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INSIDE THIS ISSUE

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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

CMS Submits PAMA Implementation Rule for OMB Review

Despite ongoing efforts to delay the changes to the Clinical Laboratory Fee Schedule (CLFS) directed by the Protecting Access to Medicare Act of 2014 (PAMA), the Centers for Medicare & Medicaid Services' final rule implementing the PAMA-mandated reforms is now under review by the White House Office of Management and Budget (OMB). The highly anticipated rule is expected to require Medicare payment for clinical laboratory tests to be based on private payor rates beginning January 1, 2017.

OMB began its review of the final rule on April 21. Regulatory clearance—and subsequent publication in the *Federal Register*—is widely expected to be imminent. CMS estimates that the new payment system will reduce Medicare CLFS payments by $360 million in FY 2017 and by $5.14 billion over 10 years.

A proposed version of the rule, published in the *Federal Register* on Oct. 1, 2015, outlined CMS' plan for determining commercial rates. It called for collecting price data from laboratories that receive at least half of their Medicare revenues from lab-test reimbursement. The potential of this approach to effectively exclude hospital-based labs raised concerns from across the industry that the resulting CLFS rates would not be representative of overall market rates. (See "Industry Comments on PAMA Guidelines Fairly Uniform," *National Intelligence Report*, 12/17/15, p. 1).

Continued on page 2

Culture-Independent Tests Gain Clinical Traction, Hamper Public Health

Laboratory developed tests are not the only item on the U.S. Food and Drug Administration's (FDA) agenda that involves the diagnostics industry. The FDA is also focusing significant resources on food safety. The FDA released in 2015 new rules under the FDA Food Safety Modernization Act (FSMA), which seeks to strengthen the U.S. food safety system. And President Obama's 2017 FY Budget Request included $25.3 million for implementing the FSMA. A study published April 15 in *Morbidity and Mortality Weekly Report* indicates the relevance of diagnostics to these national efforts to protect food safety and combat foodborne illnesses.

Continued on page 6

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CMS Submits PAMA Implementation Rule for OMB Review, *from page 1*

The schedule for implementation of CMS's new reporting and payment methodology is also a key concern. "We believe the critical alterations to the CLFS must be accomplished in a deliberate and measured manner, so that laboratories have sufficient time, once the final rule and sub-regulatory guidance are issued, to comply," wrote House Ways and Means Health Subcommittee Chairman Pat Tiberi and 26 other committee members in a March 31 letter to Acting CMS Administrator Andy Slavitt. "Given the delays in the rulemaking process, the Jan. 1, 2017, effective date for the new CLFS payment methodology is not feasible and should be delayed." For discussion of earlier congressional letters expressing concerns about PAMA implementation, see "Congress Lobbies CMS on PAMA Regulations," *National Intelligence Report*, 1/14/16, p. 1.

Takeaway: Despite industry concerns and objections, CMS takes another step forward with its final rule implementing PAMA.

Coming Soon: *Get full details on the final rule in an upcoming webinar sponsored by G2 Intelligence and the American Clinical Laboratory Association. Details of the event will be posted as soon as the final rule is published.*

FCPA Self-Disclosure Pilot Program Continues Focus on Individual Accountability

In the modern age of global commerce, the Foreign Corrupt Practices Act (FCPA) has increasing relevance for laboratories and the diagnostics industry. Alere, a point-of-care diagnostic test maker, disclosed in a Securities and Exchange Commission Form 8-K filing that the company received a grand jury subpoena in March from the U.S. Department of Justice (DOJ) "requiring the production of documents relating to, among other things, sales, sales practices and dealings with third-parties (including distributors and foreign governmental officials) in Africa, Asia and Latin America and other matters related to the U.S. Foreign Corrupt Practices Act." There could be more such investigations in the future for the diagnostics industry. *National Intelligence Report*'s sister publication, *Laboratory Industry Report*, recently highlighted the globalization of the U.S. diagnostics industry, with foreign countries seeking to gain a foothold in the U.S. market and U.S. companies taking note of foreign opportunities. (See "Inside the Lab Industry," *Laboratory Industry Report*, 3/17/16, p. 4).

