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Laws Expanding Pharmacists' Scope, Payment Could Drive Lab Testing

Transformation of the health care system is propelling the dichotomous ambition of improving patient care and outcomes, while cutting costs. Better care coordination is anticipated to play a central role in improving medication adherence and reducing hospital readmissions. And neighborhood pharmacists may be the lynchpin in enhancing care coordination by assessing medication adherence, effectiveness, and safety, in part, through ordering laboratory tests.

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Patient Identification: IT Group Seeks Solution; Safety Expert Urges Labs to Examine Internal Processes

The innovator who develops the best solution to accurately identify patients throughout the health care continuum may earn a $1 million reward.

That's the idea behind the College of Healthcare Information Management Executives' (CHIME) National Patient ID Challenge. The national association of CIOs and health IT suppliers is partnering with HeroX (a challenge-launching platform) in the year-long crowdsourcing competition that will reward the winner with $1 million.

Labs Advised to Look Internally for ID Gaps

As to labs, pathologists and laboratory leaders may tap matching technology that helps labs match patient records from multiple organizations. Systems still rely on manual entry, pointed out Tejal Gandhi, M.D., president and CEO of the National Patient Safety Foundation (NPSF). She told *National Intelligence Review (NIR)* that labs also need to look at processes within the lab itself that could lead to a potential breakdown in patient identification.

"For example, do labs have a closed-loop communication? When they send results out, do they know for certain the provider actually got them? There are lots of things that can fall through the cracks," Gandhi said in an interview with *NIR*. "So, think of processes, potential gaps, and how labs can redesign to make the processes more reliable. That is going to be real important (to patient safety and identification)," she added.

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Laws Expanding Pharmacists' Scope, Payment Could Drive Lab Testing, *from page 1*

According to the American Pharmacists Association (APhA), the majority of states allow pharmacists to fulfill preventive services called for in the Affordable Care Act, including cholesterol screening for adults with certain risk factors and type 2 diabetes screening for adults with high blood pressure. However, integration of pharmacists into routine clinical care is stymied by "antiquated" state laws that prohibit pharmacists from ordering appropriate laboratory tests or altering medication management based on test results and a lack of federal reimbursement for pharmacists' health care services. Efforts are underway to address both the state and federal regulatory shortcomings preventing pharmacists from playing a pivotal role in integrated care teams.

"The lack of reimbursement of pharmacists for services provided within their state scope of practice unnecessarily limits patient access to certain health care services and the contributions pharmacists can make to their health care and outcomes," says the APhA's Patient Access to Pharmacists' Care Coalition, in a statement. "Enabling pharmacists to practice at the top of their education and training, and be better integrated into the patient's health care team, will improve health outcomes and greatly benefit specific populations, especially those with chronic disease such as diabetes and cardiovascular disease."

Pharmacists, for decades, experts say, have played a role in the management of drugs for chronic diseases in the Indian Health Service, the Department of Veterans' Affairs and the Department of Defense. In the 1960s, the government called upon pharmacists to improve medication oversight and management of patients in long-term care through the provision of monthly medication regimen reviews (MRRs). An iteration of the MRR process now exists under the comprehensive medication review (CMR) annual benefit under Medicare Part D. CMMs will likely also play a role with calls for coordinated care with integrated care teams (that include pharmacists) under new delivery models like patient-centered medical homes and affordable care organizations. Yet, pharmacists are only paid to dispense medication.

Lab Tests Commonly Ordered by Pharmacists

- Serum creatinine
- Liver function tests
- Serum electrolytes
- Lipid panel
- hemoglobin A1c
- Prothrombin time/ international normalized ratio
- Drug serum concentrations
- Drugs/Conditions Requiring Monitoring

Drugs/Drug Classes Commonly Requiring Monitoring

- Diuretics
- ACEIs/ARBs
- Statins
- Metformin
- Warfarin
- Levothyroxine

Source: Adapted from Pharmacist's Letter online continuing education and webinars "Using Lab Tests to Monitor Drug Therapy."

Provider status bills were introduced with bipartisan support in Congress for the past two sessions. The bills, expected to be re-introduced again, propose an amendment to the Social Security Act to authorize the Secretary of Health and Human Services to federally recognize pharmacists as health care providers and develop pharmacist-specific codes for reimbursement as part of the physician fee schedule/Medicare Part B.

