G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 37th Year of Publication

Vol. 16, Iss. 9, May 12, 2016

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Upcoming Events

Webinar:

May 24, 2016, 2pm EDT

FDA Regulation of Laboratory-Developed Tests: What to Expect, How to Prepare

Mahnu Davar, Partner, Arnold & Porter

Jen Madsen, MPH, Health Policy Advisor, Arnold & Porter

Conference:

Lab Institute 2016

October 26-28. Hyatt Regency Washington on Capitol Hill, Washington, DC

www.labinstitute.com

House Appropriations Bill Seeks to Halt FDA Regulation of LDTs

With the U.S. Food and Drug Administration (FDA) on the threshold of releasing final rules for its oversight of laboratory developed tests (LDTs), the lab sector is taking a run at preserving the current regulatory model by essentially asking Congress to bring the agency to heel.

Contained in a pending FDA/agriculture appropriations bill in Congress is a provision that would suspend final regulations for the FDA's oversight of LDTs. Instead, the agency would be directed to work with federal lawmakers to create a pathway for regulating such assays.

The bill was approved by the House Appropriations Committee on a voice vote and likely has a significant swath of supporters in both the House of Representatives and the Senate, according to Alan Mertz, president of the American Clinical Laboratory Association (ACLA).

"It should send a message to the FDA that Congress is interested in a legislative solution," Mertz said, acknowledging that while Congress has weighed in on reimbursement issues for the sector on multiple occasions, it has not really involved itself on the regulatory end for decades.

Continued on page 2

CMS Unveils Proposed Rule Implementing MACRA and Replacing Meaningful Use

In January, the Centers for Medicare & Medicaid Services (CMS) Acting Administrator Andy Slavitt indicated that the "Meaningful Use program as it has existed, will now be effectively over and replaced with something better." (See *National Intelligence Report*, 1/28/16, p. 6.) CMS has now issued a proposed rule providing a look at that something better. "[W]e are proposing to incorporate the [Meaningful Use] program [into] the Merit-based [Incentive] Payment System (MIPS) in a way that makes it more patient-centric, practice-driven and focused on connectivity. This new program within MIPS is named Advancing Care Information," said Slavitt and Dr. Karen DeSalvo, national coordinator, Office of the National Coordinator for Health IT, in a CMS Blog.

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House Appropriations Bill Seeks to Halt FDA Regulation of LDTs, *from page 1*

In a statement released after the committee's action, Mertz discussed industry support for the House Appropriation Committee's efforts and efforts to achieve a legislative solution regarding LDTs: "The language in the bill report recognizes the need to suspend the Final FDA Guidance while Congressional authorizing committees work with laboratories, diagnostic manufacturers, providers and patients on a comprehensive framework that supports innovation and personalized patient care. This is consistent with ACLA's position."

> *"It would be interesting to see where Congress comes down on this debate. However, the real impact may just be a delay in regulation for some time—which, of course, most laboratories would not mind."*
>
> — Danielle Sloane, Bass, Berry & Simms

The House Appropriations Committee's language calls the FDA framework a "significant shift" concerning LDT regulation which requires public input. Most importantly, the language mirrors objections raised by ACLA that the FDA is taking the wrong path to exercising oversight of LDTs: "The FDA's guidance circumvents the normal rulemaking process and changes expectations for patients, doctors, and laboratories for the first time since the Clinical Laboratory Improvement Amendments Act was passed in 1988. The Committee directs the FDA to suspend further efforts to finalize the LDT guidance and continue working with Congress to pass legislation that addresses a new pathway for regulation of LDTs in a transparent manner."

Not everyone fully supports the bill's attempt to stall the FDA. Connecticut Congresswoman Rosa L. DeLauro stated in her "Additional Views" on the bill that "the 2017 bill contains a number of partisan ideological provisions that completely undermine our regulatory agencies' abilities to do their jobs, and puts the lives of children, seniors, and families at risk." Citing the FDA as "one of our most critical lines of defense in ensuring the health and wellbeing of Americans," DeLauro criticized the bill for restricting the FDA's oversight of these "currently unregulated," which she claimed "are the precipice for people receiving treatment [for] life-threatening diseases." She exhorted that "FDA oversight of LDTs is crucial to ensuring they have been properly validated and is essential to patient safety. This viewpoint has the support of 36 patient groups who wrote to the Committee in support of FDA's oversight of Laboratory Developed Tests."

