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Lab, Pathology Groups Seek Major Say in How the FDA Exercises More Oversight of Lab-Developed Tests

The groups want to maintain a formal dialogue with the FDA before it moves ahead to tighten the regulatory reins on lab-developed tests

As the Food and Drug Administration prepares to tighten its regulatory grip on laboratory-developed tests (LDTs), 13 organizations across a broad spectrum of pathology and laboratory medicine providers in clinical and public health lab settings have called for a formal role in crafting a framework for expanded oversight (*see also the Focus, pp. 4-6*).

In a Sept. 15 letter to Jeffery E. Shuren, M.D., J.D., director of the FDA Center for Devices and Radiological Health, the groups asked that the agency "host interactive meetings with stakeholders to discuss specific issues about the framework before [it] moves ahead with any proposal."

Expanded LDT oversight is a complex new initiative, the groups noted, and because of the operational challenges involved for those they represent, they want to be engaged in devising "solutions that will not disrupt innovation, and the value that LDTs bring to patient care and public health needs."

They questioned whether the FDA had the potential additional resources to do the job, with thousands of multiple similar, if not the same, LDTs submitted by many clinical labs for review. Oversight should be "clearly defined and balanced, because [it] is already in place by federal, state, and accreditation authorities."

Update on Labs Charged in California Medi-Cal Fraud Case

Court dates have been set for four of seven laboratory defendants in the whistleblower lawsuit, joined by the California attorney general, that seeks to recover millions of dollars in alleged illegal kickbacks under Medi-Cal, the state's Medicaid program. Two of the seven have settled and one has been dropped from the case for settlement discussions.

Quest Diagnostics companies are the first up to go to trial, scheduled for May 2, 2011. Court dates for three others are:

- ❑ Laboratory Corporation of America, a Delaware Corp., and Laboratory Corporation of America Holdings Inc.: Sept. 6, 2011.

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Update on Labs, *from p. 1*

- ❑ Physicians Immunodiagnostic Laboratory Inc.: Jan. 30, 2012.
- ❑ Whitefield Medical Laboratory Inc.: May 7, 2012.

Settlements have been reached with WestCliff Medical Laboratories Inc. and with Taurus West Inc. aka Health Line Clinical Laboratories Inc., which has been acquired by WestCliff. And settlement discussions are under way with Seacliff Diagnostics Medical Group.

While the state investigation is continuing, attorneys for the lab plaintiffs say the Medi-Cal case is not cut-and-dried. The "lowest rate" argument is subject to dispute since the law in general allows discounts to physicians. But one ruling by a California state court in a separate case concluded that labs could charge any other purchaser any fee for services as long as Medi-Cal got the best price available to other customers under comparable circumstances.

In settlements thus far, the attorney general's office said in an e-mail to *NIR*, "The government recovered $5,049,189 on its claims, and the *qui tam* plaintiffs recovered $250,000 in statutory attorney fees and expenses. The *qui tam* plaintiffs also received, in addition to their separate statutory recovery of costs and expenses, $1,011,303.05 under the California False Claims Act as the whistleblower's share of the government's recovery."

The lawsuit was transferred, on defendants' motions, from San Mateo Superior Court where it was filed to Sacramento Superior Court before being divided into separate complaints. The pending cases are there now.

Attorney General Edmund G. Brown Jr. announced March 20, 2009, that his office was joining a whistleblower suit filed against the labs by Chris Riedel, the CEO of Hunter Laboratories in Campbell, Calif. (*California ex rel. Hunter Laboratories LLC v. Quest Diagnostics Inc.*, No. CIV 450691 (Cal. Super. Ct.).

The *qui tam* suit filed under the state's False Claims Act seeks triple the amount of California's damages, civil penalties of $10,000 for each false claim, and recovery of costs, attorneys' fees, and expenses. Under the state's FCA, the whistleblower receives a share of the recovery if statutory requirements are met (*NIR 09, 6/March 30, p. 1*).