But, reimbursement is not the only challenge. For pharmacists, their scope of practice is dictated by state legislatures and regulated by a State Boards of Pharmacy and these vary state by state. According to the APhA, in 47 states and the District of Columbia pharmacists are authorized to enter into collaborative practice agreements (CPAs) with a physician or another prescriber and in 31 states pharmacists are also allowed to order and interpret lab tests as part of these CPAs. For instance, some CPAs are limited to permitting pharmacists to switch between drugs in the same class to meet formulary requirements. But CPAs in states with more progressive practice scope regulations can include ordering drug monitoring-related laboratory tests (usually CLIA-waived tests in the community pharmacy setting), initiating therapy (e.g., antibiotic therapy after a positive rapid strep test), or

adjusting drug regimens based upon test results. CPAs also vary in the autonomy provided to pharmacists to act alone or in consultation with the prescriber.

"Pharmacists are trained to do much more than dispense medication, and they could help plug the growing gaps in chronic care management in the United States," John Gums, from the University of Florida, wrote Jan. 5 in *The Conversation*. "The trouble is that state pharmacy practice statutes were written in a different era, and haven't caught up with the training pharmacists receive today."

Efforts aimed at legislatively expanding pharmacists' role in patient care are supported by societies (including the APhA and the American Society of Consultant Pharmacists). Societies are calling for recognition and compensation for pharmacists as health care providers, as well as revision of laws and regulations to "facilitate pharmacist involvement in appropriate laboratory testing and health screening as essential components of patient care."

Takeaway: Legislative efforts underway at both the state and federal levels could expand pharmacists' role in patient care and medication management. With recognition as a health care provider (and with accompanying reimbursement) pharmacists are expected to play a larger role on integrated care teams and could expand compliance with recommended testing as part of drug management. G2

CMS Issues Deficiency Letter to Theranos

Theranos is once again in the media spotlight due to negative attention it has received from a government regulatory agency. Last year, the U.S. Food and Drug Administration (FDA) released documents indicating its position that Theranos' nanotainer used for collecting blood samples is a class II medical device and listing concerns about certain aspects of operations (see box). This year, in January, the Centers for Medicare & Medicaid Services (CMS) issued a letter stating Theranos' Newark, Calif. laboratory had condition level deficiencies and posed an immediate danger to patients in the area of hematology.

The CMS letter arises from an onsite survey completed in November 2015, to determine compliance with the Clinical Laboratory Improvement Amendments (CLIA). The letter indicates the laboratory facility was not in compliance with CLIA certification conditions relating to analytic systems (42 C.F.R. 493.1250), laboratory director requirements for high complexity testing labs (42 C.F.R. 493.1441), requirements concerning technical supervisor for high complexity testing lab (42 C.F.R. 493.1447), and testing personnel conditions for high complexity testing labs (42 C.F.R. 493.1487).

As to the hematology deficiencies giving rise to immediate jeopardy, the letter explains that CLIA defines immediate jeopardy as "a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public."

CMS gave Theranos 10 days to issue a plan of correction, a typical requirement of an immediate jeopardy letter. Healthcare attorney Robert E. Mazer, of Ober Kaler in Baltimore, who assists laboratories with CMS inspection and CLIA issues, indicated he has not seen the actual survey report and therefore can't comment on the

specific nature of the alleged deficiencies but explains that this letter means that CMS has advised Theranos that "sanctions will not be imposed" if CMS is able to confirm that Theranos has demonstrated that it has "removed jeopardy" and "come into Condition-level compliance." A follow-up survey must also verify compliance with "all CLIA requirements" after corrective action evidence is supplied by the lab. "If [compliance] has not been demonstrated to CMS' satisfaction, the agency can impose various penalties, including revocation of the laboratory's CLIA certificate required to perform testing, or cancellation of its right to receive Medicare payment for its tests," Mazer adds. CMS' letter warns that civil money penalties of up to $10,000 per day of noncompliance could be imposed.

Theranos issued a statement that the problems were all but corrected and reiterated that it was among the few labs that invited a higher level of scrutiny than required. "Theranos remains the sole company to call for—and voluntarily submit itself to—stronger regulatory oversight," it said, in reference to the fact that it had decided to submit all of its test to the U.S. Food and Drug Administration for approval.

