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. 17, September 29, 2016

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Upcoming Events

Lab Institute 2016
Oct. 26-28, Hyatt Regency
Washington on Capitol Hill
www.labinstitute.com

Webinar:
Lab and Pathology Coding and Billing Update for 2017
Diana W. Voorhees, M.A., CLS, MT, SH, CLCP
Nov. 9, 2016, 2–3:30pm EST

FDA Recommendation Against Ovarian Cancer Screening

The U.S. Food and Drug Administration (FDA) recommends against using currently available tests to screen for ovarian cancer, according to a safety communication the agency issued at the beginning of September. The FDA says there are risks associated with currently marketed, but not approved, ovarian cancer screening tests and the agency is especially concerned about inaccurate results that may delay effective, preventive treatments for asymptomatic women at increased risk for developing ovarian cancer.

Despite the fact that ovarian cancer is the fifth-leading cause of cancer-related deaths among women, there is no approved or recommended screening test for the disease. Yet, cancer antigen (CA) 125 tests are extensively used.

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Providers Slower than Public to Welcome Personalized Medicine

Levels of public support for personalized medicine (PM) are seemingly outpacing organizational plans to implement PM-based clinical strategies, based on the results of two recently released surveys.

Public support for personalized medicine research is high and the majority would be willing to participate in federal research, if asked, according to a study published Aug. 17 in *PLoS ONE*. The survey was conducted as part of an early effort to understand the preferences of potential participants of the White House's Precision Medicine Initiative (PMI). The survey results were incorporated into recommendations for the design of the study.

The PMI Cohort Program aims to enroll 1 million U.S. participants willing to share long-term, prospective data about their health and lifestyle, including genetic information, to build a national resource for researchers. To be useful, data must be collected from a broad base of participants. The National Institutes of Health (NIH) anticipates launching initial phases of the cohort later this year. The survey was conducted to measure support for PMI, to measure acceptability of design features, and to identify public concerns. Incorporating these findings into the study's design, and other participant engagement efforts, are intended to help build an inclusive and trusting cohort.

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FDA Recommendation Against Ovarian Cancer Screening, *from page 1*

"From what we know anecdotally, in spite of the fact that CA 125 isn't really meant to be used that way, many women who are concerned about the risk of ovarian cancer are getting the test every year," Sarah DeFeo, vice president of scientific affairs for the Ovarian Cancer Research Fund Alliance, told STAT News. "In practice, lots of people are doing it."

Current recommendations against screening for ovarian cancer are based on the large U.S. Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, which found that annual CA 125 measurement (using a fixed cutoff value for a positive test result) and vaginal ultrasound were not associated with a reduction in ovarian cancer mortality. Additionally, screening was tied to significant harms from surgeries resulting from false-positive results.

However, the United Kingdom Collaborative Trial of Ovarian Cancer Screening, published in *The Lancet* in December 2015, similarly used multimodal screening—CA 125 and ultrasound—but relied on a risk of ovarian cancer algorithm (ROCA) instead of a fixed cutoff. Use of the algorithm did increase sensitivity and led to fewer unnecessary surgeries and a positive trend towards earlier diagnosis, but led to questionable improvements in mortality—only seen after seven to 10 years of screening. While the authors concluded by saying further follow-up was necessary "before firm conclusions can be reached on the efficacy and cost-effectiveness of ovarian cancer screening," the algorithm at the center of the protocol began to be commercially marketed, in the United Kingdom and in the United States (for $295).

Abcodia (United Kingdom), the company marketing the ROCA test, announced in mid- September that it was temporarily suspending its test in the United States while the company continues to engage with the FDA and the clinical community for further evaluation of the ROCA test.

Takeaway: FDA warns against using existing tests to screen general populations for ovarian cancer citing lack of reliability for tests results could lead to delayed preventive treatment for at risk women. G2

PAMA Update: CMS Guidance and Reporting Information Trickles In

The Centers for Medicare & Medicaid Services (CMS) promised more details would be coming once it released the final rule implementing the Protecting Access to Medicare Act of 2014 (PAMA) this past June. To date, it has issued some of those details and labs should be in the thick of preparations to comply with the reporting requirements. In fact, in the first subregulatory guidance issued this summer, CMS advised labs should be using this six-month period between the data collection period which has ended (Jan. 1 to June 30, 2016) and next year's data reporting period (Jan. 1 to March 31, 2017) to determine if the lab is an applicable lab and to "review and validate applicable information before it is reported to CMS."

