G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 37th Year of Publication

Vol. 16, Iss. 6, March 24, 2016

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CMS & NIH Focus on Relationship Between Social Issues and Health of Seniors, Children

When patients come to labs for tests, they bring more than health needs. They may come from unstable homes, be hungry, or experience difficulty finding transportation to get to the lab.

Social issues like these have been researched and linked to health for decades. But the U.S. Department of Health and Human Services (HHS) has just announced two new initiatives that take a fresh look at the relationship. Labs, as a gateway to health care, can draw value from these efforts.

The Centers for Medicare & Medicaid Services (CMS), with $157 million in HHS funding, is launching a five-year program dubbed the Accountable Health Communities Model to explore among its beneficiaries a possible link between clinical services and social needs.

Also, the National Institutes of Health (NIH) is calling for research, through January 2017, aimed at reducing health disparities among children. An American Academy of Pediatrics (Academy) policy statement, released in March, calls early detection and management of poverty-related disorders important components of pediatrics.

For laboratory leaders, these efforts are important for at least two reasons. First, they may produce data that suggest difficulties in accessing lab tests, which is the gateway to care for many people. And the studies could encourage labs to develop community outreach services, or to partner with hospital social services departments or community agencies in healthy neighborhood initiatives. For example, some labs give staff responsibilities for assisting patients with interpreting insurance plans.

Here are details about the initiatives.

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FDA Challenges DTC Genomic Tests from Startup Labs

Although the laboratory sector is at loggerheads with the U.S. Food and Drug Administration (FDA) over the regulation of LDTs, that has not prevented the agency from warning two nascent players from marketing genomic tests without the proper approvals.

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CMS & NIH Focus on Relationship Between Social Issues and Health of Seniors, Children, *from page 1*

CMS Explores How Unmet Needs Impact Care Access & Costs

The CMS program is the agency's first model aimed at beneficiaries struggling with unmet health-related social needs and helping them learn of community-based services that can help. As part of the program, "bridge organizations" will screen seniors and Medicaid beneficiaries to find out if they face issues such as housing instability, food insecurity, utility needs, interpersonal violence and transportation limitations, according to a CMS statement.

One in five U.S. children under age 18 lives in poverty, according to U.S. census data.

The 44 "bridge organizations" (hospitals, physician practices, community-based organizations and other award recipients) may help connect beneficiaries—who perhaps choose to pay an electric bill over going to the lab for a blood test—to services such as the Low Income Home Energy Program. "For decades, we've known that social needs profoundly affect health, and this model will help us understand which strategies work to help improve health and spend dollars more wisely," said Patrick Conway, MD, CMS deputy administrator and chief medical officer, in a statement.

Effectiveness of the model will be assessed in reduced health care costs, emergency department visits and inpatient hospital readmissions, according to CMS.

NIH Funds Children's Health Studies

Meanwhile, the NIH announced in December available funds to study factors that affect children's health including: 1) lab-related areas of biological health—genetics, cellular and organ systems; 2) lifestyle factors 3) physical and family environments; 4) social; 5) economic; 6) institutional; and 7) cultural influences.

An NIH notice identifies these segments for studies: low literacy; rural and low-income populations; geographically isolated; hearing and visually impaired; physically or mentally disabled; migrant workers' and immigrant and refugee family children; and language minority children.

Pediatricians Asked to Help Screen for Poverty

One in five U.S. children under age 18 lives in poverty, according to U.S. census data. And research links children in poverty with toxic stress that can alter gene expression and brain function and contribute to chronic cardiovascular, immune and psychiatric disorders, as well as behavioral difficulties, according to a policy statement by the Academy, "Poverty & Children's Health in the U.S.," which appears in the April 2016 issue of *Pediatrics*.

Early detection and management of poverty is a part of the pediatrics practice, according to an Academy statement. The organization calls on pediatricians to ask at patient check-ups questions (aimed at identifying people who need help from community resources) such as, "Do you have difficulty making ends meet at the end of the month?"