"It's important to note this particular survey was conducted months ago and is not a reflection of the current state of our lab in Newark, CA," the statement continued. "As the survey took place we were simultaneously conducting a comprehensive review of our laboratory's systems, processes and procedures to ensure that we have best-in-class quality systems. CMS' findings included standard and condition-level deficiencies, and one finding at the "immediate jeopardy" level ... To be clear, that finding does not apply to the whole lab, and none of these findings relate to our Arizona lab, where we currently process over 90 percent of our tests."

With regard to the personnel-related deficiencies cited in the letter, Theranos said it has added two new key personnel: Kingshuk Das, M.D. a board-certified pathologist and associate medical director of UCLA Health's Clinical Laboratories; and Waldo Concepcion, M.D., chief of clinical transplantation and professor of surgery at Stanford University Medical Center.

"In some cases, a laboratory may attempt to satisfy CMS that all of its concerns have been addressed through changes in laboratory operations, without admitting that condition-level deficiencies had actually existed," says Mazer. "This is because if CMS rejects the allegations of compliance and correction and seeks to impose penalties and the laboratory files an administrative appeal, the lab will have to prove that each finding of a condition-level deficiency had been incorrect. The lab cannot avoid penalties imposed by the agency by contesting CMS' determination, rejecting a so-called 'credible allegation of compliance.'"

Takeaway: Theranos continues to face scrutiny from federal regulators as it reiterates its commitment to work with those regulators to achieve approvals for its testing technologies. G2

Theranos Addresses FDA Scrutiny

Late last year, Theranos received two Form 483s from the U.S. Food and Drug Administration (FDA) indicating that its nanotainer is a class II medical device and expressing concerns with regard to complaint handling, audits, design validation and documentation regarding risk analysis. Theranos responded to the FDA reports publicly, stating "none of these observations were specific to Theranos' analytical devices, software, or chemistries, or the manufacturing infrastructure for Theranos' analytical devices or chemistries. All observations from this inspection pertained to quality systems associated with the use of one of our Nanotainer tubes under the CLIA lab quality framework instead of the FDA quality framework." Theranos also emphasized that these 483s were not final agency determinations of compliance but rather observations made by FDA during inspection visits. FAQs on the FDA website confirm that 483s are not final agency determinations as to compliance and are issued "when an investigator(s) has observed any conditions that in their judgement may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."

Theranos has voluntarily pledged to put the company's assays through the FDA's approval process. In a March 6, 2015 statement regarding the FDA's framework for overseeing laboratory developed tests (LDTs), the company stated: "Theranos is submitting and will continue to submit all our tests to the FDA. We are not required to do so, but we have made this commitment because we believe that FDA oversight plays a critical role in ensuring that individuals and their physicians get the most accurate test results." So far, in July 2015, the FDA approved one of the tests on Theranos' menu—it herpes simplex 1 virus IgG assay.

Few Non-Academic Hospitals Planning for Precision Medicine

One year after the Obama administration launched a $200 million precision medicine initiative, except for academic medical centers, few hospital executives see personalized medicine playing a significant role at their organization, according to a new nationwide survey, conducted by the analytics firm Health Catalyst. A White House blog released following the President's January 2015 State of the Union announcing the initiative noted the challenges ahead: "The potential for precision medicine to improve care and produce new treatments has only begun to be tapped. Translating initial successes to a larger scale will require a coordinated and sustained national effort."

Unfortunately a coordinated nationwide effort has not yet been achieved. The Health Catalyst survey revealed that more than two-thirds (67 percent) of non-academic executives see precision medicine as having no role, a small role, or an average role in their organization in the next five years. By comparison, 71 percent of academic health care executives see precision medicine as playing a "significant" role in their organization in the next five years.

"This survey shows that leaders in academic medicine are already moving to adopt precision medicine, but the rest of healthcare has a lot of catching up to do," said David Crockett, Ph.D., senior director of research and predictive analytics for Health Catalyst, in a statement. "We live in a remarkable era of information, when all that is known about a person—from family history and genetics to location history and environment—can be balanced against all that is known in the medical domain. This big-picture view of medical decision making can allow providers to focus both prevention and intervention on appropriate individuals, while avoiding unnecessary costs and unwanted side effects for those patients who wouldn't benefit."

