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Congress Lobbies CMS on PAMA Regulations

Since mid-December members of the House of Representatives and the Senate have sent letters to Centers for Medicare & Medicaid Services (CMS) imploring it to delay and make significant changes to the implementation of the Protecting Access to Medicare Act (PAMA). Their missives echo demands being made by the laboratory sector as a whole.

CMS issued proposed regulations for the implementation of PAMA in the second half of last year, and the laboratory sector vigorously lobbied to make significant changes in the final regulations. Final PAMA rules were initially expected to be issued by CMS late last year, but it has yet to issue them. The agency issued proposed rules in October, and accepted more than 1,000 comments during the public comment period. (See the December 2015 issue of *National Intelligence Report* for discussion of industry comments). CMS is legally required to finalize the rules by June 30.

On Dec. 14, 2015, 19 U.S. Senators signed a letter to Andy Slavitt, acting CMS administrator expressing their concern "that the proposed rule and implementation timeline impose a significant burden on clinical laboratories across the country and may threaten access to clinical laboratory services for Medicare beneficiaries." The Senators requested CMS delay implementation and "engage in constructive dialogue with stakeholders." Their objections to the proposed rule included a lack of necessary information and a reasonable time frame that will facilitate laboratories' compliance with reporting requirements, exclusion of a "significant part of the laboratory market," and the definition of Advanced Diagnostic Laboratory

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Trust for America's Health Report: Public Health and Clinical Laboratories Need to be Ready for New Disease Threats

When it comes to detecting and responding to disease outbreaks, more than half of the U.S. scores a five or lower out of 10 on a readiness scale, according to a new report from the Trust for America's Health (TFAH). The document also makes a number of recommendations for public health laboratories.

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Tests (ADLTs). They argued that the "unrealistic" initial reporting deadlines "risk[] unduly rushed data collection that could lead to inaccurate rate setting." Finally, the Senators criticized a lack of "transparency and clarity" in the reporting system that leaves labs with no understanding of how new rates are calculated.

"Protein-based diagnostics are being used to make clinical decisions regarding patient care today, and encouraging further development in this area is crucial."

The House of Representatives followed up a few days later with a letter on Dec. 16, signed by 44 members, both Republicans and Democrats. That letter also noted that a "number of laboratories are prohibited from participating in the reporting process. We are deeply concerned that this prohibition will skew the market data, resulting in Medicare rates that are not reflective of true market prices." Instead, the members asked that CMS implement a "more inclusive approach to determining which laboratories should report data and to allow any laboratory to voluntarily report data."

While neither the House or Senate letters specify which labs are being excluded, the laboratory sector has expressed concern to CMS that the exclusion of hospital-based laboratories—which tend to be paid at higher rates than standalone labs—would dramatically ratchet down Medicare reimbursements. Under PAMA, laboratories receiving at least $50,000 annually in payments through the Clinical Laboratory Fee Schedule would have to submit payment data for evaluation.

The House members also asked CMS to expand its definition of an ADLT to include protein biomarkers, which it said had been inexplicably excluded from the proposed regulations. Laboratory lobbies have also asked that protein biomarkers be included.

"Protein-based diagnostics are being used to make clinical decisions regarding patient care today, and encouraging further development in this area is crucial," the House letter said.

In addition to expressing this concern, the House members also emphasized the need for more flexibility regarding the reporting deadlines for data, which under the proposed guidelines could begin as soon as this month. "The proposed timeline presents a significant challenge to the laboratory community as it provides little time to prepare, certify and submit upwards of millions of data points based on a yet-to-be released set of agency requirements," they wrote. The lab sector has also asked that deadlines for gathering and reporting data be set back, possibly into 2017.

"This Dear Colleague letter vigorously illustrates that the proposed timeline for reporting data and pricing will result in skewed data and Medicare rates that do not reflect the market," American Clinical Laboratory Association (ACLA) President Alan Mertz said in a statement, regarding the Dec. 16 letter. "This strong, bipartisan statement is in alignment with the position of clinical lab community, strongly urging CMS to delay implementation of the PAMA CLFS reforms until improvements can be made, not only to protect access to clinical laboratory services for Medicare beneficiaries, but also to ensure continued diagnostic innovation."

