G2Intelligence.com

Labs Finalizing Policies and Procedures Under Patient Access Rule

With less than two month to go before laboratories will be required to provide patients with access to completed test reports upon request, most labs are putting the finishing touches on new or revised policies and procedures.

Effective Oct. 6, 2014, labs will have 30 days from receiving a request to provide the patient with completed results. In cases where a test may take more than 30 days to analyze and complete, the lab may have a 30-day extension. Labs that fail to provide test results upon request face monetary penalties.

While the large national labs already have patient portals in place to deal with provision of test results, most midsize and smaller laboratories will have to provide results either through mail, in-person pickup, or through encrypted e-mail.

Prior to April 7, 2014, a handful of states and territories allowed patients to access test results directly from labs. Other states either

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FDA Plans to Regulate Lab-Developed Tests Could Increase Time and Cost of Development

While it's too soon to say what effect the Food and Drug Administration (FDA) decision to move forward with plans to regulate lab-developed tests (LDTs) will have on clinical and anatomic pathology laboratories, many in the lab industry believe that the move will increase the time and cost needed to develop such tests.

Reaction from industry groups to the July 31 announcement was mixed, with the American Clinical Laboratory Association (ACLA) urging caution, and other groups saying they need more time to assess the impact.

ACLA President Alan Mertz expressed concern that another layer of regulation could stifle diagnostic innovation and ultimately jeopardize patient access to timely and effective treatments. "Laboratories have been regulated for decades by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) and by state law," said Mertz. "Under the CLIA framework, a thorough and detailed regulatory process, we've seen an explosion of innovation in laboratory diagnostics that has allowed labs to diagnose and measure disease with an accuracy and precision never before possible."

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FDA Plans to Regulate Lab-Developed Tests, *from p. 1*

The College of American Pathologists (CAP), which had put forth its own oversight proposal based on a three-tier risk-based system, says it is still analyzing the FDA framework. Under the CAP proposal, each laboratory would determine the LDT classification based on the FDA's criteria for low-, moderate-, and high-risks tests.

In its July 31 notice to Congress, the FDA outlined how it plans to regulate LDTs, previously known as "home brew" tests. Notably, the agency says it would phase in oversight requirements over nine years and would focus oversight on the tests where a wrong result would pose the highest level of risk to patients. Tests for which there are no approved alternatives and tests for rare diseases would be exempt from FDA regulation.

The FDA estimates that there are currently 11,000 LDTs offered by 2,000 laboratories.

Test kits or components sold to hospitals, laboratories, and doctors' offices have long been regulated by the FDA as medical devices. Tests developed and performed by a single laboratory, however, have been regulated by CMS under CLIA but have not been regulated by FDA. Although the FDA has claimed to have legal authority to regulate LDTs, it has said in the past that it was exercising "enforcement discretion" not to do so.

Agency officials now say that such discretion must end because LDTs, which were once fairly simple, are now more complex and are being developed by companies and marketed widely. Some common commercial tests have never been reviewed by the FDA, including Myriad Genetics' breast cancer tests and the Oncotype DX tests from Genomic Health.

The FDA estimates that there are currently 11,000 LDTs offered by 2,000 laboratories.

In recent months, members of Congress have been putting pressure on the Office of Management and Budget (OMB) to release the FDA's draft guidance, which has been under review for a couple of years. Subsequently, a group of physicians working in academic medical centers urged the OMB not to issue any guidance or rule that puts LDTs under FDA authority. The FDA first proposed regulating LDTs in 2006.