So… is this bill an actual legislative solution—or an end run around the FDA's regulatory authority? Experts on the FDA and the laboratory sector suggest the latter.

"It would be an end run around the FDA if it were adopted," said Jeff Gibbs, a director with the law firm of Hyman, Phelps & McNamara in Washington, D.C. Gibbs added that the move should also be construed as a "warning shot" against the agency, although he does not believe the FDA would be deterred from issuing the final regulations.

"It would be interesting to see where Congress comes down on this debate. However, the real impact may just be a delay in regulation for some time—which, of course, most laboratories would not mind," said Danielle Sloane, a member of the law firm Bass, Berry & Simms in Nashville, Tenn.

Appropriations Bill Also Highlights Resources for Foodborne Threats

On an unrelated note, the same bill that attempts to stall FDA regulation of laboratory developed tests also addresses potential pilot programs to address laboratories available to handle foodborne illness and health threats. The Committee would require the FDA to report within 90 days of the bill's enactment on "the potential for implementing pilot programs" fostering public-private partnerships "in an effort to increase the number of FDA-certified public or private labs located near major ports of entry to provide services on weekends and holidays, reduce the risk of foodborne illnesses, and enhance the capacity of local officials in dealing with foodborne threats."

Potential stalling tactics aside, a significant majority of the laboratory sector has been opposed to the FDA's regulation of LDTs. They say that tweaks to the existing CLIA regulations would address the pertinent issues.

However, the FDA has been fairly relentless in its move to try to regulate LDTs, claiming their growing complexity could place patients in danger if their accuracy and efficacy is not closely monitored. Last year, it issued a paper that listed 20 LDTs that possibly placed patients in danger—essentially a first for the agency. Meanwhile, Mertz believes that a bill in some form that preempts the proposed regulations stands a good chance of passing both chambers.

Gibbs is not so sure. He noted that there are still many steps involved in keeping the language in a final bill that would pass both houses of Congress. He also added there is resistance from test kit manufacturers, whose assays are already regulated by the FDA, as well as consumers concerned about safety issues surrounding LDTs.

"This is obviously a very unusual set of circumstances," he said.

Nevertheless, whether Congress or the FDA has the final word, both Sloane and Gibbs expect that LDTs will eventually come under tighter regulation.

"However, the lingering uncertainty is ... unsettling," Sloane said.

Takeaway: The laboratory sector appears to be attempting an end run around the regulation of LDTs.

OIG Issues Advisory Opinion for Group Purchasing Organization That Includes Labs

Group purchasing organizations (GPOs) are entities that act as a purchaser of supplies and equipment for a number of other entities—usually health care providers such as hospitals. Laboratories can play a role in such arrangements. For example, just last year, molecular laboratory NeoGenomics announced it was entering into a three-year agreement with a GPO named Premier. The arrangement made NeoGenomics an in-network laboratory provider for Premier and gave the lab access to a significant number of hospitals participating in the Premier network. The volume purchasing made possible by GPOs provides the opportunities for discounts and cost savings.

This month, the U.S. Department of Health and Human Services Office of Inspector General released Advisory Opinion 16-06 addressing whether a proposed GPO arrangement, which included laboratory participants, would run afoul of the Anti-Kickback Statute. The GPO negotiated "with vendors regarding products and pricing to be offered to the GPO['s]" members and vendors paid the GPO administrative fees (set forth in written agreements) according to a "percentage of the value of sales to members."

That GPO's membership included more than 84,000 health care entities including hospitals, nursing facilities, clinics, physician practices, home care and laboratories. The GPO originally had two owners: a health system and a Co-owner owned by 120 health care providers and suppliers. The health system proposed to acquire the individual entities owning the Co-owner to increase efficiencies in the GPO

operations. The end result would be that the GPO would still be owned by two entities: The Health System and a New Co-Owner that the Health System would wholly own. 800 of the 84,000 GPO members were also owned or operated by the Health System.