Laboratories and diagnostics companies looking at global opportunities should be mindful of recent developments relating to enforcement of the FCPA. The FCPA has two main purposes: 1) to prevent payments to foreign government officials to obtain or retain business, or direct business to any person—i.e., bribes; and 2) to require covered corporations to maintain accurate books and records of corporate transactions and adequate internal accounting controls. The anti-bribery provision applies not just to U.S. persons but also to foreign entities who cause corrupt payment to occur within the territory of the U.S.

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The DOJ is ramping up enforcement of this law, issuing a memorandum April 5, 2016, titled "The Fraud Section's Foreign Corrupt Practices Act Enforcement Plan and Guidance"—outlining three steps of "enhanced FCPA enforcement strategy."

> *"[i]f a company opts not to self-disclose, it should do so understanding that in any eventual investigation that decision will result in a significantly different outcome than if the company had voluntarily disclosed the conduct to us and cooperated in our investigation."*
>
> — Leslie R. Caldwell, Assistant Attorney General, DOJ Criminal Division

Step one involves "intensifying its investigative and prosecutorial efforts" by adding new resources such as 10 new prosecutors for the FCPA Unit (a 50 per cent increase in that unit), and three new squads of agents focused on FCPA investigations and prosecutions. Step two involves strengthened U.S. "coordination with foreign counterparts in the effort to hold corrupt individuals and companies accountable." Such coordination includes sharing leads, documents and witnesses with foreign law enforcement entities. The third step is a one-year pilot program in the Fraud Section's FCPA Unit intended to "promote greater accountability" by encouraging self-disclosure, cooperation with Fraud Section investigations, and remediation of compliance programs.

Assistant Attorney General Leslie R. Caldwell, with the DOJ Criminal Division, explained in a statement that the pilot program promotes transparency by letting companies know what they can expect in FCPA enforcement and what penalties will result from certain conduct, and it "enable[s] companies to make more rational decisions when they learn of foreign corrupt activity by their agents and employees." The April memo makes clear: "Nothing in the Guidance is intended to suggest that the government can require business organizations to voluntarily self-disclose, cooperate, or remediate. Companies remain free to reject these options and forego the credit available under the pilot program." However, Caldwell cautioned that "[i]f a company opts not to self-disclose, it should do so understanding that in any eventual investigation that decision will result in a significantly different outcome than if the company had voluntarily disclosed the conduct to us and cooperated in our investigation."

The DOJ explained that this new guidance supplements the Principles of Federal Prosecution of Business Organizations (known as the USAM Principles)—which address whether and what type of criminal disposition against a corporation is appropriate—and the U.S. Sentencing Guidelines (USSG) which provide for reduced fines and penalties for organizations that voluntarily disclose misconduct and cooperate in investigations. The DOJ's FCPA guidance also explains when additional credit can be granted in FCPA cases beyond credit provided under the USSG. It applies to all FCPA cases in which companies self-disclose or cooperate during the pilot period—even if the case lasts after the pilot ends.

But to benefit from that credit, an organization must meet the following three requirements:

1. **Voluntary self-disclosure of FCPA misconduct**. The disclosure must be made before an "imminent threat of disclosure or government investigation" and within a "reasonably prompt time after becoming aware of the offense" and must include all relevant facts regarding the conduct and the individuals involved.
2. **Full cooperation.** This includes compliance with the Yates memo's principles requiring disclosure of facts that identify culpable officers, employees or agents of the corporation. The FCPA guidance also emphasizes the need for cooperation

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to be "proactive…rather than reactive"—meaning the company must disclose information that is not even asked for and must "identify opportunities for the government to obtain relevant evidence" the company doesn't have or the government doesn't know about. Note too that this requires disclosure of overseas documents unless foreign privacy law prevents such disclosure.

3. **Remediation.** Remediation requires appropriate discipline of employees who are identified as responsible for misconduct and implementation of an effective compliance and ethics program including: a culture of compliance, an independent compliance function, sufficient resources, involvement of experienced compliance personnel, compliance programs that match results of risk assessments, auditing of compliance programs, and compensation and promotion of compliance staff comparable to other employees. The corporation must also take any other steps necessary to demonstrate "recognition of the seriousness of the corporation's misconduct," accept responsibility and reduce risk of reoccurrence.

An entity that fails to self-disclose but does satisfy requirements to cooperate and remediate can still receive limited credit under the pilot program.