Three-Tiered Oversight

The FDA proposes to have a three-tiered system for oversight of LDTs, with high-risk tests receiving the most stringent oversight. According to the outline submitted to Congress, the agency will propose the following:

- **High-risk LDTs (Class III medical devices)**. Registration and listing (with the option to provide notification) and adverse event reporting beginning six months after the guidance is finalized. Premarket review requirements begin 12 months after the guidance is finalized for the highest-risk devices and phased in over four years for the remaining high-risk devices. Devices would remain on the market during review and FDA's consideration of applications. FDA's focus on high-risk devices begins with the following: (1) LDTs with the same intended use as a cleared or approved companion diagnostic, (2) LDTs with the same intended

use as an FDA-approved Class III medical devices, and (3) certain LDTs for determining the safety or efficacy of blood or blood products.

- **Moderate-risk LDTs (Class II medical devices)**. Registration and listing (with the option to provide notification) and adverse event reporting begin six months after the guidance is finalized. Premarket review requirements begin after the high-risk (Class III) LDTs are completed, meaning five years after the guidance is finalized, and phased in over four years. FDA intends to utilize FDA-accredited third-party review of premarket submissions as appropriate.

The FDA intends to exercise enforcement discretion for applicable premarket review requirements and quality system requirements but enforce other applicable regulatory requirements, including registration, listing, and adverse event reporting, for low-risk LDTs (Class I devices), LDTs for rare diseases, and LDTs for unmet needs (meaning no FDA-approved or cleared equivalent device is available).

In addition, the FDA will continue to use enforcement discretion for LDTs used solely for forensic (law enforcement) purposes and for LDTs used in CLIA-certified, high-complexity histocompatibility laboratories for transplantation. For these tests, FDA does not intend to enforce applicable registration and listing (nor is FDA requesting notification), adverse event reporting, premarket review, or quality system requirements.

The FDA also says it will continue to exercise enforcement discretion with respect to premarket review requirements for "traditional LDTs, which are those IVD devices that reflect the types of LDTs available when FDA began its policy of generally exercising enforcement discretion over LDTs in 1976." In considering whether to exercise enforcement discretion for traditional LDTs, the FDA intends to consider the following factors:

1. Whether the device meets the definition of LDT in the guidance (a device designed, manufactured, and used by a single laboratory);
2. Whether the LDT is both manufactured and used by a health care facility laboratory (such as one located in a hospital or clinic) for a patient that is being diagnosed and/or treated at that same facility or within the facility's health care system;
3. Whether the LDT is composed of only legally marketed components and instruments (e.g., analyte-specific reagents, general purpose reagents, and various classified instruments); and
4. Whether the LDT is interpreted by qualified laboratory professionals, without the use of automated instrumentation or software for interpretation.

The FDA will officially publish its draft guidance around the end of September.

Takeaway: Industry groups are still analyzing the likely impact of the FDA's proposal to regulate lab-developed tests.

focus on: Clinical Laboratory Fee Schedule

Industry Groups Give Recommendations on 2015 Lab Test Codes

Leading lab and pathology groups recently made recommendations to the Centers for Medicare and Medicaid Services on new and revised codes that will be added to the Clinical Laboratory Fee Schedule effective Jan. 1, 2015. This is the second part of coding recommendations; the first part of the recommendations was included in the July 24, 2014, issue of *National Intelligence Report*.

MEDICARE LAB FEE SCHEDULE FOR 2015: NEW CPT CODES AND PAYMENT RECOMMENDATIONS		
CODE DESCRIPTOR	*CODE CROSSWALK OR GAP-FILL*	*PROPOSED NLA*
GENOMIC SEQUENCING PROCEDURES		
81410X Aortic dysfunction or dilation genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 2	— $1,292.48
81411X Aortic dysfunction or dilation (duplication/deletion analysis), panel must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 2	— $904.74
81415X Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 9.9	— $6,397.78
81416X Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswak to 81292 x 9.9	— $6,397.78
81417X Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence	ACLA, ASCP, AACC, ASCLS: Gap-fill	
81420X Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 4	— $2,584.96
81425X Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis	ACLA, ASCP, AACC, ASCLS: Gap-fill	
81426X Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome	ACLA, ASCP, AACC, ASCLS: Gap-fill	
81427X Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence	ACLA, ASCP, AACC, ASCLS: Gap-fill	
81430X Hearing loss, genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, and WFS1	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 4	— $2,584.96
81431X Hearing loss, duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 0.7	— $452.37
81435X Hereditary colon cancer syndromes, genomic sequence analysis panel, must include analysis of at least 7 genes, including APC, CHEK2, MLH1, MSH2, MSH6, MUTYH, and PMS2	ACLA, ASCP, AACC, ASCLS: Gap-fill	

