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INSIDE THIS ISSUE

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FDA LDT Regulation Could Affect 60,000+ Tests

The U.S. Food and Drug Administration's (FDA's) proposed regulation of laboratory developed tests (LDTs) could affect 60,000 genetic tests, according to analysis by Tenn.-based IT firm NextGxDx. Depending on the ultimate classifications of risk, nearly 8,000 genetic tests could face premarket review requirements with a high-risk device designation. Accurate estimates of the number of tests currently on the market are important as the FDA finalizes its oversight plan, designs implementation strategies, and allocates adequate resources towards operationalizing for the new regulatory scheme.

Many have been trying to estimate the number of currently marketed genetic tests. The FDA and industry sources have publicly quoted that 11,000 laboratories are offering as many as 100,000 molecular LDTs in the United States. GeneTests.org, a wholly owned business unit of BioReference Laboratories, maintains that as of Feb. 25, 2016 there are 55,574 genetic tests available from 678 laboratories internationally. The National Institute of

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Presidential Election Campaign Sets Tone for 2017 Congressional Activity

Pathologists and laboratory leaders who have not yet had their fill of politics just need to wait. As 2016 progresses, Republican and Democratic Presidential candidates are likely to create significant health care market noise, according to a Cain Brothers report, "Strategies for Healthcare Leaders: 2016 Healthcare Industry Outlook."

The health care investment banking firm said the Presidential campaign is setting the tone for Congressional activity. "If Republicans recapture the White House, they will almost certainly retain control of both chambers of the Congress and be in a good position to repeal ObamaCare early in 2017," the authors write. They also acknowledge that details about how candidates will actually do that are still lacking.

And if a Democrat wins? "They are likely to continue to encounter major difficulties engaging Republicans on legislation to fix difficulties that have emerged in implementing the Affordable Care Act (ACA)," the authors continue.

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FDA LDT Regulation Could Affect 60,000+ Tests, *from page 1*

Health's Genetic Testing Registry, which requires test providers to voluntarily input test information, has records for 32,000 genetic tests including prenatal, somatic, and pharmacogenetic tests.

Since the vast majority of new molecular diagnostics have come to market under CLIA, the proposed regulations represent a significant shift. With the FDA indicating it will utilize a risk-based approach to regulation and prioritization, laboratories are assessing where their tests will fall along the spectrum.

As of Jan. 11, 2016, NextGxDx estimates that there are 60,482 genetic testing products on the market, with an additional eight to 10 tests entering the market daily. In 18 months from July 2014 to January 2016, the company's databases show that 5,674 new testing products entered the market, with panel entrants growing 24 percent in that time period.

Using data from October 2015 (53,000 genetic testing products), NextGxDx analyzed tests under three different risk classification scenarios, recognizing the FDA's stated intention to use expert advisory panels to guide decisions about risk status. The company's bioinformatics specialists estimate that, depending on the definition of risk, anywhere from 1.12 percent to 14.43 percent of tests could fall under high-risk regulation, which translates to between 587 and 7,568 tests. One major variable in the different risk scenarios is whether the FDA includes the American College of Medical Genetics and Genomics' 56 recommended genes to report incidental findings in its definition of high-risk tests. If the FDA does include these genes, NextGxDx says tests for these genes alone would involve: 121 laboratories, 331 clinical categories of tests, and 3,455 different testing products.

	Test Categories	Number of Tests	Percent of Genetic Testing Market
High Risk Test Scenario 1	Products similar in nature to those already regulated by the FDA: ■ Class III kits & devices ■ Companion Diagnostics	587	1.12%
High Risk Test Scenario 2	■ Companion Diagnostics ■ Class III kits & devices ■ Tests that target one of the ACMG 56 genes ■ Panels that include tests targeting one of the ACMG 56	3452	6.58%
High Risk Test Scenario 3	■ Companion Diagnostics ■ Class III kits & devices ■ Tests that target one of the ACMG 56 genes ■ Panels that include tests targeting one of the ACMG 56 ■ Pharmacogenomic Tests ■ Non Invasive Prenatal Tests (NIPTs) ■ All Oncology tests	7568	14.43%

Source: NextGxDx, October 2015.