Takeaway: Two federal agencies are exploring social determinants of health and health disparities. CMS seeks to help its beneficiaries with community-based services that could improve their health. The NIH has funds to study diverse factors affecting children's health and how they can be addressed. The American Academy of Pediatrics says detection of poverty and related disorders is part of the pediatrics scope of practice. Labs, as gateways to heath care, may see opportunities to reach out in healthy neighborhood initiatives. G2

Research Shows Effects of Policies on Care Costs and Use

Lab leaders often read about national and state policies. But effects of them may be harder to discover. The Health Care Cost Institute (HCCI) was motivated to find answers. Six recently released research reports—ranging from cancer treatment spending and nurse practitioners to opioid use and more—show impact of national and state policies on health care costs and utilization, an HCCI statement pointed out. For labs, the information is significant because it suggests the importance of developing testing services that are of the greatest value to payers, physicians and patients.

Studies were conducted by independent researchers using HCCI's claims data for more than 50 million people insured by Aetna, Humana and UnitedHealthCare. Of the six reports, the topics of consolidation effects on cancer costs and use of nurse practitioners in primary care may be of most interest to lab leaders. Consolidation among providers drives up cancer treatment spending, according to a University of Chicago analysis. Findings include: consolidation among outpatient oncology providers and hospitals intensified during 2010 and 2011; greater provider consolidation results in increased spending on outpatient prescription drug-based cancer treatment; driving the rise are facility fees hospital outpatient departments charge payers.

Telehealth services claims increased from 1,246 in 2009 to 2,558 in 2013, but they are reimbursed 40% less than non-telehealth care, noted research conducted at the University of Nebraska Medical Center.

Prices for primary care services fell by 1 to 4%, but spending on care increased, noted a study by the University of California San Francisco that explored effects of laws in states from 2008 to 2012 allowing nurse practitioners to treat patients without supervising physicians. Higher total health care costs may be a result of stepped-up volume in services, stemming from greater access to care, the researchers said.

The other four studies found: Opioid use and emergency room visits decrease when patients with low back pain are given unrestricted access to physical therapy, according to a study by the University of Washington involving six northwest states. Patients paid less out-of-pocket for physician and outpatient visits, hospital and pharmacy care as compared to other patients, study findings suggest.

When patients have an incentive to choose low-cost, reference-based pricing for colonoscopy, per-procedure costs fall 8.5%, a study by the University of California Berkeley shows. Researchers estimate the U.S. can save $95 million annually on medical spending if just three insurers—Aetna, Humana and UnitedHealthCare—adopted reference-based colonoscopy programs.

Telehealth services claims increased from 1,246 in 2009 to 2,558 in 2013, but they are reimbursed 40% less than non-telehealth care, noted research conducted at the University of Nebraska Medical Center.Visits to mental health providers did not increase despite passage of the Mental Health Parity and Addiction Equity Act, research by the University of Colorado School of Medicine found. The HCCI, established in 2011, promotes independent research and analysis on U.S. health spending causes and increases.

Takeaway: Claims data from more than 50 million insured Americans were used by HCCI to develop six studies about health insurance and impact of new policies ranging from consolidation to nurse practitioners and telehealth. For labs, research suggests importance of showing value to payers. G2

Lab Role Starts Small As Precision Medicine Initiative Evolves

The Obama administration has redoubled its effort to encourage the use of precision medicine, although the role of laboratories in the initiative has mostly been limited to small-bore ambitions for now. On Dec. 18, legislation authorizing more than $200 million to fund the initiative was signed into law. On Feb. 25, the one-year anniversary of the precision medicine initiative announced by President Barack Obama, the White House announced a slew of specific new projects involving regulatory agencies, research hospitals and universities, and a sprinkling of commercial laboratories. Of that latter group, many are relatively new to the field and limited in what they may be able offer.

The most well-known laboratory involved in the initiatives was Cambridge, Mass.-based Foundation Medicine. It announced its intention to release its genomic dataset of pediatric cancers for researchers. The Obama administration said it would be the largest dataset in this area to be made publicly available.