Most recently, Chairman of the Senate Committee on Finance, Orrin Hatch, and Ranking Member Ron Wyden issued their own letter to Slavitt on Jan. 6, 2016. Reiterating the criticisms expressed in the House and Senate letters, Hatch and Wyden provided more specific objections and detailed suggestions. They criticized use of Tax Identification Numbers to identify reporting laboratories saying it was

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>
> — Alan Mertz, President, ACLA

"too limiting" and would exclude "important segments of the laboratory market, especially hospital outreach laboratories," which they note serve beneficiaries and compete with community-based labs. Instead, they suggest Clinical Laboratory Improvement Act numbers be used to identify reporting labs, while maintaining the $50,000 annual revenue threshold. Like the other letters, Hatch's and Wyden's comments also criticize the reporting timelines as "particularly unrealistic given that a final rule containing the information that laboratories will need to report has yet to be published."

ACLA praised the Senators' leadership in sending the letter and referenced their request to include outreach laboratories, with Mertz commenting in a statement: "It is clearly the intent of Congress that the entire clinical laboratory community report payment rates, including independent, physician, and hospital outreach laboratories. Leaving out major segments of the market, as the proposed CMS rule does, will only skew the data and lead to a misrepresentation of payment rates in the marketplace." Similarly, the National Independent Laboratory Association (NILA) also lauded the Senate leaders for their letter and claimed "The Hatch/Wyden letter came as a result of NILA's aggressive advocacy efforts, including grassroots outreach to the Senate Finance leaders, persuading them to press CMS that the timing of the PAMA rule is impossible and CMS's proposed methodology violates the statute."

As the efforts to resolve objections to PAMA continue, the industry waits for CMS to issue a final rule.

Takeaway: Members of Congress have been recruited to voice the concerns of the laboratory sector to CMS regarding the proposed PAMA regulations. G2

Insurers' Genetic Counseling Requirements Impede Testing, ACOG Says

With increasing availability and surging demand for multi-gene panel tests for hereditary cancer, insurers are expanding requirements for pre-test counseling by a 'genetics professional.' The American College of Obstetricians and Gynecologists (ACOG) says these requirements will markedly limit access to BRCA testing for hereditary breast and ovarian cancer, particularly for patients in non-urban areas. In a position statement released in mid-December, ACOG reiterates its claim that board-certified obstetrician-gynecologists (ob-gyns) remain appropriate and qualified providers for pre-test counseling.

"Ob-gyns around the country screen women for a variety of cancers every day," Mark DeFrancesco, M.D., ACOG's president, said in a statement. "Ob-gyns know how to discuss the risk of cancer with their patients, and women are accustomed to having these important conversations with their ob-gyns. We are dedicated to ensuring that our patients receive the care they need, when they need it, and by physicians they trust."

ACOG claims that historically the majority of BRCA testing has been ordered by ob-gyns and insurers' requirements are restricting the scope of practice of ob-gyns. The group says the 'genetics professional' requirement imposes "unnecessary" and "not medically indicated" barriers to timely care. Furthermore, ACOG says its

position statement is aligned with the American Medical Association Policy (H-460.902) "Opposition to Genetic Testing Restrictions Based on Specialty," which specifically opposes limiting the ordering of genetic testing based solely on physician specialty and opposes requirements for utilization of non-affiliated medical specialists or non-physicians prior to ordering genetic testing.

"ACOG reaffirms its position that ob-gyns are fully trained and qualified to counsel patients regarding genetic issues specific to pregnancy and women's health- associated cancers, and that the ordering of genetic testing should not be restricted by a requirement for pre-testing genetic counseling by a separate provider," the position statement says.

These pre-test counseling requirements and pre-authorizations are part of a trend among large insurers. *National Intelligence Report* sampled policies and found:

"ACOG reaffirms its position that ob-gyns are fully trained and qualified to counsel patients regarding genetic issues specific to pregnancy and women's health- associated cancers, and that the ordering of genetic testing should not be restricted by a requirement for pre-testing genetic counseling by a separate provider."

- As of Jan. 1, United Healthcare requires genetic counseling by an independent genetics provider (not employed by a testing lab) prior to BRCA mutation testing. The policy notes, however, a physician "with experience in cancer genetics" (defined as having received specialized, ongoing training in cancer genetics) can document medical necessity and provide test-related counseling.
- In 2015, the Centers for Medicare & Medicaid Services issued a draft local coverage determination proposing that pretest genetic counseling by a cancer genetics professional would be required for patients undergoing multi-gene panel testing.
- Cigna requires precertification for all BRCA tests and dating back to 2013 requires pre-testing genetic counseling from an independent board-certified genetic counselor or clinical geneticist for hereditary conditions, including breast and ovarian cancer, colorectal cancer syndromes, and Long QT syndrome.