The credit that may be gained by satisfying voluntary self-disclosure requirements, including compliance with the Yates memo and the USAM Principles, could include up to 50 percent reduction "off the bottom end of the Sentencing Guidelines fine range" and "generally should not require the appointment of a monitor" if the company already has an effective compliance program.

Additionally, the Fraud Section's FCPA Unit may consider declination of prosecution—but, the government will also consider the seriousness of the offense, involvement of the company's executive management, significance of profit to the company from the conduct (in relation to company size), prior noncompliance, and prior resolution of a matter with the DOJ within the past five years.

An entity that fails to self-disclose but does satisfy requirements to cooperate and remediate can still receive limited credit under the pilot program. However, the guidance warns "[s]uch credit will be markedly less than that afforded to companies that do self-disclose wrongdoing." At most, that will be a 25 percent reduction from the "bottom of the Sentencing Guidelines fine range."

Takeaway: Laboratories seeking to enter the global market need to heed the DOJ's stepped-up enforcement of the FCPA. Such enforcement also re-emphasizes the government's focus on pursuing liability for culpable individuals within the corporations found to have violated the law.

List of Top 10 Patient Safety Concerns Implicates Lab-Related Issues

Four of the top 10 patient safety concerns, compiled from reports of more than 1.2 million safety events, literature review and expert opinion, have relevance for laboratories and diagnostics. ECRI Institute's third annual *Top 10 Patient Safety Concerns for Healthcare Organizations 2016* includes "real things that are happening," stated Associate Director for the ECRI Institute PSO, Catherine Pusey, RN, MBA in the Executive Summary. They aren't the most frequently cited or the most severe issues, according to Bill Marella, MBA, MMI, ECRI's executive director,

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PSO operations and analytics. "We're trying to pick out the things that are relatively novel or that are not necessarily new but are manifesting themselves in a new way because of changes in the healthcare system."

Labs will find most relevant the safety issue appearing at number five on ECRI's list: Inadequate Test-Result Reporting and Follow-up. Factors that affect test reporting safety issues included inadequate communication among providers and failure to follow-up on test results and their health implications with and by patients.

There are several other items that are also of relevance to laboratories on the list. The number one safety concern cited was "Health IT configurations and organizational workflows that do not support each other"—meaning that operationally, people don't adjust to new IT systems. This disconnect affects communication and prevents up-to-date sharing of information about patients including, for example, lab test results. This is an issue very relevant to laboratories who utilize IT systems to communicate with referring providers regarding test orders and test results.

"Action is needed now to avoid an antibiotic apocalypse."

— Sharon Bradley, RN, CIC, ECRI Institute

The second item on the list is patient identification errors—which ECRI notes have "broad implications" and "serious consequences." *National Intelligence Report (NIR)* has previously highlighted the importance of the lab's role in patient identification (see *NIR*, Feb. 11, 2016, p. 1). Tejal Gandhi, M.D., president and CEO of the National Patient Safety Foundation (NPSF) told *NIR* that labs need to look at internal processes that could lead to a potential breakdown in patient identification. For example, they need to consider how certain they are that results are received by providers and identify communication gaps so they can make processes more reliable. The same article highlighted a National Patient ID Challenge launched by the College of Healthcare Information Management Executives (CHIME). CHIME pointed out that the error rate in matching patients to their records is usually 10 to 20% within a health care system and can rise to 50 to 60% when organizations exchange data through the care continuum.

Two issues at the bottom of the top 10 should resonate for labs as well: inadequate antimicrobial stewardship (ninth on the list of top 10 safety issues) and failure to embrace a culture of safety (10th). Antibiotic resistance is a national concern receiving not just media attention but significant federal funding. ECRI raises the alarm stating "Action is needed now to avoid an antibiotic apocalypse," said Sharon Bradley, RN, CIC, ECRI Institute's senior infection prevention analyst, in ECRI's executive summary. As *NIR* has previously reported, diagnostics play a key role in the fight against antibiotic resistance. In fact, the federal government's Combating Antibiotic-Resistant Bacteria (CARB) National Action Plan includes efforts to "advance the development of diagnostics to detect antimicrobial resistance."