CMS has released the following additional information since the June final rule:

- The list of HCPCS codes to be used in reporting. That list was accompanied by a short explanatory key to the Medicare Status Indicators that apply to the codes.
- Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for

Collecting and Reporting Data for the Private Payor Rate-Based Payment System.

- Fee-for-Service Data Collection System: Clinical Laboratory Fee Schedule Data Reporting Template.

CMS's guidance on collecting and reporting data described four steps to determining applicable laboratory status. CMS advises labs ask the following four questions to determine if they are an applicable lab:

1. Does the lab have a CLIA certificate?
2. Does the lab have its own National Provider Identifier under which it bills Medicare?
3. Does the lab get more than 50 percent of its total Medicare revenue under the CLFS and the Physician Fee Schedule (PFS)? CMS offers this equation: CLFS revenue + PFS revenue/total Medicare Revenues > 50 percent
4. Does the lab get at least $12,500 in CLFS Medicare revenue (NOT including PFS revenue) during the six month data collection period?

The July guidance also provides seven examples of scenarios involving labs to show how the calculations work in hypothetical situations.

The information collected and reported for Clinical Diagnostic Laboratory Tests (CDLTs) is defined in the final rule to include private payor rates "for which final payment has been made" during the collection period plus the number of tests performed at that rate and the HCPCS code for the test. CMS' guidance document clearly lays out for labs in the July guidance what does and doesn't qualify as reportable:

Here's what does need to be reported:

- Tests paid under the CLFS
- Secondary insurance payments
- Non-contracted or out of network payments for lab services
- Patient cost sharing amounts are included in determining the final payment amount
- Final payments determined as a result of an appeal and paid within the data collection period

The following don't get reported:

- Private payor payments for test codes payable only under the PFS
- Payment rates adjusted by waivers of patient' deductibles, copays or coinsurance
- Denied payments (what CMS calls "zero payments")
- Any claims still under review or under appeal during that data collection period (even appeals concluded in the data collection period aren't reported if the payment isn't made within the data collection period)
- Capitated payments
- Payments made when the volume of tests associated with that payment can't be determined
- Bundled payments –where HCPCS codes are bundled into single encounter that isn't characterized by a single HCPCS code

Finally, this month CMS provided a template for reporting the data. The template doesn't provide new information, simply addressing the four elements that must be reported: HCPCS Code, payment rate, volume of tests, and the lab's NPI. It does provide a User Guide however, addressing how to navigate the template. CMS

Editor's Note: For the latest insight on PAMA, attend G2 Intelligence's 34th Annual Lab Institute, Oct. 26-28 in Washington D.C. A Thursday general session featuring Alan Mertz, President of the American Clinical Laboratory Association, Tim Kuruvilla, Co-Founder and Chief Commercial Officer of Viewics, Inc., and Rina Wolf, Vice President, Commercialization Strategies, Consulting and Industry Affairs, at XIFIN, Inc. will discuss the latest updates on PAMA implementation and how labs will play a role in supporting MACRA's implementation. Can't attend Lab Institute? A G2 Intelligence webinar, hosted June 28, 2016 in partnership with the American Clinical Laboratory Association, provides analysis of and tips for complying with the new final rule. To purchase a recording of the webinar, The PAMA Final Rule: What You Need to Know and Do NOW to Comply with the New Payment Rules and Protect Your Lab Revenue, visit our website or contact customer service at 1-888-729-2315. Three states earned As - Colorado, Maine, and New Hampshire.

notes that the data collection system is undergoing testing and won't be accessible to labs until November 2016.

All these documents and future guidance can be found on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html

Takeaway: As PAMA's reporting deadlines draw closer, CMS has shared HCPCS Codes and reporting templates to help labs begin preparing.

New Massachusetts Law Affects Recruiting and Hiring Practices

Massachusetts recently signed into law An Act to Establish Pay Equity, S.2119, which takes effect on July 1, 2018. The new law prevents wage discrimination based on gender. The law includes several noteworthy changes related to the employment process, but perhaps the most significant is that it prohibits employers from requiring applicants to provide their salary history before receiving a formal job offer.

The intention is to close the salary gap. Women have historically been paid less than men, and once a salary gap is established, typically early in a woman's career, it's difficult to close that gap.

Although the law only applies to Massachusetts employers and employees, it is expected to have far-reaching implications. As with other changes related to hiring, large companies will likely amend their policies to ensure they do not inadvertently violate the law. In addition, given the national attention this law has garnered, these companies will want to be viewed as non-discriminatory—or better yet, pro-equality.