Reiterating that board-certified ob-gyns have "more-than-sufficient training" to order genetic testing and to counsel patients, ACOG cites their previously released Committee Opinion on Ethical Issues in Genetic Testing, which lays out the role ob-gyns should play in genetic counseling. Ob-gyns, it says, should be aware of: appropriate test use; which test to order; what information the test can provide and the limitations of the test; how to interpret positive and negative results in conjunction with the patient's medical or family history; and the medical management options available, including appropriate specialist referral.

Takeaway: ACOG challenges requirements for pre-test counseling for genetic tests relating to hereditary cancers. G2

Palmetto Issues New Codes For BRCA, "Hotspot" Testing

Medicare fiscal intermediary Palmetto GBA quietly released new payment guidelines last month for several molecular tests under its MolDX program.

Palmetto issued new codes related to BRCA testing, tied to 146 specific genes. It approved 26 CPT codes for 40 separate BRCA tests for what it called "limited payment." They include tests being performed by Roche, Veracyte, CardioDX and oth-

CDC Year in Review and Future Plans Include Laboratory Safety

Laboratory safety and diagnosis of infections figure prominently in the Centers for Disease Control and Prevention's (CDC) review of 2015 and its agenda for 2016. The agency's Year in Review highlighted "the most pressing public health challenges of 2015" and areas of focus for 2016.

Those areas of focus included:

- **Ebola.** Following up on its efforts to control the Ebola outbreak in West Africa in 2015, the agency says its 2016 plans include establishing permanent offices in Guinea, Liberia and Sierra Leone to help detect and address new outbreaks and helping the African Union develop centers for disease control and prevention.
- **Antibiotic resistance.** The CDC intends to release a report in 2016 addressing prescribing practices and antibiotic resistance and will provide an interactive web platform offering access to relevant antibiotic resistance data.
- **Global Health Security.** A five-year roadmap is in the works to help the agency promote the Global Health Security Agenda that seeks to enable detection and prevention of infectious diseases throughout the world.
- **Lab Safety.** After establishing the Office of the Associate Director for Laboratory Science and Safety (OADLSS) in 2015, the agency said its goals for 2016 include using "lessons learned and best practices to mitigate" lab risks. The OADLSS was established to provide "scientific, technical, and managerial expertise and leadership in the development and enhancement of laboratory safety programs," "provide transparent flow of information across the laboratory community regarding laboratory science, safety and quality and sharing of best practices," and oversee lab safety and quality management at the CDC.

Takeaway: The CDC's new year's agenda touches on several laboratory and diagnostic related issues.

er well-known labs. It assigned the same code, 81162, for tests being performed by Ambry Genetics, LabCorp, Myriad Genetics and Quest Diagnostics. The effective date for the Myriad test was in 2006, while the others had an effective date in 2014. That reflects the rise of competition for BRCA testing services after a 2013 U.S. Supreme Court decision that a patent could not be held on a single gene, invalidating the patent and monopoly Myriad had on BRCA testing.

Ten other labs were also assigned the unlisted CPT code 81479. They include Foundation Medicine's Foundation One test, Agendia's MammaPrint, and variants on the BRCA test offered by LabCorp and Myriad. Altogether, Myriad has been assigned five different codes for its BRCA variants.

The assignment of so many codes at once may help mute some of the grumbling from molecular labs that the MolDX program has been slow to create straightforward payment pathways for their tests.

Another significant change by Palmetto was a determination that so-called next-generation sequencing "hotspot" tumor panels (between five and 50 genes being assayed) should be billed differently than sequencing panels, which include more than 50 genes. Palmetto issued three new codes for testing: 81445 (for a solid tumor of five to 50 genes); 81450 for the same testing for hematologic tumors, and 81455 for any tumor assay involving more than 50 genes.

"This may be a relief to some labs, because two of these codes were given very low list prices by CMS through the 2015 gapfill method," wrote Bruce Quinn, M.D., a senior director at FaegreBD Consulting, on his blog. Those codes, 81445 and 81450, will begin paying at around $700 apiece as of Jan. 1 of this year.

Palmetto also issued a hotspot code for BRCA testing, 88145. That was assigned to just one assay, the CANCER26 test performed by the Medical University of South Carolina.

However, Palmetto has still left unresolved billing for comprehensive genomic profiles (CGPs). "Because CGP includes SNVs, small and large insertions and deletions, CNVs, and rearrangements, CPT codes 81445, 81450, and 81455 do NOT describe a CGP service," Palmetto posted on its website. "Therefore, to report a CGP service, test providers should use CPT code 81479 - Unlisted molecular pathology procedure."

Takeaway: A national study suggests dramatic improvements in matching patients to their health records and among providers and other organizations is possible.