Finally, all health care organizations including laboratories should be concerned about a culture of safety. "[E]mbracing a culture of safety is the foundation for mitigating any of the concerns on the Top 10 list," according to ECRI Institute patient safety analyst and consultant, Mary Beth Mitchell, MSN, RN, CPHQ, CCM, SSBB, who advised in the report that leadership must set the tone by publicly embracing patient safety.

Takeaway: Laboratories and diagnostics can play a central role in addressing top patient safety concerns for health care organizations.

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Culture-Independent Tests Gain Clinical Traction, Hamper Public Health, *Continued from bottom of p.1*

A clear shift is underway in the way foodborne illness is diagnosed. Testing for enteric pathogens is rapidly moving away from culture-based methods and towards culture-independent diagnostic tests (CIDTs), according to the study. The researchers say while CIDT can more rapidly diagnose illness, it poses a challenge for identifying antibiotic resistance and outbreaks. To address these concerns, regulators, laboratories, and public health must work together to address strategies, such as reflex culturing positive CIDT cases, in order to ensure appropriate data for public health practice.

> *"The ability to assess and interpret change is impeded as the number of positive CIDT reports continues to rise because of important limitations in the understanding of CIDTs and possible changes in clinician and laboratory practices surrounding them."*
>
> — Jennifer Huang

"The continued shift from culture-based methods to CIDTs that do not produce the isolates needed to distinguish between strains and subtypes affects the interpretation of public health surveillance data and ability to monitor progress toward prevention efforts," write the authors led by Jennifer Huang, from the National Center for Emerging and Zoonotic Infectious Diseases at the U.S. Centers for Disease Control and Prevention (CDC). "Expanded case definitions and strategies for obtaining bacterial isolates are crucial during this transition period."

The researchers analyzed data from the CDC's Foodborne Diseases Active Surveillance Network (FoodNet), which has been tracking the incidence of laboratory-confirmed infections caused by nine pathogens (Campylobacter, Cryptosporidium, Cyclospora, Listeria, Salmonella, Shiga toxin–producing Escherichia coli [STEC], Shigella, Vibrio, and Yersinia) commonly transmitted through food. FoodNet—a collaboration between CDC, 10 state health departments, the U.S. Department of Agriculture's Food Safety and Inspection Service, and the FDA—conducts population-based surveillance at 10 U.S. sites that account for about 15 percent of the U.S. population.

In 2015, FoodNet reported 20,107 confirmed cases (defined as culture-confirmed bacterial infections and laboratory-confirmed parasitic infections), as well as 4,531 hospitalizations, and 77 deaths. FoodNet also received reports of 3,112 positive CIDTs without culture-confirmation in 2015. STEC was the only infection for which the majority of cases were identified by CIDT. The percentage of foodborne infections diagnosed only by CIDT nearly doubled compared to 2012-2014. CIDTs were most commonly used for Campylobacter and STEC, while the highest percentage increase in use, compared with the previous 3-year average, was seen for Shigella and Salmonella. The researchers say this was most likely due to laboratories using newly available DNA-based syndrome panels. On the other hand decreased incidence of salmonella, they say, is likely due to poultry vaccines, implementation of new performance standards, and other preventive efforts.

"The ability to assess and interpret change is impeded as the number of positive CIDT reports continues to rise because of important limitations in the understanding of CIDTs and possible changes in clinician and laboratory practices surrounding them," writes Huang and her colleagues. "For example, analyses need to consider the likelihood of false-positive CIDTs and of CIDTs that are more sensitive than routine culture methods. … The availability of CIDTs might also increase testing for some pathogens. Surveillance systems need to adapt to these changes by expanding case definitions to include positive CIDT reports."

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Huang explains that isolates are still needed for antimicrobial susceptibility testing, serotyping, subtyping, and whole genome sequencing. To address this need for isolate in the short term, the researchers propose clinical laboratories perform a culture with positive CIDT results. For a longer-term solution, CDC is working with partners to develop advanced testing methods that, without culture, will give health care providers information to diagnose illness, but also provided detailed information about the bacteria so that public health officials can detect and investigate outbreaks. Ideally these methods, Huang says, would include the ability to detect the genetic sequences of pathogens directly and rapidly from stool specimens, which could benefit both clinical and public health practice.

Takeaway: The search is on for diagnostic methods that can help diagnose individuals with foodborne illness and also assist public health authorities detect and investigate outbreaks.