The broader issue posed by the litigation is whether California's lead will prompt other states with similar laws to follow suit to scrutinize lab charges and curb rising costs in their Medicaid programs.

Under California law, "no provider shall charge [Medi-Cal] for any service . . . more than would have been charged for the same service . . . to other purchasers of comparable services . . . under comparable circumstances," Brown noted. Yet, the defendant labs charged Medi-Cal up to six times as much as they charged some of their other customers for the very same tests, he continued.

Brown said the allegations revealed a pattern of fraudulent overcharging and kickbacks that developed over the past decade. Specifically:

- ❑ The labs provided deep discounts when paid directly by doctors, patients, or hospitals. Prices were often below the lab's cost and sometimes free.
- ❑ In exchange, the labs expected customers to refer all of their other patients (where the lab was paid by an insurance company, Medicare, and Medi-Cal) to its lab. Under California law, this amounted to an illegal kickback.

- ❑ The sharply reduced prices were not made available to Medi-Cal. In effect, the labs shifted the costs of doing business from the private sector to Medi-Cal.
- ❑ Additionally, the labs offered their clients who paid them directly (not through Medi-Cal or other insurance) deeper and deeper discounts in order to get a larger share of the lab testing business. This created an unfair playing field, and laboratories that followed the law could not effectively compete and sometimes were forced to sell or close down.

MedPAC Takes 'Go Slow' Approach on Self-Referral Issues

The Medicare Payment Advisory Commission (MedPAC) continues to voice concern over the growth in volume and increased Part B spending associated with physician investment in ancillary services under the Stark self-referral exception. But it is not yet ready to make recommendations on the issues in its next report to Congress.

The panel appears to favor more scrutiny of options to address overutilization concerns and avoid for now major self-referral changes in light of health care reform initiatives in the offing, which some members said could resolve key issues, such as new delivery and payment models that reward quality and efficiency in coordinated care, including accountable care organizations (related story, p. 8).

Instead, at its Sept. 13-14 meeting in Washington, D.C., the panel continued its discussion of a range of policy options to address overutilization of in-office services (IOAS), including anatomic pathology and clinical laboratory tests, and to curb medically unnecessary testing. The options for diagnostic imaging and lab tests, outlined in the recent CAP *Statline* included:

- ❑ Exclude services from the in-office exception unless provided on the same day as the visit.
- ❑ Exclude from the exception unless the practice is clinically integrated.
- ❑ Reduce payments for tests performed by self-referring physicians where abusive utilization patterns are identified.
- ❑ Require prior authorization for advanced imaging services.
- ❑ Package or bundle payment for testing services. Bundling refers to a per-episode-of-care payment for multiple procedures by several providers. Packaging refers to a single payment for multiple services by a single provider.

MedPAC members favored reducing payments where abusive utilization patterns are found but split on prior authorization from Medicare, which some warned created a new administrative burden that could impede access by patients to timely magnetic resonance imaging testing.

InfoGard Labs Named to Certify E-Health Records

InfoGard Laboratories Inc. in San Luis Obispo, Calif., is the third entity authorized by the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) to test and certify electronic health record (EHR) systems.

The first two selected were the Certification Commission for Health Information Technology in Chicago and the Drummond Group Inc. in

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focus on: FDA Regulation

Expanding Oversight of Lab-Developed Tests: How Far Should the FDA Go?

Now that the Food and Drug Administration has decided to step up its oversight of laboratory-developed tests (LDTs) under its medical device authority, the key concerns for pathology and lab medicine providers, test manufacturers, and other stakeholders are how far will the agency go and what process will it follow in crafting a new regulatory framework.

While the FDA asserts it has jurisdiction over all medical devices, including LDTs, it has thus far limited its enforcement discretion to analyte-specific reagents used in the test and to a category of tests known as in vitro diagnostic multivariate index assays (IVDMIAs).