When asked about the relevance of DNA sequencing to the individual organization's patient treatment strategies, respondents' answers again revealed a divide between academic and non-academic institutions. Nearly 100 percent of academic respondents declared DNA sequencing results to be relevant or very relevant to patient treatment strategies, compared to only 39 percent of non-academic center respondents. Not surprisingly, academic centers are more active in making plans to incorporate genomic data into electronic medical records. Nearly two-thirds of academic respondents (64 percent) said such plans were underway, compared to only 29 percent of non-academic respondents.

The online survey was conducted between November and December 2015. The majority of the 60-plus respondents were health care executives including chief information officers, and chief medical officers, the data-warehousing and analytics firm Health Catalyst says.

Takeaway: One year after the President launched a precision medicine initiative, significant challenges remain with a recent survey revealing that many hospitals are not expected to wholly embrace its use for many more years. G2

■ Patient Identification, *Continued from bottom of p.1*

Patient Identification's Important

Indeed, patient identification is important, Challenge organizers also say, because errors continue to occur in health care organizations due to lack of a universal way of accurately identifying a patient.

> *"As we digitize health care and patients move from one care setting to another, we need to ensure with 100% accuracy that we identify the right patient at the right time. Anything less than that increases the risk of a medical error and can add unnecessary costs to the health care system."*
>
> — Marc Probst, CHIME

In fact, the error rate in matching patients to their records is usually 10 to 20% within a healthcare system. It can rise to 50 to 60% when organizations exchange data through the care continuum, CHIME pointed out in a statement. CHIME data suggest that 60% of members use some form of a unique patient identifier to match patient data within their organizations. Others rely on complicated algorithms. About 20% of CHIME members said at least one adverse medical event can be associated with incorrect patient matching.

"As we digitize health care and patients move from one care setting to another, we need to ensure with 100% accuracy that we identify the right patient at the right time. Anything less than that increases the risk of a medical error and can add unnecessary costs to the health care system," said Marc Probst, CHIME board of trustees chair. He is also vice president and CIO, Intermountain Healthcare, Salt Lake City, which spends between $4 million and $5 million each year on patient identification-related technologies and processes, according to a CHIME statement.

Challenge Guidelines and Deadlines

The Challenge seeks to establish a more secure method of patient identification than the social security number, which is also tied to financial and personal records and could be stolen, CHIME pointed out on the HeroX Web site.

Conversely, a stolen national patient identification number—unlike a social security number—can be terminated and replaced with a new number, CHIME added.

Submissions for the Challenge Concept Blitz Round are due April 8 with final submissions (whether or not people participate in the Concept Blitz) due Nov. 10. The winner will be announced Feb. 19, 2017. A CHIME spokesperson told *NIR* that 86 innovators have signed up at this writing.

CHIME said it is seeking the best plan, strategies, and methodologies that will accomplish the following: 1) easy and quick identification of patients; 2) 100% accuracy in patient identification; 3) patient privacy protection 4) patient identity protection; 5) adoption by vast majority of patients, providers, insurers, and other stakeholders; and 6) scale to handle all U.S. patients.

Gandhi said the NPSF does not have a Challenge entry, but she may be involved another way. "We support the project, because we think patient identification in all these areas is a big issue," she said.

Takeaway: A national IT organization hopes to find an answer to the complex problem of patient identification and protecting patients from medical errors as electronic health records proliferate. A patient safety expert also encourages lab leaders to look at their internal processes and how they help ensure patient identification and accuracy. G2

White House Requests $1.8 billion & CDC Issues Guidance to Fight Zika Virus

The Zika virus is getting increased attention from U.S. media and the Centers for Disease Control and Prevention (CDC) now that the first case of the infection has been detected in a "non-traveler" in the continental U.S. The CDC has updated guidelines and resources for diagnosing and preventing transmission of the Zika virus and the White House has asked Congress for over $1.8 billion to fund efforts to fight the virus.

Testing can be complicated by the fact that cross-reacting antibodies for other viruses such as dengue and yellow fever viruses may lead to false positive results for Zika.