Millennium and Ameritox Graphic Test Reports Raise Intellectual Property Dispute

Along with the shift in reimbursement models from volume to value and the rise of more collaborative, coordinated care, laboratories have been seeking ways to provide more value for clinicians and patients in their test result reporting. Thus laboratories are developing reports with more user-friendly, visual formats. One of those formats has raised an intellectual property dispute between two laboratories.

"Although Congress does not want consumers to be confused about a product's source, it also does not want to restrict the availability and use of functional features that enhance the utility of the product."

— Ninth Circuit Court of Appeals

Millennium Laboratories sued Ameritox Ltd. claiming trade dress infringement—i.e., that Ameritox was using a "confusingly similar" urine test report that copied Millennium's format. The Lanham Act allows for damages if a competitor uses "any word, term, name, symbol or device, or any combination thereof…" "likely to cause confusion" regarding the origin or source of the product. It includes protection for trade dress, which courts have defined as the "total image of a product" including its graphics. Millennium also sued for unfair competition under California state law.

The lab reports at issue used graphics to depict current and historical diagnostic data. Millennium's R.A.D.A.R.® Report included a graphical format it described as "'side-by-side presentation of a bell curve on the left, and a historical plot graph on the right.'" It also included "'a combination of bold and dashed lines on the bell curve graph and a combination of numbers and letters on the plot graph on the right.'" There was minimal wording beside the graphics and charts and the graphic features were surrounded by a solid border. Millennium claims protection not for the idea of using graphs but rather for the layout of its report. In 2012, Ameritox revised its single graph report and the proposed versions for its new format were similar to Millennium's form.

There is an exception to the law's protection of trade dress: design elements that have a functional purpose aren't eligible for trade dress protection. "Although Congress does not want consumers to be confused about a product's source, it also does not want to restrict the availability and use of functional features that enhance the utility of the product," the Ninth Circuit Court of Appeals explained.

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But what is functional? That is at the heart of the dispute. A trial court ruled in favor of Ameritox, granting it summary judgment after finding that, based on the facts and the law, the layouts of the two labs' reports had a functional purpose and thus weren't protected from trade dress infringement. But earlier this month, a federal appeals court, the Ninth Circuit Court of Appeals, reversed that ruling saying that prior courts have determined graphical layouts can merit trade dress protection. The appeals court applied a two-step test in reaching its decision: whether the aspect to be protected was functional—that is, it is "essential to the use or purpose"—or affects cost or quality (if yes, there is no protection). However, if it isn't functional the second step is to determine if protecting the feature would put others at a "non-reputation-related competitive disadvantage." The court said a four-factor test was used to determine if a feature was functional: 1) whether it provides a utilitarian advantage, 2) existence of alterative designs, 3) if the utilitarian advantage of the feature is promoted in advertising and 4) manufacturing the feature is simple or inexpensive. Under this test, the Ninth Circuit determined a jury could decide that placing graphs on the same page is aesthetic and not functional, there were other alternative layouts, and that advertisements focused on the benefit of reporting with graphs rather than the specific layout. Thus the court ruled that the first three factors could be applied to determine that a jury should have the opportunity to review the case and granting summary judgment to Ameritox was inappropriate. As to the fourth factor, the court said adding graphs to the report increased rather than decreased costs.

"The key point is that even if a comparison of results is functional, this could be presented in many ways, and the precise format used by company asserting trade dress is not necessarily functional."

— Ninth Circuit Court of Appeals

"The key point is that even if a comparison of results is functional, this could be presented in many ways, and the precise format used by company asserting trade dress is not necessarily functional." The court then turned to step two to consider whether the layout gave competitive advantage to Millennium. The layout was intended to distinguish Millennium's report from those of its competitors and thus was source-identifying, which also meant a jury should be able to determine if it is functional or not. Finally, the court of appeals explained that Millennium's unfair competition claim depended on the trade dress infringement claim so it also ruled that should go to a jury.

The Ninth Circuit's ruling gives hope to labs seeking to distinguish themselves from competitors by the layout and visual aids in their test reports.

Takeaway: Labs looking to provide visual reports with graphics should be careful when designing their layout to distinguish them from and avoid confusion with other competitors' reports, at the same time investigating the ability to assert intellectual property protection for the layout design of their reports.

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