NextGxDx provides an online genetic testing marketplace that offers health care providers and hospitals the ability to compare up-to-date listings of all genetic tests from CLIA-certified laboratories, order tests online, and manage results and utilization electronically within the HIPAA-compliant portal.

"We see great value in data-driven stakeholder dialog throughout the regulatory process," says Gillian Hooker, Ph.D., vice president of clinical development at

NextGxDx. "We provide an innovative way to track parts of the market and bring transparency to everyone. We play a role in informing multiple stakeholders."

Once laboratories understand the risk profile of their tests, Hooker says laboratories are waiting to see what evidentiary standards the FDA requires.

"If there are high evidentiary standards, this could be the most costly part of getting a test approved," says Hooker. She adds that the next step in this analysis is incorporating cost data to estimate the potential financial impact of complying with the proposed regulations on laboratories.

Takeaway: As the industry awaits the FDA's finalization of LDT regulation criteria, NextGxDx is helping to inform estimates of how many LDTs could fall under the FDA's purview and in what risk category. G2

ACLA Uses Cancer Initiative to Lobby on PAMA, LDTs

The American Clinical Laboratory Association (ACLA) has applauded the Obama Administration's proposal for a $1 billion cancer "Moon Shot Task Force" that would drive researchers closer to a cure for the disease. But the lobbying organization also asked that more earthly matters not be ignored at the expense of the new initiative.

"ACLA supported the legislative changes and has sought to collaborate with the Centers for Medicare & Medicaid Services since the enactment of PAMA."

— Alan Mertz, President, ACLA

According to a Feb. 9 letter sent to Vice President Joe Biden by ACLA President Alan Mertz, the lobbying group asks specifically for more attention regarding regulatory intrusion into the way labs conduct business and how they are reimbursed from government payers.

Specifically, the ACLA asked that the U.S. Food and Drug Administration (FDA) not be allowed to regulate laboratory-developed tests—a contentious issue in the laboratory sector. The FDA has issued draft guidance on regulation, to which labs have objected. "Often LDTs are the only available options for clinicians and patients, particularly when it comes to cancer. Additional FDA oversight through the proposed Guidance would institute an arduous and unnecessary regulatory barrier," Mertz wrote. "Therefore, in order to support the goals of the Cancer Moonshot Task Force and facilitate the continued unfettered development of new diagnostics, the FDA should withdraw" the draft guidance.

The ACLA also asked the Obama administration to keep in mind its concerns regarding the draft guidance under the Protecting Access to Medicare Act (PAMA). The organization has been particularly concerned that the proposed mechanism for setting new Medicare reimbursement rates leaves out most hospital-based laboratories, which are often paid at higher rates.

"ACLA supported the legislative changes and has sought to collaborate with the Centers for Medicare & Medicaid Services since the enactment of PAMA," Mertz wrote. "We are hopeful that a predictable market-based payment model, which reflects the broad scope of the laboratory market, will encourage continued advancements in diagnostic innovation."

Takeaway: Labs are using the Obama administration's desire to fund cancer eradication efforts to support their own agenda. G2

focus on: CMS Offers Long-Awaited Clarification of Deadline for Returning Overpayments

Labs and other providers are required by a provision enacted in the Affordable Care Act to return overpayments to Medicare within 60 days of identifying the overpayment. Violations of the rule subject the provider to False Claims liability and civil monetary penalties including treble damages and a fine ranging from $5,500 to $11,000 per claim. What constitutes identification of an overpayment, however, has caused much debate and concern. A 2012 proposed rule didn't add much clarity and a New York federal court decision last year in *U.S. ex rel. Kane v. Continuum Health Partners, Inc.*, caused much consternation.