To get advice on how to proceed, the FDA kicked off a public comment period at a July forum, where agency officials said they planned to develop a draft LDT oversight framework later this year, based on the level of risk associated with a test, that would be phased-in over time (*NIR 10, 14/July 23, p. 1*).

The FDA is now digesting advice received at the forum and during the comment period that ended Sept. 15. On that same date, a broad alliance of clinical and public health lab organizations appealed to Jeffery Shuren, M.D., J.D., director of FDA's Center for Devices and Radiological Health, to continue an interactive, transparent approach to developing the draft framework (*see box*).

Signatories to Letter to Shuren

- American Association for Clinical Chemistry
- American Clinical Laboratory Association
- American College of Medical Genetics
- American Medical Technologists
- Association for Molecular Pathology
- American Pathology Foundation
- American Society for Clinical Laboratory Science
- American Society for Clinical Pathology
- American Society for Microbiology
- Association of Public Health Laboratories
- Clinical Laboratory Management Association
- Coalition for 21st Century Medicine
- College of American Pathologists

In their Sept. 15 letter to Shuren, the organizations urged the FDA to host formal workshops with stakeholders to discuss specific issues before the FDA moves ahead with any proposal in this area. There are major challenges in finding the right regulatory fit for LDTs, the groups noted. For example, LDTs and test kits requiring premarket review are operationally different. Clinical labs offering LDTs provide a service, not a test kit that is sold nationwide for use in clinical practice. Another big challenge the groups cited is whether the FDA has the potential additional resources to handle the review of thousands of tests without disrupting patient access to cutting-edge technology.

Why FDA Is Pressing Forward

The FDA's move to reconsider LDT oversight comes in the wake of a bid last May by Pathway Genomics to sell its genetic tests directly to consumers through the Walgreens national pharmacy chain. The FDA blocked that plan, saying the tests are subject to premarket review. The case also drew the agency's attention, and ultimately that of a congressional committee, to

other genetic testing companies making online direct-to-consumer (DTC) sales, with follow-up warnings to these companies that the FDA considers their tests to be medical devices subject to premarket review. The controversy further prompted the FDA to take a new look at how it handles the broader field of LDTs.

Most LDTs are regulated by the Centers for Medicare and Medicaid Services (CMS) and its accrediting bodies under the Clinical Laboratory Improvement Amendments (CLIA). Under FDA policy, standards for LDTs differ from the premarket review required of test kit manufacturers. Claiming this puts them at a competitive disadvantage, biopharma giant Genentech and AdvaMed, the medical device makers' lobby, have petitioned the FDA to treat LDTs the same as their products.

What's at Stake Over LDTs?

Lab-developed tests are in vitro diagnostics manufactured by and performed in the same clinical laboratory certified for high-complexity testing under CLIA.

Estimated to number in the thousands, they range from modifications of routine tests to complex genetic tests used to screen, diagnose, and treat patients with a wide range of cancers, cardiovascular and neurological disease, and Alzheimer's.

LDTs also have provided a rapid response to infectious disease outbreaks and other emerging public health threats, such as avian flu, West Nile virus, and H1N1.

But the FDA is concerned that offering LDTs through a CLIA-certified lab created specifically for that purpose is now frequently used as a mechanism for market entry, allowing novel tests to reach the national market without going through the FDA. "We see LDT being used more and more as a loophole," said FDA official Elizabeth Mansfield, Ph.D., director for personalized medicine. "Preliminary medical data is being packaged as medical information."

Though the FDA aims to hold more LDTs to a higher standard, officials conceded at the public forum that they have no clear idea of the scope of the LDT market and said that efforts to learn who is offering what tests would be coordinated with the National Institutes of Health's genetic testing registry.

Options on the Table

In statements submitted to the FDA at the public forum and in the subsequent comment period, pathology and laboratory groups presented a range of proposals for how the agency should address the scope and operational complexities in expanding its regulatory reach over LDTs.