Research/Applied Project Opportunities from the International School of Biomedical Diagnostics at Arizona State University

The International School of Biomedical Diagnostics (ISBD) at Arizona State University (ASU) recently invited companies in biomedical diagnostics and affiliated fields to partner with ISBD on research projects addressing issues in the diagnostics industry. Industry partners will benefit from projects executed by an inter-disciplinary team of students in ISBD's Biomedical Diagnostics online Master's degree program that have significant value to the company's business. "An ideal project is one which is multi-faceted and requires an inter-disciplinary team to address a challenge or problem the company has but [doesn't] have the resources to do at that time," explains Carl Yamashiro, Associate Research Professor, Biomedical Informatics at ISBD. He indicates some of the past projects have provided competitive intelligence to the host company on industry developments and the status of diagnostics in a particular area–which can, for example, allow the company to determine whether they can and should develop a product that will be competitive in that area. Other potential subjects for research projects include regulatory, bioethics and quality systems issues and challenges. Given the online nature of the degree program, laboratory-based research cannot be considered for these projects.

"By partnering with ISBD and ASU on supporting such projects, you are playing a very significant role in educating future leaders in the diagnostics and allied fields, and possibly identifying future colleagues to help drive the long term success of your company," said the ISBD/ASU announcement inviting research proposals. ISBD's Master's degree program "is designed to provide students a broad perspective of the field with a focus on applied research, technology development, reimbursement and regulation and current perspectives in the biomedical diagnostics field."

Many of the students already have professional experience working in laboratories and bring their own expertise to their projects, notes Yamashiro. Additionally, partnering companies also benefit from the breadth of knowledge available to the students from university faculty, several having more than 20 years experience in the diagnostics industry. While the research program operates within the department of biomedical informatics, the program can draw on expertise in the other schools and colleges within ASU in disciplines such as bioengineering, health economics, regulatory science, law and nursing. "[I]f there's a need for expertise in a particular discipline, … [the research team] can go to a resident expert here at the university that can give them advice," says Yamashiro.

Companies whose research proposals are selected will be asked to provide a mentor to work with a team of 3-4 master's students, spending an average of 1-2 hours per week overseeing progress of the research and providing practical advice. Teams will be conducting projects from March 14 - July 8, 2016. Proposals with a description of the scope of work must be submitted by January 29, 2016, to Carl Yamashiro at carl.yamashiro@asu.edu. For more information, contact Carl by email or call (480) 884-0348.

FDA Looks Back at Successes and Details Plans for 2016, Including LDTs

In a series of three recent *FDA Voice* blog articles, the FDA looks back at its accomplishments in 2015 and highlights issues on the agenda for 2016. The FDA also issued its annual list of guidance documents that it plans to finalize in 2016. Both of these releases address issues of importance for the clinical diagnostics industry.

The first *FDA Voice* blog focused on medical product innovation, noting "unprecedented innovation in the sectors we regulate" and touts a 36% drop in the agency's average time to decide on pre-market approval applications since 2009. A word of advice was also shared, recommending drug and device makers engage in conversations with the FDA "at the early stages of development" to weed out products that are likely to fail. In that blog, Stephen M. Ostroff, M.D., acting commissioner of Food and Drugs addressed next generation sequencing tests and the agency's efforts to facilitate development of new technologies and achieve more precise diagnosis using "state of the art diagnostics"—including the launch of its precisionFDA web platform that allows stakeholders to "come together" to further this technology.

In the annual report listing guidance documents to be issued in 2016, the agency lists its policy for regulatory oversight of laboratory developed tests (LDTs) as a guidance document to be finalized. LDT guidance was listed on the "A-list" as a prioritized guidance document intended to be published during 2016. The A-list also includes draft guidance regarding companion diagnostics co-development.

The B-list, for documents the agency intends to issue as "resources permit," includes blood glucose monitoring test systems for prescription point-of-care use and self-monitoring blood glucose meters for over-the-counter use. Dual 510(k) and Clinical Laboratory Improvement Amendments Act (CLIA) Waiver by application also appears on the B-List. Previously issued guidance documents the Agency lists for retrospective review in 2016 include:

- Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations
- Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery
- Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices
- Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable

Takeaway: The FDA once again reiterates its commitment to finalize LDT guidance this year. G2

Trust for America's Health Report, *Continued from bottom of p.1*

The report, entitled "Outbreaks: Protecting Americans from Infectious Diseases," calls on states to maintain and modernize basic capabilities such as epidemiology and lab abilities needed to respond to new and ongoing outbreaks.

"Public health labs must have the staff and capabilities to rapidly detect and test for potential infectious disease outbreaks. Quickly understanding where an outbreak is occurring—or about to occur—is key to preventing or controlling an outbreak," Rich Hamburg, deputy director of TFAH, told *National Intelligence Report*.