The OIG evaluated applicability of two Anti-Kickback Statute safe harbors—the discount safe harbor and the GPO safe harbor. The discount safe harbor was relevant to the discounts the GPO negotiated with vendors for the GPO members and the vendor administrative fees the GPO distributed to members. The GPO safe harbor was relevant to the administrative fees the vendors paid the GPO. There were no issues regarding whether the discount safe harbor would be satisfied.

However, the proposed arrangement would cause the GPO to be owned by the same entity that owns one percent of the pool of GPO members—which would mean the GPO wouldn't satisfy the definition of a GPO under the GPO safe harbor. But the OIG decided that such ownership arrangement didn't increase the risk to federal health care programs. The OIG explained that the purpose of the GPO safe harbor was to recognize that GPOs "help reduce health care costs" by the volume discounts it can achieve on goods and services purchased. Specifically referencing laboratories' participation in such arrangements, the OIG noted that in a 1991 final rule regarding the safe harbor a commenter had asked if "a nursing home chain requesting percentage payments from laboratories as GPO fees would qualify for the safe harbor." The final rule stated that wholly-owned subsidiaries couldn't do what the owner of the subsidiary couldn't—i.e., get vendors to pay fees in exchange for referrals. But this proposed arrangement was very different than that laboratory arrangement described in the 1991 final rule, the OIG explained in the Advisory Opinion. Instead, the OIG said, the members owned by the same entity that also owned the GPO were only one percent of the total GPO members. And all the members were subject to the same terms in their GPO agreements whether they were affiliated with the Health System owning the GPO or not—so, the members related to the Health System didn't get better terms than any other members. Therefore, because the GPO would still operate as a purchasing agent for a group of entities a majority of whom were unrelated to the GPO, the arrangement presented "an acceptably low risk of fraud and abuse in connection with the anti-kickback statute."

The Advisory Opinion applies only to the parties requesting it. But the fact that the OIG was willing to look beyond the "letter of the law" in terms of whether the safe harbor was met and look at the realities of the arrangement is encouraging and allows an arrangement intended to save health care costs and increase efficiencies.

Takeaway: OIG says a GPO arrangement presented an "acceptably low" risk despite the fact it didn't meet the exact definition of a GPO in the GPO Anti-Kickback safe harbor.

First Commercial Lab Gets FDA Emergency Clearance for Zika Test

The Zika virus continues to receive attention from federal agencies as Quest Diagnostics recently received emergency clearance from the U.S. Food and Drug Administration to distribute its molecular assay for detecting the Zika virus.

The emergency clearance from the FDA is the first for a test developed by a commercial venture in the U.S. The only other rapid detection assay that was previously approved for use was developed by the U.S. Centers for Disease Control and Prevention.

> *"The availability of our new molecular Zika test provides physicians broad access to a diagnostic tool for managing the Zika outbreak"*
>
> — Rick L. Pesano, M.D., Quest

The test can detect RNA from the Zika virus using specimens from patients. It was developed by the Quest subsidiary Focus Diagnostics. The Zika outbreak, originally confined to South America, has been spreading. The CDC has noted that the virus has been transmitted by mosquito in Puerto Rico, the U.S. Virgin Islands and American Samoa. Cases have also been reported in the continental U.S., although most have been related to patients being infected overseas. The virus can cause severe birth defects in children if a pregnant woman is infected with Zika. As of May 11, 2016 there were no locally transmitted (mosquito borne) cases of the infection reported in the continental U.S. However, the Centers for Disease Control and Prevention (CDC) reported that as of that date there were 503 travel associated cases for the continental U.S. and 698 locally acquired cases reported for the U.S. territories. U.S. Health and Human Services (HHS) Secretary Sylvia Burwell recently visited Puerto Rico to meet with local authorities and CDC and HHS staff working in Puerto Rico to assist with infection surveillance and managing demand for laboratory testing and research.

"The availability of our new molecular Zika test provides physicians broad access to a diagnostic tool for managing the Zika outbreak," said Rick L. Pesano, M.D., Quest's vice president of research and development, in a statement. "Quest's expertise in molecular, infectious disease, and women's health diagnostics, and relationships with half of the country's physicians and hospitals, allow us to quickly make useful tests widely available for clinical use. This capability uniquely positions Quest to complement the response of public health laboratories for Zika outbreaks where access to FDA authorized diagnostic tests can potentially influence the quality of patient management."