> *"The challenge is to find and validate good biomarkers that will help provide good diagnostic insight. And that by and large depends on having more data available."*
>
> — Juergen Klenk, Deloitte Consulting, LLP

"There are few things in life as devastating as when a child is diagnosed with cancer. It's critically important to the achievement of our corporate mission that the robust genomics information we have amassed is freely and easily accessible to researchers and utilized as an important tool to address the significant unmet medical need in pediatric cancers," said Foundation Medicine Chief Executive Officer Michael Pellini, M.D., in a statement.

Illumina, the San Diego-based company that primarily manufactures and distributes sequencing platforms, is involved in an initiative with the University of Chicago, Argonne National Laboratory, the Minority Coalition for Precision Medicine and The BioCollective to research the environments in which children are raised in conjunction with their microbiomes and whether it plays a role in their susceptibility to post-traumatic stress disorder. One of the more intriguing projects that was announced involved Pairnomix, a Minnesota-based laboratory. It would be working with Harvard Medical School, the University of Utah, Boston Children's Hospital and Recursion Pharmaceuticals to create a system wherein patients with serious illnesses would be more rapidly matched with potential drug therapies through the use of tailored testing. Under this initiative, known as the Patient-Empowered Precision Medicine Alliance, Pairnomix would construct models of individual genetic mutations and perform "highly personalized" drug screenings.

Color Genomics, another nascent laboratory, was involved in a third initiative promising to double the number of free BRCA tests it offers through its Every Woman program, as well as double the number of cancer centers through which those tests are offered. Currently, Color offers the free testing in conjunction with cancer providers at the University of California San Francisco, the University of Pennsylvania, the University of Washington and the Morehouse College School of Medicine. That labs have limited participating in the personalized medicine initiative at the moment may actually be following a logical path, according to Juergen Klenk, a principal with Deloitte Consulting, LLP, who is focused specifically on its precision medicine efforts.

"Where do you first light the fire to get this going?" Klenk said. "The challenge is to find and validate good biomarkers that will help provide good diagnostic insight. And that by and large depends on having more data available."

Indeed, many of the projects that were announced last month were focused on making data more available and easily shared by both providers and patients. The Washington, D.C.-based Advisory Board Company, for example, will create a standard application programming interface (API) for up to five pilot health care organizations that will allow them to communicate more efficiently with vendors and patients. Allscripts, athenahealth, Cerner, drchrono, Epic and McKesson are also collaborating to create APIs that would allow individuals to contribute their data for research initiatives. Acute care providers such as Hackensack University Medical Center, Carolinas Healthcare System, Intermountain Healthcare, Ochsner Health System, St. Joseph Health, the University of California health system, and Yale New Haven Health all announced they would make it easier for patients to access their data, as well as share it with researchers.

The White House also announced that the Office of the National Coordinator for Health IT and the National Institute of Standards and Technology would develop security frameworks for handling precision medicine data. And the U.S. Department of Health and Human Services Office for Civil Rights issued additional guidance on individuals' rights to access their health information under the Health Insurance Portability and Accountability Act (HIPAA). Specifically, the new HIPAA guidelines address the rights of individual patients to have copies of their health data sent to anyone they designate, including contributions for research.

The creation of such frameworks to regulate the sharing of genomic and related health care data is only the first step in creating regulatory guidelines that will allow laboratories to more widely participate in the precision medicine initiative, according to Dan Housman, chief technology officer of ConvergeHEALTH, a Deloitte affiliate. "We don't yet have mature systems in place for handling the funding and approval of companion diagnostics that bring down the cost of medications for findings from genomics," he said. He believes those issues likely won't even be addressed until key regulations are in place to control personalized patient care—as well as guidelines for how providers should act on test results and inform patients—including findings that may or may not be incidental to treatment. In the meantime, Housman believes that many labs are still ramping up their abilities to process large amounts of genomic data—another requirement that would be key to their participation in the precision medicine initiative on a larger scale.