The CDC's Jan. 29 issue of *Morbidity and Mortality Weekly Report* (MMWR) indicated that by Jan. 20, 2016, "locally-transmitted cases had been reported to the Pan American Health Organization from Puerto Rico and 19 other countries or territories in the Americas" and infections had been reported in U.S. for returning travelers. Feb. 5, the CDC reported that "in collaboration with the Dallas County Health and Human Services" it has confirmed the first case of the infection in the continental U.S. involving an individual who hadn't traveled to a country experiencing an outbreak of the virus. In that case, the infection was sexually transmitted. The CDC indicates that other documented means of transmission for the Zika virus have included intrauterine transmission, intrapartum transmission from mother to newborn, blood transfusion, and laboratory exposure.

The CDC's Feb. 5 interim guidelines address when testing is recommended for pregnant women, indicating Zika testing can be offered to pregnant women 2-12 weeks after returning from outbreak locations, regardless of whether they have symptoms. Testing for the Zika virus is currently being performed at the CDC and four state health department laboratories and the CDC says it is working to expand laboratory diagnostic testing to additional states. Testing can be complicated by the fact that cross-reacting antibodies for other viruses such as dengue and yellow fever viruses may lead to false positive results for Zika.

The CDC also addressed lab safety, advising in a Jan. 13 memo that the virus is classified as a biological safety level (BSL) 2 pathogen and "should be handled in accordance with Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines and a risk assessment performed for each laboratory for the specific procedures utilized."

Finally, the White House is asking Congress to fund efforts at diagnostic development, "enabling the testing and procurement of vaccines and diagnostics," education, "improving epidemiology and expanding laboratory and diagnostic testing capacity," and mosquito control, among other initiatives. The funding requests relevant to laboratories and diagnostics include:

- $828 million to the CDC to help "improve laboratory capacity and infrastructure to test for Zika virus and other infectious diseases" as well as improve diagnostics and support "advanced methods to refine tests;"
- $200 million to the Department of Health and Human Services to fund "research, rapid advanced development and commercialization of new vaccines and diagnostic tests for Zika virus;"

- $335 million to the U.S. Agency for International Development to "create new incentives for the development of vaccines and diagnostics" and "[s]timulate private sector research and development of vaccines, diagnostics" and other innovations.

Takeaway: As spring approaches the CDC ramps up its efforts to call attention to the Zika virus and the White House asks Congress to fund the search for diagnostics and vaccines. G2

Shire and ACMG Partner to Support Medical Geneticist Training

"As a result of advances in the area of genetic and genomic research and diagnostic testing, it is anticipated that the need for medical geneticists will grow considerably," according to the National Human Research Institute's website www.genome.gov. The Bureau of Labor Statistics (BLS), U.S. Department of Labor, concurs, noting in its *Occupational Outlook Handbook, 2016-17 Edition, Genetic Counselors*, that "[o]ngoing technological innovations, including improvements in lab tests and developments in genomics … are giving counselors the opportunities to conduct more types of analyses." The BLS predicts employment of genetic counselors will increase 29 percent between 2014 and 2024—but given the size of the occupation that growth will add "only about 700 new jobs" during that period.

With that need for geneticists in mind, Shire has committed $1.65 million to support the ACMG Foundation for Genetic and Genomic Medicine training programs for medical geneticists during the next three years. "The partnership between Shire and the ACMG Foundation will help foster a generation of geneticists around the world who will play crucial roles in the diagnosis and care of patients with rare and common diseases." The funds will be used for 10 one- to two-year training fellowships for medical geneticists "We have reached a critical juncture in terms of the integration of medical genetics into health care," said ACMG Foundation Executive Director, Michael S. Watson, PhD, FACMG. "Though geneticists are essential to the diagnosis and management of rare diseases and for the care of individuals with genetic conditions, we are faced with a significant deficit in the number of laboratory and clinical geneticists in the United States."

BLS explains that geneticists provide patients and referring physicians with consultation reports on "complex genomic concepts," evaluate lab tests and use the results to counsel patients and advise other health care providers, and help patients and family members understand genetic risks and inherited conditions. Geneticists also help patients and providers understand genetic testing options as well as the risks, benefits and limitations of such testing.

Takeaway: The rising importance and value of involving geneticists in the diagnostic process is evidenced by Shire's commitment to training geneticists. G2

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Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Lori Solomon and Donna Marie Pocius, Contributing Writers; 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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