All agree that any expanded oversight must involve better coordination between FDA and CMS to avoid any regulatory duplication and allow flexibility to encourage innovation of new diagnostic tests. It also must define the roles that federal agencies and accrediting bodies will assume under a new oversight scheme, including use of CLIA inspectors for LDT review.

In its comments on LDT oversight, the College of American Pathologists (CAP) proposed a three-tier, risk-based approach in concert with third-party accreditors, with risk classified as low, moderate, or high, according to the potential harm of incorrect or misinterpreted test results. CMS and its deemed accreditors would continue LDT oversight, validating tests rated low and moderate risk and approve those ranked moderate before the lab could begin clinical testing. High-risk tests would require FDA review and approval of clinical claims, with CMS and deemed accreditors overseeing laboratory compliance.

The American Society for Clinical Pathology and the Joint Commission on Accredi-

tation of Healthcare Organizations proposed that high-complexity LDTs fall under FDA's purview, while moderate-complexity LDTs, those not deemed to be in vitro diagnostic multivariate index assays, should continue to be regulated by CLIA.

In their joint statement, the two groups cautioned that lengthy approval procedures could delay implementation of new tests, stifle innovation, increase development costs, and thus limit patient access to potentially beneficial assays. Further, gaining approval for low-volume LDTs, such as those used to diagnose rare genetic disorders, would be difficult because of the small populations available for clinical trial testing.

The American Clinical Laboratory Association (ACLA) noted in its comments that labs continually seek ways to improve tests. "This might include adjusting the assay to allow for increased test volumes, shifting sequence position of primers or probes when new variants are recognized, validating additional sample types or collection devices when appropriate, or improving reagent concentration. Resubmission to FDA for every change improvement of an assay could delay innovation or be a disincentive for assay improvement."

ACLA urged the FDA to work toward consensus on the criteria for risk-based categorization of tests and the appropriate evidence requirements linked to each risk-based category. The agency also should "grandfather" the vast majority of well-accepted and well-understood tests already in clinical use to avoid disruption in patient care, ACLA said.

The American Association of Bioanalysts (AAB) pointed out in its comments that many LDTs are developed by research and smaller labs for rare and unusual diseases or conditions. Requiring all LDTs to undergo formal FDA review as medical devices would be cost- and time-prohibitive and would restrict LDTs to large, publicly traded companies that have the resources to pursue the review process. However, AAB said, even for low-volume LDTs designed for rare or unusual diseases, patients need to be assured that the tests are accurate, reliable, and reproducible.

As a result, AAB proposed a tiered system whereby all LDTs above a certain test or dollar volume would undergo premarket review. LDTs below the threshold would continue to be regulated under CLIA, and CLIA inspectors would be required to review their validation data, not just the validation process. Though data review is required, AAB said, "It is our understanding that many inspectors do not conduct the review due to time constraints." As a possible alternative for tests below the threshold, AAB proposed a "modified" proficiency testing (PT) program, enrolling a minimum of three labs in a specimen exchange program, with one portion forwarded to a CLIA-approved PT program. Test results from all participating labs would be compared and reported back to them and to the CLIA compliance program. If the results are comparable, this could be substituted for the required review of validation data.

The tiered system should also provide an "Emergency Health Event" exception, AAB said, whereby the formal device review process can be temporarily suspended for infectious disease outbreaks, epidemics, pandemics, or other public health emergencies.

InfoGard Labs, *from p. 3*
Austin, Texas (*NIR 10, 16/Sept. 9, p. 7*). Additional applications are under review, according to ONC.

The selection of InfoGard Laboratories offers another avenue for EHR vendors to have their products certified as meeting the certification and standards criteria issued earlier this year by HHS, including key criteria to support "meaningful use" (*NIR, 10, 14/July 23, p. 4*).

Demonstration of meaningful use of EHRs by physicians and other eligible professionals as well as hospitals is required in order to qualify for new incentive payment programs to encourage providers to switch from paper-based medical records to electronic ones.