CODE DESCRIPTOR	CODE CROSSWALK OR GAP-FILL	PROPOSED NLA
GENOMIC SEQUENCING PROCEDURES		
81436X Hereditary colon cancer syndromes, duplication/deletion gene analysis panel, must include analysis of at least 8 genes, including APC, MLH1, MSH2, MSH6, PMS2, EPCAM, CHEK2, and MUTYH	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 2	— $1, 292.48
81440X Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes.	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 3.9	— $2,520.34
81445X Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 3.9	— $2,520.34
81455X Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 3.9	— $2,520.34
81460X Whole mitochondrial genome, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 3.6	— $2,326.46
81465X Whole mitochondrial genome large deletion analysis panel	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 3.6	— $2,326.46
81470X X-linked intellectual disability	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 4	— $2,584.96
81471X X-linked intellectual disability	ACLA, ASCP: Gap-fill AACC, ASCLS: Crosswalk to 81292 x 4	— $2,584.96
MULTIANALYTE ASSAYS WITH ALGORITHMIC ANALYSES		
815XX Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score Oncotype DX® Breast Cancer Assay (Genomic Health, Inc.)	ACLA, ASCP, AACC, ASCLS: Gap-fill	
CHEMISTRY		
83005X Growth stimulation expressed gene 2 (ST2, interleukin I receptor like-1)	ACLA, ASCP, AACC, ASCLS: Crosswalk to 82777	$30.01
MICROBIOLOGY		
8751X1 Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen, 3-5 targets	ACLA, ASCP, AACC, ASCLS: Crosswalk to 87631	$175.02
8751X2 Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen, 6-11 targets	ACLA, ASCP, AACC, ASCLS: Crosswalk to 87632	$291.18
8751X3 Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen, 12-25 targets	ACLA, ASCP, AACC, ASCLS: Crosswalk to 87633	$568.60
876XX3 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg 6,11,42,43,44)	ACLA, ASCP, AACC, ASCLS: Crosswalk to 87621	$47.87
876XX4 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg 16,18,31,33,35,39,45,51,52,56,58,59,68)	ACLA, ASCP, AACC, ASCLS: Crosswalk to 87621	$47.87
87806X Infectious agent antigen detection by immunoassay with direct optical observation; HIV-1 antigen(s), with HIV-1 and HIV-2 antibodies	ACLA, ASCP: Crosswalk to 87389 AACC, ASCLS: Crosswalk to 87390	$32.86 $42.76
REPRODUCTIVE MEDICINE PROCEDURES		
893XX7 Cryopreservation; mature oocytes	ACLA, ASCP: Crosswalk to 89258	No NLA listed in 2014 CLFS
G CODES		
GXXXX Colorectal cancer screening; stool-based DNA and fecal occult hemoglobin (e.g., KRAS, NDRG4 and BMP3)	ACLA, ASCP: No comment, pending discussion AACC, ASCLS: Crosswalk to 82274 + 81275 + 81315	— $501.78

Source: G2 Intelligence from association comments.

Labs Finalizing Policies and Procedures Under Patient Access Rule, *from p. 1*

allowed test results to be released only to providers, allowed test results to patients with provider approval, or had no state law addressing the issue.

PAML, a large reference lab based in Spokane, operates in a state—Washington—where patients have been allowed to access their medical information, including laboratory test results. In the past, PAML would require a patient to make a request in person at a patient service center and to show an identification card with a photo, according to Marguerite Busch, vice president and chief compliance officer for PAML and PAML Ventures. The patient then would be required to come back to pick up a hard copy, or a hard copy would be mailed to the patient.