Housman has worked with the Department of Veterans Affairs and the Department of Defense on the Million Veterans Project, an initiative to create a large research cohort for precision medicine. He noted that one of the biggest challenges has been finding enough labs with the capacity to process the data that would be gathered. "Labs are still good for (crunching data) on traditional lab tests. But because genomic tests have a very specific profile, it will require data analytics on very high scale," he said.

However, Housman said that labs should be able to meet the challenge. He observed that there is a "deep bench" of startups that should be able to crunch genomic data on a large scale in the near-term. And both LabCorp and Quest Diagnostics have been working on their initiatives in precision medicine, he added. "I can only imagine that they will be major players in high-volume sequencing, either through acquisitions or organic growth," he said.

Takeaway: The Obama Administration is continuing to press its initiative regarding precision medicine. However, the role that commercial laboratories are playing at the moment is small, although that will likely change as the initiative moves forward. G2

FDA Challenges DTC Genomic Tests from Startup Labs, *Continued from bottom of p.1*

Last month, the FDA issued letters to Sure Genomics and Solopap International questioning whether the labs were marketing molecular tests without proper clearance from the regulator. On Feb. 16, the agency sent a letter to the Utah-based Sure Genomics, raising concerns about its $2,500 in-home SureDNA sequencing test.

In a statement, Sure said the process for its SureDNA assay "is similar to 23andMe or AncestryDNA – you sign up, receive a kit, spit in a tube and wait a few weeks. The difference is Sure Genomics promises full DNA analysis from more than 70,000 biomarkers and will update and add upon information every six weeks as new information becomes available."

Sure did not mention that 23andMe tangled with the FDA back in 2013, when the agency ordered it to stop marketing its direct-to-consumer genome test with interpretative data because it did not have the necessary approval to do so. Direct-to-consumer tests usually require FDA approval. The FDA raised a similar issue with Sure Genomics in its correspondence.

"The SureDNA test appears to meet the definition of a device as that term is defined in section 201 (h) of the Federal Food Drug and Cosmetic Act," the letter said. "We have conducted a review of our files, and have been unable to identify any FDA clearance number for the Sure DNA test." The agency asked Sure Genomics to provide a specific number.

The Nevada-based Solopap is selling through its website a $50 home test for pap smears and the presence of the human papilloma virus. Solopap charges an additional $90 to process the assay and issue test results to the consumer.

The FDA contacted Solopap the day after Sure Genomics. Its letter suggests there may be more leeway in the Solopap assay, which appears to be a more traditional assay as opposed to a molecular test. It may be either processed by its lab or by the buyer's own physician, according to information on the Solopap website. The agency asked Solopap to provide a rationale if it does not believe the tests require FDA approval, and to furnish "a sample laboratory report which provides the test results to the medical practitioners."

The issue over smaller startup labs such as Sure and Solopap comes as the FDA appears poised to issue final regulations regarding the oversight of laboratory developed tests later this year. Its proposal has created fierce opposition in the laboratory sector, with most recently, the American Association of Clinical Chemistry issuing a position paper in support of maintaining the current CLIA regulations for laboratory developed tests.

Takeaway: The FDA has cracked down on two startup labs and their marketing practices prior to its issuance of final guidelines for the regulation of laboratory-developed tests. G2

ACLA Seeks Better Medicare Coverage for Vitamin D Testing

The American Clinical Laboratory Association (ACLA) has asked regional fiscal intermediary Novitas—and by extension, much of the Medicare program—to reconsider its austere position on testing for some vitamin deficiencies. In particular, the ACLA has asked Novitas to reconsider its position regarding testing for vitamin D.

"Vitamin D deficiency is an important contributor to the development of osteoporosis; specific patient populations with specific diagnoses are at substantially increased risk for complications related to Vitamin D deficiency," said the comment letter the ACLA sent to the Pittsburgh-based Novitas and authored by ACLA Senior Vice President JoAnne Glisson.

According to data from the National Osteoporosis Foundation, as many as 54 million Americans over the age of 50 either suffer from osteoporosis or relatively low levels of bone mass that put them at risk for developing the disease later in life.