> *"Our general aim of this final rule is to strengthen program integrity and to ensure that the Medicare Trust Funds are protected and made whole and that taxpayer dollars are not wasted. An overpayment must be reported and returned regardless of the reason it happened—be it a human or system error, fraudulent behavior or otherwise."*
>
> — Centers for Medicare & Medicaid Services (CMS)

That court said the 60-day deadline for returning overpayments is triggered when providers are *on notice* that they may have received overpayments—not after they've determined with certainty the precise amount. The court argued that triggering the 60-day deadline only after providers did all they needed to "determine conclusively the precise amount owed to the Government" created "a perverse incentive to delay learning the amount due and relegat[ed] the sixty-day period to merely the time within which they would have to cut the check."

Now, however, Centers for Medicare & Medicaid Services (CMS) has issued a final rule interpreting the 60-day repayment requirement. The agency says, in its press release announcing the final rule, that it includes "clarification around: the meaning of overpayment identification; the required lookback period for overpayment identification; and the methods available for reporting and returning overpayments to CMS." On those three issues, the final rule states:

- An overpayment is identified "when the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment."
- The lookback period is six years, meaning if an overpayment is identified within six years of the date payment was received, the recipient must comply with the 60-day rule.
- Repayments must be achieved using "an applicable claims adjustment, credit balance, self-reported refund, or another appropriate process."

CMS clearly emphasizes in the preamble to the rule that an overpayment is any amount which a lab receives to which it isn't entitled—whether the result of fraud, inadvertent error or mistake. This interpretation of what constitutes an overpayment is in keeping with CMS' stated objective: "Our general aim of this final rule is to strengthen program integrity and to ensure that the Medicare Trust Funds are protected and made whole and that taxpayer dollars are not wasted. An overpayment must be reported and returned regardless of the reason it happened—be it a human or system error, fraudulent behavior or otherwise." CMS also emphasized it didn't exclude overpayments that were outside of the control of the provider.

Until now, CMS's pronouncements on the repayment of overpayments left labs and providers with three major questions. Here's what CMS had to say in the preamble to the final rule with regard to those questions.

When is an overpayment identified?

As we said, contrary to the *Continuum Health* court's interpretation, CMS has now said a claim is identified when a lab should have (or has) identified the overpayment amount through reasonable diligence.

CMS rejected comments and suggestions that the rule only apply when a provider has actual knowledge of an overpayment, stating that such a rule would allow providers to easily avoid returning overpayments and the objective of the rule "would be defeated." CMS said it's clarification about when a claim is identified was made "after careful consideration" of comments received. "We believe that the final rule strikes the right balance between creating a flexible yet strong standard that applies to many different circumstances."

The new guidance does raise an additional question, however: What's reasonable diligence? CMS defines it to be both proactive and reactive including "proactive compliance activities" that monitor receipts and look for overpayments *and* investigations in response to "obtaining credible information of a potential overpayment."

Note too that the 60 days for returning overpayments starts when the reasonable diligence is completed. But, if a party fails to exercise reasonable diligence, the 60-day time frame for returning an overpayment runs from the time the entity received credible information about a potential overpayment (that is, when it *should have* started exercising reasonable diligence to address the potential overpayment).

Reasonable diligence also means not just repaying one identified overpaid claim but CMS says it believes "it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim."

Additionally, in discussing when a significant increase in Medicare revenue should trigger the need for reasonable diligence, a commenter pointed out that labs aren't "in a position to determine the medical necessity of the services they provide because they do not order the tests," and thus they shouldn't be expected to "proactively conduct an inquiry into whether an overpayment exists based on the volume of Medicare work it conducts." CMS responded: "All providers and suppliers have a duty to ensure that the claims they submit to Medicare are accurate and appropriate. There may be situations where a significant increase in Medicare revenue should lead a laboratory to conduct reasonable diligence."

How far back does this apply?

Abandoning the originally proposed 10-year lookback period, CMS explained it decided upon the six-year look back period because it was consistent with False Claims Act and civil monetary penalty statutes of limitations and general medical records retention periods. The lookback period runs from the date the overpayment is identified.

How do we return overpayments?