Under the new mandate, however, labs are required to provide results "in the form and format requested if a copy in that form or format is readily producible," which means that PAML must be prepared to e-mail results upon request. Labs must also be prepared to authenticate the identity of the requestor even in cases where the person is not able to appear in person.

Busch advises labs to consider a delay in release of sensitive test results for at least 21 days to allow the ordering provider ample time to communicate results to the patient.

Busch and Bill Tilton, senior vice president, operations, for American Pathology Partners (AP2) in Nashville, Tenn., discussed practical strategies for compliance with the new mandate during a July 31 webinar sponsored by G2 Intelligence (recording at available at *www.G2Intelligence.com*).

Authentication options being tested at PAML include having a patient request form notarized, FaceTime communication with the patient holding a photo ID, and verbal authentication with certain identifiers provided by the patient matching lab information.

Challenges and suggestions for compliance with the Oct. 6 mandate are discussed below.

Secure Delivery of Results

One challenge that PAML, AP2, and other labs face is how to ensure that results are delivered securely. Labs that e-mail results must do so in an encrypted format. The patient may need to verify that his or her e-mail system can accept and open an encrypted e-mail sent from the lab. If the patient cannot verify the ability to open an encrypted e-mail, the lab should consider declining to send results in an unsecured manner, advises Busch.

Sensitive Tests

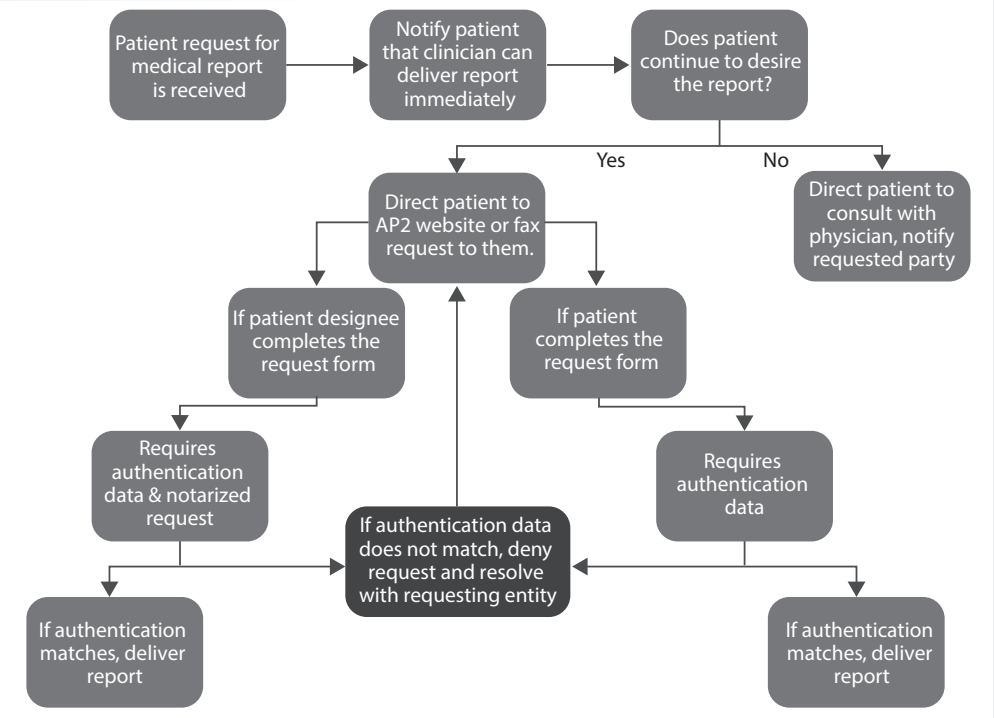
Under the new rule, with a very limited exception, labs may not deny an individual access to health information based on the information's sensitive nature or potential for causing distress. The limited exception is for cases where a licensed health care professional has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person, and the individual is provided a right to have the denial of access reviewed by an unaffiliated health care professional.