As to clinical labs, staff must be trained to ensure familiarity and adherence with protocols for handling, packaging and preparing dangerous pathogens and waste for transport, TFAH said.

"Public health laboratories play a critical role for surveillance of antimicrobial resistance. Data from these labs can shape the development of new antibiotics and promote better stewardship of antibiotic use."

— Chris Mangal, APHL

New Disease Threats Deserve Attention

New national infectious disease threats deserving a redoubling of professional efforts are: MERs-CoV and antibiotic-resistant superbugs and resurging illnesses including whooping cough, tuberculosis and gonorrhea, TFAH said in a statement.

"Health care professional societies and unions, hospital administrators, laboratories and others must ensure their workforces are informed and well-trained on appropriate procedures for newly emerging and ongoing threats," the TFAH report said.

Also, new diagnostics are needed to respond to threats, and a collaboration among labs and test manufacturers can possibly bring them about, according to the Association of Public Health Laboratories (APHL).

"The number of antimicrobial-resistant organisms continues to increase globally. It will be important for test manufacturers, in collaboration with laboratories, to develop new diagnostics to detect these changing threats," said Chris Mangal, APHL's director of public health preparedness and response.

"Public health laboratories play a critical role for surveillance of antimicrobial resistance. Data from these labs can shape the development of new antibiotics and promote better stewardship of antibiotic use," she also told *National Intelligence Report*.

Electronic Reporting and Messaging Important

Speaking of data, the TFAH report also recommended public health labs boost electronic reporting to enable real-time data sharing with public health officials.

The APHL Informatics Messaging Services (AIMS) is a secure cloud-based environment that accelerates implementation of public health messaging solutions, according to Mangal. It offers secure electronic data messaging needed across the public health community and provides shared services to aid in the transport, validation, translation and routing of electronic data, Mangal said.

Key Findings: Biosafety, Infections, HIV

The TFAH report, released in December, shared these key findings, among others:

- Only 36 states have a biosafety public health professional. The job entails responsibilities relative to detection, diagnosis and containing disease outbreaks. Mangal told *National Intelligence Report* that reductions in Public Health Emergency Preparedness (PHEP) funding have, over time, eroded biosafety programs. But

public health labs accessed Centers for Disease Control (CDC) Epidemiology and Laboratory Capacity (ELC) Ebola supplemental funding to rebuild these biosafety programs. The labs also turned to clinical labs to strengthen their system, she said. "One success is the hiring of biosafety officers across the country," she said, adding that APHL calls for increased funding for the PHEP Cooperative Agreement and ELC to enable labs to respond to threats.

- One out of 25 hospitalized patients gets a health care-associated infection, which leads to 75,000 deaths annually.
- Only nine states reduced standardized infection ratio for central-line-associated bloodstream infections between 2012 and 2013.
- More than two million Americans contract antibiotic-resistant infections each year, leading to more than 23,000 deaths, TFAH noted. The superbugs reportedly cost health care $20 billion and result in more than $35 billion in lost productivity.
- More than 1.2 million Americans live with HIV, and about one in eight do not know they have it.

America's Infectious Disease Report Card

Here's a look at how TFAH said U.S. states scored on readiness for disease outbreaks with zero the lowest and 10 the highest possible score:

- **8 out 10:** Delaware, Kentucky, Maine, New York, Virginia
- **7 out of 10:** Alaska, California, Maryland, Massachusetts, Minnesota, Nebraska
- **6 out of 10:** Arkansas, Illinois, Iowa, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Vermont, West Virginia, Wisconsin
- **5 out of 10:** Arizona, Colorado, Connecticut, Georgia, Hawaii, Mississippi, Missouri, Montana, Pennsylvania, Rhode Island, Texas, Washington
- **4 out of 10:** Alabama, District of Columbia, Florida, Indiana, Louisiana, Nevada, South Carolina, South Dakota, Tennessee, Wyoming
- **3 out of 10:** Idaho, Kansas, Michigan, Ohio, Oklahoma, Oregon, Utah

Trust for America's Health is a Washington, D.C.-based non-profit organization that says it is focused on prioritizing disease prevention. The report was done in partnership with the Robert Wood Johnson Foundation.

Takeaway: More than half of U.S. states scores a five or lower on key indicators related to diagnosing and responding to infectious disease outbreaks, a new Trust for America's Health report finds. Laboratory executives are urged to ensure workers are informed and prepared for threats. Electronic reporting and data messaging; and collaboration among labs and test manufacturers toward new diagnostics are still other implications for labs. G2

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