Use of the test is limited to qualified laboratories Focus designates and the emergency clearance does not mean the test has FDA clearance or approval. Rather the FDA has cleared it for use during the public health emergency, which was declared in February 2016. It is authorized for use in detecting RNA from Zika virus and diagnosing the Zika virus in patients "meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria" such as a history of living in or traveling to a location dealing with a Zika outbreak. During the emergency use authorization, the FDA will waive certain requirements such as quality system requirements and labeling requirements. Focus must track adverse events and report them to the FDA and document test performance such as false positives and false negatives and satisfy numerous other conditions to the emergency authorization.

Takeaway: The battle against Zika continues with the first commercial test becoming available under an emergency use authorization.

CMS Unveils Proposed Rule Implementing MACRA, *Continued from bottom of p.1*

Slavitt's and DeSalvo's blog statement was made in connection with the April 27 release of a proposed rule to implement the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA was signed into law April 16, 2015, and repealed the sustainable growth rate formula and emphasized the new Merit-Based Incentive Payment System (MIPS) and incentive payments for participation in certain Alternative Payment Models (APMs).

The U.S. Department of Health & Human Services said in its announcement of the proposed rule that currently, "a patchwork of programs" measures value and quality of care. The proposed rule on the other hand provides a "unified framework called the Quality Payment Program" consisting of the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). The goal of the proposal is to provide flexible, practical ways to measure performance that work with the way physicians practice medicine rather than a "one-size-fits-all program." U.S. Department of Health and Human Services Secretary Sylvia Burwell said the program allows "every doctor … to be paid more for better care" and have "more freedom to care for patients the way they were trained, the way that makes the most sense to them and is best for the patients."

"Today's rule incorporates input from patients, caregivers, clinicians, health care professionals, and other stakeholders, but it represents only the first step in an iterative implementation process."

— HHS

MIPS will "consolidate components of three existing programs, the Physician Quality Reporting System (PQRS), the Physician Value-based Payment Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for Eligible Professionals (EPs)" but will continue to emphasize quality, resource use, and use of certified EHR technology (CEHRT). MIPS measures value through four performance categories:

- Quality—physicians must report on six measures chosen "from among a range of options that accommodate differences among specialties and practices."
- Advancing Care Information—providers can select "customizable measures" for reporting their day-to-day use of technology and demonstrate interoperability. CMS says the goal is to provide a more flexible approach than the current Meaningful use program and allow physicians to choose measures based on their own daily practice and eliminating "all-or-nothing EHR measurement."
- Clinical Practice Improvement Activities—practice improvement activities (chosen from a list of 90 activities) such as care coordination and patient safety will be rewarded.
- Cost—based not on physician reporting but on Medicare claims data that use "40 episode-specific measures."

The proposed rule also encourages participation in alternative payment models (APMs). APM participation will exempt providers from MIPS reporting obligations provided they accept sufficient risk and reward in striving to provide quality, coordinated health care services. Two types of APMs are included in the proposal: Advanced APMs and Other Payer Advanced APMs (both require use of certified EHR technology and providing payment based on quality measures similar to those in MIPS).

"Today's rule incorporates input from patients, caregivers, clinicians, health care professionals, and other stakeholders, but it represents only the first step in an iterative implementation process," HHS said in its announcement.

Comments on the proposed rule must be submitted by June 26, 2016. If the proposal is finalized, it would take effect Jan. 1, 2017. The performance period for which measurements will be applied will be 2017 with reporting required in 2018 and payment adjustments will be effected in 2019.

For more information, including informational webinars, fact sheets, training slides, and instructions on how to submit comments regarding the proposed rule, see CMS' website at http://go.cms.gov/QualityPaymentProgram.

Takeaway: CMS reveals next steps in moving away from old measurements and incentives to patient-centered and practical alternatives intended to streamline reporting for physicians.