Originally relying on the existing voluntary refund process, CMS has revised the final rule to allow for repayments to be made by claims adjustment, credit balance, self-reported refund, "or another appropriate process to report and return overpayments." CMS explains that "[t]his position preserves our existing processes and preserves our ability to modify these processes or create new processes in the future."

CMS also notes that when overpayment amounts are extrapolated, providers should explain how the overpayment was calculated. Additionally, CMS notes in its release that reporting through CMS' Self-Referral Disclosure Protocol or the OIG's Self-Disclosure Protocol complies with the rule if the reporting provider is "actively engaged in the respective protocol." Such participation in those protocols must also result in a settlement agreement.

Takeaway: CMS finally provides more definitive guidelines for labs and other providers about when and how to return overpayments, effectively overruling a court's stringent interpretation of the 60-day time deadline for repayments. G2

Presidential Election Campaign Sets Tone for 2017 Congressional Activity, *Continued from bottom of p. 1*

Below is an overview of the leading Presidential candidates' views and plans for health care. While labs are not specifically mentioned, readers may be able to draw some conclusions on policies' likely effects.

Bernie Sanders announces "Medicare for all" and a federally administered single payer health care program.

Republicans (included are candidates leading in polls at this writing) *Ted Cruz* expresses intent to reform Veterans Administration (VA) health care. He plans to bring "accountability back to the VA," notes the campaign Web site, and expand options for service members that include more choices and faster service.

Cruz has also supported a repeal of ObamaCare, according to *On the Issues*, a non-profit organization that provides information to voters.

Marco Rubio articulates a program to replace ObamaCare. His campaign Web site shares these details on the replacement:

- Provide Americans with an advanced, refundable tax credit to be used to purchase insurance;
- Ensure access for vulnerable populations by expanding access to consumer-centered health plans and reforming insurance regulations;
- Give states a per-capita block grant, preserving funding for Medicaid.

Rubio also shares a plan to strengthen Medicare by, in part, providing seniors with choices for private plans and traditional fee-for-service Medicare.

Donald Trump voices intent to replace ObamaCare with Health Savings Accounts, according to *On the Issues*.

Democrats

According to *Hillary Clinton*, affordable health care is a basic human right. She has a plan to:

- Defend the ACA and build on it to slow growth of out-of-pocket costs;
- Address rising prescription drug prices and encourage drug companies to invest in research instead of price increases;
- Protect women's access to reproductive health care.

Bernie Sanders announces "Medicare for all" and a federally administered single payer health care program. Here are some of his program's details, according to the candidate's Web site:

- The plan will cover the entire continuum of care and include prescription medications, medical equipment, diagnostics and treatments;
- People can choose a health care provider;
- The plan will be paid for by: a 6.2% income-based health care premium paid by employers; a 2.2% income-based premium paid by households; progressive income tax rates; taxing capital gains and dividends the same as income from work; limit tax deductions for wealthy people; a responsible estate tax; and savings from health tax expenditures.

Takeaway: Presidential candidates' health care plans differ in specificity. Candidates say they either intend to repeal and replace the ACA, or build on it. Health care will likely get a lot of attention as the Presidential election nears. And the make-up of Congress will be a factor in repeal or repair of the ACA. G2

Labs and Diagnostics Central to 2017 Federal Budget Requests

Diagnostics figure prominently in key portions of the federal budget for Fiscal Year 2017. Significant funding is devoted to precision medicine, cancer, antibiotic resistance, and of course, Medicare enforcement. Here's a rundown on some of the numbers in the budget requests from key agencies of interest to labs:

Office of Inspector General

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) is requesting a total budget of $419 million to oversee the administration of the HHS programs—that includes $334 million for oversight of Medicare and Medicaid and the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative. Specific targets for enforcement will be "fraud and wasteful spending, including improper payments, unsafe or poor quality health care and security of data and technology."

The OIG justified its budget requests stating, "The OIG is a leader in the fight against Medicare and Medicaid fraud and we will continue to use sophisticated data analytics and state-of-the-art investigative techniques to detect and investigate fraud." The OIG boasts its most recent return on investment for the Health Care Fraud and Abuse Control Program (which fights fraud and abuse against public and private payers) at "approximately $7.7 to $1, the third highest in the history of the program."