Individual physicians and other eligible professionals can receive up to $44,000 through Medicare and almost $64,000 through Medicaid. Hospitals can receive millions. The payments were authorized under the American Recovery and Reinvestment Act of 2009, which provided as much as $27 billion in incentive outlays.

For information about the ONC certification programs, visit *http://healthit.hhs.gov/certification*. For information about the Medicare and Medicaid EHR Incentive Programs, go to *http://www.cms.gov/EHRIncentivePrograms*.

CMS Announces New Waived Tests, Billing Codes

The Oct. 1, 2010, update by the Centers for Medicare and Medicaid Services (CMS) to the list of test devices waived under the Clinical Laboratory Improvement Amendments (CLIA) includes the latest approved by the Food and Drug Administration for this category. New waived tests are approved on a flow basis and are valid as soon as approved.

CPT Code	Effective Date	Description
G0430QW	Jan. 1, 2010	Noble Medical Inc. Split-Specimen Cup
82274QW, G0328QW	March 1, 2010	Inverness Medical Clearview iFOBT Complete Fecal Occult Blood Test
82010QW, 82962	March 2, 2010	Nova Biomedical Nova Max Plus Glucose and B-Ketone Monitoring System
83986QW	April 15, 2010	Common Sense Ltd. VS-Sense Test [qualitative]
85610QW	April 15, 2010	CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use)
G0430QW	April 21, 2010	Redwood Toxicology Laboratory Inc. Reditest Freedom Cup
G0430QW	April 21, 2010	Noble Medical Inc. NOBLE 1 Step Cup [OTC]
G0430QW	April 30, 2010	Express Diagnostics, DrugCheck Waive Cup
G0430QW	April 30, 2010	Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups
81003QW	June 3, 2010	Cole-Talyor Marketing Inc. CTI-120 Urine Strip Analyzer

When billing for the tests below, use the QW modifier so your local Medicare contractor can recognize the code as CLIA waived. Prior to approval for payment, your claims are checked to see whether you are certified for waived testing.

Contractors are not required to search their files to either retract payment or retroactively pay claims, but they are to adjust claims brought to their attention.

Scrutiny of Legal Issues Related to ACO Payment Model

Input is invited in particular on whether to grant a waiver or create a new Stark self-referral exception and anti-kickback safe harbor to counter legal risks posed by the ACO payment incentive program and encourage its spread as part of long-term health care reform.

On Oct. 5, the Federal Trade Commission will co-host a workshop on legal issues associated with Accountable Care Organizations (ACOs), authorized by the health care reform law, to allow them to deliver quality coordinated care to Medicare beneficiaries and share in the savings achieved by efficiencies in delivering that care.

Joining the FTC in hosting the event are the Centers for Medicare and Medicaid Services (CMS) and the Health and Human Services Office of Inspector General. The workshop, which will be held at CMS headquarters in Baltimore, Maryland, is free and open to the public, including physicians, physician associations, hospitals, health systems, payers, consumers, and other stakeholders.

The voluntary ACO program is set to get under way in 2012. The ACO's core is primary care and related services by a patient-centered team, including pathologists and clinical lab professionals. The workshop is designed to address ACO issues under antitrust, self-referral, anti-kickback, and civil monetary penalty laws.

• Upcoming G-2 Events •

Webinar
2 p.m. – 3:30 p.m. (Eastern)

Sept. 29
Health Care Reform: Implications and Opportunities for the Lab Industry
Discussing key drivers for success in this new environment, including the electronic medical record, global payment structures, and the aggregation of health care provider organizations and physicians into large integrated networks

Conferences

Oct. 13
Lab Leaders Summit
Come for the Summit and Stay for Lab Institute
Crystal Gateway Marriott
Arlington, Va.

Oct. 13-15
28th Annual Lab Institute
Making Change Work for You
Crystal Gateway Marriott
Arlington, Va.

Dec. 8-10
Laboratory Sales and Marketing 2010
The Venetian Las Vegas
Las Vegas

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