Focus Diagnostics Simplexa Test Kit Faces Recall

The U.S. Food and Drug Administration (FDA) has issued a rare recall of a laboratory test kit, claiming a fault in its manufacturing process could endanger patients.

The test in question is manufactured and distributed by Focus Diagnostics, based in Cypress, Calif. The test, branded as Simplexa, tests for the herpes simplex virus and the group A version of streptococcus bacteria. Focus' specialty is on assay kits that rapidly test for herpes and similar viruses.

> *"There is no new product recall related to Simplexa Direct Test kits. In close collaboration with the FDA, we notified our customers in February 2016 about the affected test kits."*
>
> — Focus Diagnostics

According to the FDA, the recall is connected to "poor lamination between the sample reaction wells. This poor lamination may lead to leakage into adjacent wells causing cross-contamination between samples, which could yield false positive, false negative, or invalid test results. Inaccurate diagnostic test results may lead to improper patient treatment for herpes simplex or group A streptococcus and may cause serious adverse health consequences, including death."

According to the regulatory agency, the recall affects 1,658 test kits that were manufactured between last July and this February.

The FDA regulates laboratory test kits as a medical device. It currently does not regulate tests that are designed to be performed in a laboratory setting.

Focus issued a statement trying to blunt the notion the FDA recall was an ongoing issue for the company, and point out that it had been resolved last March. The FDA did remark in its recall notice that Focus had taken corrective actions.

"There is no new product recall related to Simplexa Direct Test kits. In close collaboration with the FDA, we notified our customers in February 2016 about the affected test kits," the company said. "We have since resolved the issue with the manufacturer of the discs, which were the principal source of concern. We are confident in the corrective actions that we have implemented."

Takeaway: The Food and Drug Administration has issued a rare recall of a laboratory test kit.

CMS Grants International CLIA Certificate to ImmunID for Laboratory in France

Recognizing a trend in the diagnostics industry with an increasing number of global transactions, deals and partnerships, (see "Inside the Laboratory Industry," *Laboratory Industry Report*, p. 4, 3/17/16), the Centers for Medicare & Medicaid Services (CMS) is providing a process for CLIA certification of foreign laboratories processing specimens from the U.S.

> *"We are proud to be the first French company to receive this lab certification from the US Department of Health and Human Services' CMS and are very excited to start providing American doctors with a medical routine assay to evaluate their patients' immune status."*
>
> — Dr. Bernhard Sixt, CEO, ImmunID

CMS has posted a document on its website entitled "International Laboratory CLIA Certification Process" that offers a blueprint for labs operating outside of the United States to legally accept and process samples from the U.S.

CMS' web page "How to Apply for a CLIA Certificate, Including International Laboratories" instructs that laboratories outside the U.S. or its territories seeking CLIA certification should first contact CLIA-IOIntake@cms.hhs.gov before completing the certification application form.

ImmunID, a diagnostics company that provides immune molecular diagnostics services to assist clinicians in providing personalized immunotherapy to cancer patients, announced this month that it has received certification from CMS under the Clinical Laboratory Improvements Amendments (CLIA) for a laboratory located in Grenoble, France.

CMS explains on its website that human specimens collected in the United States or its territories and laboratories that perform tests on those specimens are subject to CLIA regulation. An international laboratory for purposes of CLIA certification is one located outside the U.S. (or its territories) that performs lab tests on human specimens when the test is referred by and results are reported to a person or facility located in the U.S. (or its territories).

ImmunID's new certification authorizes the company to receive and test specimens received from inside the United States using its ImmunTraCkeR® Dx assay. "We are proud to be the first French company to receive this lab certification from the US Department of Health and Human Services' CMS and are very excited to start providing American doctors with a medical routine assay to evaluate their patients' immune status," said ImmunID Chairman and Chief Executive Officer Dr. Bernhard Sixt, in a statement. ImmunID explains that its ImmunTraCkeR® Dx assay focuses on the patient's immune system rather than the drug or disease.

Takeaway: Globalization of the diagnostics industry continues with ImmunID receiving CLIA certification for its laboratory in France.

National Intelligence Report (ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315 • Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Ron Shinkman, Contributing Writer; Stephanie Murg, Managing Director; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Michael Sherman, Director of Marketing; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
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