U.S. Food and Drug Administration

The U.S. Food and Drug Administration (FDA) budget request for 2017 totals $5.1 billion—8 percent more than the budget enacted last year. The importance of diagnostics is demonstrated throughout FDA budget requests. Three of five key areas cited by the FDA in its $2.8 billion budget request for Medical Product Safety and Availability involve diagnostics: 1) evaluating Precision Medicine-based diagnostics and treatments, 2) combating antibiotic resistant bacteria, and 3) improving cancer diagnostics and treatments.

While there is no specific mention of the FDA's intentions with regard to oversight of laboratory developed tests, there are plenty of references to precision medicine. The FDA's budget justification document notes the "success of Precision Medicine depends on having accurate reproducible, and clinically useful companion diagnostic tests to identify patients who can benefit from targeted therapies." With that in mind, $200,000 is earmarked for the FDA's precisionFDA platform, which "supplies a platform where the commercial and academic communities can test, pilot, and validate new approaches to ensure the accuracy of genetic tests."

But receiving the most coverage and public interest is the Vice President's Cancer Moonshot Initiative, which President Obama announced in his recent state of the union address. A White House Fact Sheet explains that this a "$1 billion initiative to provide the funding necessary for researchers to accelerate the development of new cancer detection and treatments." The budget allocates $195 million to the National Institutes of Health (NIH) for cancer-related efforts, $755 million for cancer-related research activities.

The Budget also calls for establishing an Oncology Center of Excellence "to streamline collaboration across FDA's Human Drugs, Biologics, and Devices and Radiological Health, Programs." The center will involve staff from other programs and will

work closely with the NIH National Cancer Institute. One goal is development of "new and advanced diagnostics for early screening and detection of cancer." Highlighting the need for developments in companion diagnostics and precision medicine, budget discussions explain the FDA "needs to take an integrated approach in its evaluation of products for the prevention, screening, diagnosis, and treatment of cancer."

The FDA's budget justification document also indicates other laboratory-related efforts that will benefit from budgeted funding:

- **Bioinformatics**—the FDA acknowledges that "with the increasing amounts of data being generated by new technologies, FDA must have the software and database tools to manage the large amount of scientific data required to improve product development, safety assessments, and risk analysis." Indeed, informatics and bioinformatics are expected to significantly affect future operations for labs. The rise of informatics is the subject of a one-day workshop presented by G2 Intelligence in collaboration with Arizona State University International School of Biomedical Diagnostics, April 6, 2016 in Chandler, Ariz.
- **Antibiotic resistance**—Diagnostics are also a component of the FDA efforts to fight antibiotic resistant bacteria—an item that also got significant attention and funding in last year's budget. The Administration's Combating Antibiotic-Resistant Bacteria (CARB) National Action Plan includes efforts to "advance the development of diagnostics to detect antimicrobial resistance."
- **Next generation sequencing (NGS)**—The budget justification indicates the Devices Program "aims to ensure that NGS tests provide accurate, reproducible, and meaningful results relevant to a person's medical condition while continuing to foster innovation so that people have access to the best available results possible."

CDC and ONC

Finally, funding for the Centers for Disease Control and Prevention (CDC) should also be of interest to laboratories. HHS's rundown on the budget requests indicates "CDC is committed to continuous improvements in laboratory science and safety, as well as the quality of its public health laboratory services" and $33 million of the budget is pegged to support CDC's "implementation of laboratory safety recommendations."

"This funding will enable CDC to maintain its ability to respond to outbreaks, determine unexplained illnesses, support state and local diagnostics, improve pathogen identification of emerging and re-emerging diseases and maintain the world's most advanced, state-of-the-art infectious disease and environmental public health laboratories," according to HHS.

Takeaway: 2017 Budget requests indicate continued government attention to fraud enforcement and support for precision medicine, particularly with regard to the fight against cancer. Labs and diagnostics will play a role in many of the areas receiving funding attention. G2

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