Because large companies will adopt new policies and procedures, job candidates will expect small and midsize employers to follow suit. Like other human resource trends, the changes as a result of this law, and other state and federal legislation that may follow, will eventually impact your lab or pathology practice. It is therefore prudent to familiarize yourself with what is happening in Massachusetts, and even get ahead of the curve and make necessary adjustments to your hiring processes.

Here are some highlights of the provisions in the new Massachusetts Law:

- "Comparable work" is defined to mean work that is "substantially similar," performed under similar conditions and "requires substantially similar skill, effort and responsibility."
- Employers can't discriminate based on gender when paying wages for comparable work unless the difference in wages is based on certain facts such as seniority, level of training or a bona fide merit system.

- Employers can't a) ban employees from talking about their salaries, b) screen job applicants based on salary history, such as by asking applicant to reveal salary history, c) ask prior or current employers for salary history of applicants until a formal job offer is made and the prospective employee consents.
- Employers who violate the law can be liable for unpaid wages, liquidated damages and attorney's fees.
- Employers get credit for evaluating their own practices and showing successful efforts to get rid of any gender based differences in pay for comparable work.
- Employers must post notice of this law at their workplace.

Takeaway: Labs and pathology practices need to consider how laws such as Massachusetts' pay equity law affect what job applicants are asked during the interviewing process.

Providers Slower than Public to Welcome Personalized Medicine, *Continued from bottom of p.1*

Survey participants answered a 44-question online survey (May to June 2015) to assess how different consent models affect participants' willingness to participate and share data. More than 2,600 participants, representative of the U.S. population, were randomized to one of eight different consent scenarios. The scenarios varied by the structure of consent (broad, study by study, menu, or dynamic consent) and the presence or absence of access to a website where participants would be able to see what studies are going on, which studies are using their information, and what each study has learned.

Overall, 79 percent of the respondents expressed support for PMI, and 54 percent said they would definitely or probably participate if asked versus 46 percent that stated they would definitely or probably not participate, if asked. These findings were fairly constant across racial and ethnic groups. Only those with less than a high school education showed lower support for PMI (less than 70 percent).

"Maximizing information shared with research participants will be a key challenge of the PMI."

— David Kaufman

Broad consent received less support when modeled alone, but showed similar support if broad consent was coupled with availability of a website that displays how samples and data are being used. People were most likely to report willingness to share personal data with researchers at the NIH (79 percent) and U.S. academic researchers (71 percent). Respondents were more reluctant to share data with pharmaceutical company researchers (52 percent) or university researchers in other countries (39 percent).

Respondents expressed high willingness to share multiple types of personal data, including: blood samples (73 percent); genetic information (76 percent); family medical history (77 percent); soil and water samples from their home (83 percent); and data on their lifestyle, diet, and exercise (84 percent). By contrast, only 43 percent of those with social media accounts said they would share social media information. People who said they supported the study, but would not participate were more likely to be concerned about privacy and the amount of time the study would take.

The greatest incentive for participation was information about their health (90 percent). Specifically, they wanted lab results, such as cholesterol and blood sugar levels (75 percent), genetic information (75 percent), and a copy of their medical records (68 percent).

"Maximizing information shared with research participants will be a key challenge of the PMI," write the researchers, led by David Kaufman, from the National Human Genome Research Institute. "The return of information may also benefit research, encouraging participants to stay engaged and enrolled, and to take part in other research studies based on their results."

Despite public opinion supporting PM research, the majority of health care organizations say they are not ready to invest in PM, yet, and current adoption is "limited," according to a new survey from HIMSS Analytics, released Aug. 30.

Representatives from 137 hospitals were surveyed online. Respondents represented multi-hospital systems (36 percent), stand-alone hospitals (29 percent), academic medical centers (13 percent), and integrated delivery networks (10 percent). More than 60 percent of respondents were from hospitals with 250 or more beds and approximately 30 percent represented hospitals with more than 500 beds.

Less than one-third of respondents (29 percent) indicated their organizations conduct PM. PM programs are in place at larger, research-based organizations such as academic medical centers (35 percent), multi-hospital health systems (25 percent), and organization's with over 500 beds (41 percent). Of those using PM, 80 percent do so for cancer, followed by 38 percent for neurology, 31 percent prenatal screening, and 28 percent cardiology. HIMSS Analytics noted that the federal Precision Medicine Initiative and its associated funding is among the reasons that the focus has been on cancer.