Busch advises labs to consider a delay in release of sensitive test results for at least 21 days to allow the ordering provider ample time to communicate results to the patient.

At AP2, when a patient requests a test report, the lab will first direct the patient to the clinician. If the patient still wants the report from the lab, then he or she must fill out a request form with appropriate data elements to be used for authentication purposes. The request must include the patient full name, date of birth, address, phone number, clinician name, group name, group address, and date of service. If

the request comes from the patient, a photo ID will be required. If the request comes from an authorized representative, notarization will be required.

AP2 Process Flowchart



Source: American Pathology Partners

Physician Education

Both Busch and Tilton advise labs to educate referring physicians about the new rule. This is especially important in states that have not allowed labs to release test results in the past. Information to consider letting physicians and other health care providers know:

- ❑ Labs may delay all releases of test results to patients for 48 hours (or other time frame) after the ordering provider would have received results;
- ❑ Labs may delay release of test results for certain "sensitive tests" for 21 days to give the provider time to communicate with the patient; and
- ❑ These decisions can be made by each lab.

Fees

Although the Centers for Medicare and Medicaid Services (CMS) will allow labs to charge individuals a reasonable, cost-based fee to cover the cost of providing the lab test results, both Busch and Tilton say their labs do not plan to charge a fee. CMS estimates that it will take a lab 10 to 30 minutes to handle a request at a cost of about $10 to $30 per request. Both Busch and Tilton say that if they find the cost of providing results is greater than they expect, they would reconsider revisiting the issue of charging a nominal fee.

Takeaway: Labs must be prepared to comply with the patient access rule come Oct. 6, 2014. While policies and procedures may vary from lab to lab, certain requirements must be met by all labs.

Colon Cancer Screening Test Gets FDA Approval, Proposed Medicare Coverage

The Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA) concurrently issued decisions Aug. 11 aimed at providing access to the first noninvasive DNA screening test for colon cancer.

The FDA approved Cologuard, a stool-based DNA screening test used to detect abnormalities that may indicate colon cancer. The test is manufactured by Exact Sciences Corp. of Madison, Wis. The FDA's Molecular and Clinical Genetics Panel March 27 voted 10-0 in favor of approval for the Cologuard test.

Cologuard was approved under a pilot program involving the FDA and CMS conducting a parallel review. The agencies first announced the parallel review program in October 2011.

The FDA's approval coincided with CMS Aug. 11 issuing a proposed coverage decision (CAG-000440N) for Cologuard. The coverage decision said the "CMS proposes to cover the Cologuard screening once every three years for beneficiaries who meet" specified criteria. The colon cancer screening test is the first product approved under the parallel review pilot.

Exact Sciences requested that CMS consider a national coverage determination for Cologuard. Comments regarding the proposed coverage decision are due Sept. 10.

Eligibility Criteria

To fulfill the eligibility coverage for the Cologuard test, the proposed coverage decision said beneficiaries must meet the following conditions:

- ❑ Be 50 to 85 years old;
- ❑ Be asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test); and
- ❑ Be at average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's disease and ulcerative colitis and no family history of colorectal cancers or an adenomatous polyp, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer).

Reminder: August is a one-issue month for *NIR*.

The coverage decision also said Cologuard would be covered under Medicare Part B, which pays for medically needed services and supplies and preventive care. It noted that other colon cancer screening procedures are covered by CMS. However, "Since Cologuard cannot be classified in any existing" colon cancer screening category, the agency said it needed to create a new category specifically for tests screening stool or examining fecal DNA.

CMS's proposed coverage decision is available at *www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=277*. The FDA announcement is available at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm409021.htm*.

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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.

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

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