Currently, Medicare does not reimburse for many forms of vitamin or micronutrient testing, considering such tests to be medically unnecessary. It makes a few exceptions for patients with specific diseases or medical conditions, but they are generally narrow.

The draft local coverage determination released by Novitas mostly reiterates that position: "Vitamin or micronutrient testing may not be used for routine screening. Once a beneficiary has been shown to be vitamin deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished. Thereafter, annual testing may be appropriate depending upon the indication and other mitigating factors."

However, the aging U.S. population has seen an uptick in the cases of osteoporosis, a weakening of bone density that can lead to serious fractures often requiring hip replacements and other expensive orthopedic surgical procedures. Cases of osteopenia—a precursor to osteoporosis—have also risen in recent years. According to data from the National Osteoporosis Foundation, as many as 54 million Americans over the age of 50 either suffer from osteoporosis or relatively low levels of bone mass that put them at risk for developing the disease later in life. That's about 60 percent of that particular age demographic in the U.S.

The ACLA noted that vitamin D deficiency can be linked to individuals undergoing bariatric surgery to address severe obesity. Such procedures rose nearly 15 percent between 2011 and 2013, with 179,000 such procedures performed in the latter year, according to statistics from the American Society for Metabolic and Bariatric Surgery.

Vitamin D deficiencies have also been linked to patients suffering chronic renal disease, as well as those taking steroids and cholesterol-lowering medications over the long-term.

Although the draft LCD currently provides testing coverage for Medicare enrollees diagnosed with rickets, osteomalacia, osteoporosis, chronic kidney disease and some digestive disorders such as irritable bowel syndrome and Crohn's disease, the ACLA wants coverage to include other patients as well.

The organization is asking for coverage of patients who have been diagnosed with cystic fibrosis, undergone bariatric surgery or suffered from radiation enteritis—an inflammation of the digestive system due to radiation treatments for cancer. It is also asking for coverage for patients diagnosed with several forms of lymphoma and histoplasmosis.

ACLA is also requesting some clarity regarding coverage for patients who are taking certain drugs. "We note ... that many times clinicians will report the condition for which those drugs are used rather than the chronic drug use codes," Glisson wrote. "For some of these medications (e.g., HIV therapy, anticonvulsants) there would be a very clear map to the condition for which those drugs are prescribed. We would recommend, therefore, incorporating those conditions into the LCD."

Although vitamin testing is a relatively low-cost assay, if it's adopted as part of routine preventive care, tens of millions of such procedures could be performed in the U.S. and eventually be extensively covered by the Medicare program and Medicare Advantage payers

Takeaway: The ACLA and other laboratory lobbies are pushing to try to get a longstanding Medicare coverage ban on vitamin testing to be lifted. G2

HHS Task Force Announcement and $3.9 HIPAA Settlement Focus Attention on IT Security

A $3.9 million settlement arising from a potential HIPAA breach and an announcement regarding a U.S. Department of Health and Human Services Task Force emphasize the risks to the privacy and security of patients' health information.

Feinstein Institute for Medical Research, a biomedical research institute based in New York, agreed to the settlement which includes a corrective action plan after a laptop was stolen from an employee's car, according to an HHS Office for Civil Rights (OCR) March 17 press release. "This case demonstrates OCR's commitment to promoting the privacy and security protections so critical to build and maintain trust in health research," HHS said. The settlement is the result of an investigation following the organization's filing of a breach report concerning the 2012 theft of the laptop, which reportedly held about 13,000 patients' and research participants' health information. OCR asserted the organization failed to have adequate policies and procedures and safeguards with regard to laptops.

Just a day earlier, HHS had also announced membership of the Health Care Industry Cybersecurity Task Force which includes government and private sector leaders. The Task Force will seek "the best ways organizations of all types are keeping data and connected medical devices safe and secure" and report to Congress within the next year before the Task Force's term ends in March 2017. The Task Force arises out of the Cybersecurity Information Sharing Act of 2015 and will also develop materials to help organizations ensure security of health information. G2

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

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