More than 60 percent of respondents indicate the largest challenge to precision medicine is the integration of clinical data systems and clinical and genomic data. They are being held back by limitations in funding, technology, and expertise.

As an alternative, 26 percent of respondents said they performed precision medicine through the use of third party laboratories, while a third used a combination of in-house and third-party services.

Takeaway: Public support for PM may be outpacing actual implementation in the clinical setting, although public willingness to participate in PM research may accelerate future adoption.

Lab Settlements Resolve False Claims Cases

Several recent settlements demonstrate vigorous continuing government enforcement of the False Claims Act against providers. The following cases highlight three top compliance issues of current concern to laboratories: the 60-day deadline to repay overpayments, medical necessity, and appropriateness of drug testing.

Continuum Settles Reverse False Claims

Case: Facing the uncertainty of trial, Continuum has officially settled reverse false claims allegations for $2.95 million. The government had claimed the company failed to comply with the 60-day deadline to repay Medicaid overpayments. In September 2015, a New York federal court denied Continuum's request to toss out the case without a trial. A software glitch had caused Continuum to submit roughly 450 erroneous claims to Medicaid between 2009 and 2010 resulting in $800,000 worth of overpayments. Continuum paid the money back but not within 60 days of first learning of the potential overpayment and not in one lump sum but rather via 30 installments made over the course of two years. The government had claimed that delay was deliberate and brought the "reverse false claims act" action against Continuum.

Significance: Continuum is a landmark case because it was the first federal enforcement action against a provider for failing to meet the *Affordable Care Act* requirement that overpayments be repaid in full within 60 days of identifying the overpayment. And the case was launched before the CMS issued guidance to help providers comply. Although it came too late for Continuum, the CMS finally laid down some guidelines in February 2016. *Bottom Line:* According to the Final Rule, providers must exercise what CMS calls "reasonable diligence" in identifying, calculating and repaying overpayments.

Editor's Note: For a list of six specific things you should do to meet reasonable diligence criteria, see "Avoid False Claims Liability: CMS Clarifies How to Comply with 60-Day Deadline for Returning Overpayments," G2 Compliance Advisor, April 2016, pp 5-8.)

[*U.S. v. Continuum Health Partners, Inc.*, 11 Civ. 2325 (ER), USDC (S.D.N.Y.), August 23, 2016].

Questions on Medical Necessity of Drug Testing Lead to $7.4 Million Settlement

Case: Quantitative drug tests that count illicit drug particles in urine are rarer and more expensive than qualitative tests that simply detect the drug's presence. So when data analytics showed that a Florida pain clinic was a statistical outlier for Medicare billing of quantitative tests, federal investigators swooped in. The DOJ filed False Claims Act charges, claiming the clinic did quantitative tests on elderly patients routinely, regardless of medical necessity, even when patients' qualitative tests came back negative. Rather than slug it out in court, the clinic settled the case for $7.4 million [*Physicians Group Services, P.A., dba Coastal Spine and Pain*, USAO, M.D. Fla., Aug. 31, 2016].

Significance: Coastal is the latest in a series of enforcement actions for false billing of medically unnecessary urine drug screening tests:

- On Aug. 18, two former lab professionals convicted at trial of such charges were sentenced to 36 months in prison and ordered to pay $1.437 million in restitution; and
- Similar charges were among the allegations of a pair of whistleblowers settled by PremierTox 2.0, Inc. for $2.5 million in April.

[See, Drug Testing Gives Rise to Convictions and Costly Settlement in Recent Enforcement Cases, *NIR*, April 18, 2016]

Settlement Resolves Claims of Medically Unnecessary FISH Testing

Case: A Florida urologist agreed to pay $250,000 to settle claims of falsely billing Medicare and Tricare for medically unnecessary *fluorescence in situ hybridization*, aka, FISH tests, which are performed on urine to detect genetic abnormalities tied to bladder cancer. The case, which began as a former medical assistant's whistleblower suit, also alleged that the urologist received bonuses based on the number of FISH tests he ordered [*Robert A. Scappa*, USAO, M.D. Fla., Aug. 17, 2016].

Significance: FISH tests conducted by a urologist are deemed medically reasonable and necessary for Medicare coverage purposes in only two limited situations:

- To monitor for tumor recurrence in patients previously diagnosed with bladder cancer; or
- Where after a full workup of a patient with hematuria, i.e., blood in the urine, the urologist has reason to suspect bladder cancer.

Takeaway: Medical necessity and drug testing continue to be hot enforcement topics for laboratories and the 60-day rule regarding repayment of overpayment yields major settlement.

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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