Put It on the Board, 5/14

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FDA clears FilmArray GI Panel

BioMérieux affiliate BioFire received Food and Drug Administration 510(k) clearance for the FilmArray Gastrointestinal Panel. The 22-target panel allows a syndromic approach to the diagnosis of infectious diarrhea, the company says, as it includes bacteria, viruses, and parasites in one test. It is the most comprehensive gastrointestinal test to be cleared by the FDA and contains several pathogens cleared for the first time.

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Major disruption ahead for labs, says industry analyst

A shrinking pool of cash to pay for medical care, the decline of private practice medicine, and recently enacted federal legislation will combine to put the squeeze on medical laboratories. That was the stark and sobering message delivered to the hundreds of administrators, pathologists, and other lab professionals who gathered in New Orleans in late April and early May for the Executive War College.

The bearer of the bad news was Robert L. Michel, editor-in-chief of *The Dark Report*, which hosts the annual meeting. Michel said the biggest threat facing labs is implementation of the Protecting Access to Medicare Act of 2014. The legislation, signed into law April 1, contains a one-year delay in big Medicare physician pay cuts due to the sustainable growth rate formula. But it also includes major changes to the Medicare clinical laboratory fee schedule that will pose a huge challenge to labs, Michel said.

“The April 1 bill signed into law by president Obama is probably the single biggest change to happen to the clinical lab industry since CLIA ‘88,” Michel told the audience. Sections of the law have the potential to trigger “the most radical disruption” to the clinical lab testing marketplace in four decades, for an important reason, he said. “As of 2017, every one of you is going to face a different price structure as part of the clinical lab fee schedule. And starting in 2016, you will have to deliver reams and reams of paper to the government about every lab test you do.”

The law gives the Centers for Medicare and Medicaid Services expanded authority to set lab test prices based on market data. Starting Jan. 1, 2016, labs will have to report how many times they performed each test and what they were paid for those tests by each health plan, Medicare Advantage plan, and Medicaid managed care organization. Payments under capitated arrangements, however, would be exempt. Labs failing to provide the information could be fined as much as $10,000 a day.

The CMS will then use the median market-payment rates to set new Medicare pay rates starting in 2017. Potential cuts in test pay rates would be limited to 10 percent each year from 2017 to 2019, and could be slashed by another 15 percent each year from 2020 to 2022.

Labs big and small stand to be punished under the law, Michel said. He noted that just six tests—comprehensive metabolic panel, lipid panel, vitamin D, glycosylated hemoglobin, thyroid stimulating hormone, and CBC with automated differential white blood cell count—accounted for more than a third of Medicare payments to labs in 2012, totaling $1.73 billion. Just 20 tests accounted for nearly half of Medicare lab test volume and 56 percent of lab payments of $2.72 billion, Michel added.

If the Protecting Access to Medicare Act is not repealed or substantially altered, national labs might approach managed care plans to try to convert their highly discounted fee-for-service contracts for high-volume clinical lab tests to capitation as a way to avoid having to report their pay rates to Medicare. Smaller labs already feeling the financial pinch could go under as a result of further pay cuts, Michel said. It is possible, he added, that national labs would then be free to cherry-pick the failed labs' best clients even as they refuse to serve the nursing homes that were clients of the failed clinical labs.

The CAP opposed the legislation, also known as HR 4302, because it did not permanently repeal the SGR, left open the self-referral loophole, and did not address pathologists' concerns about participation in the Medicare pay-for-performance program. The law "would drastically alter the payment system for clinical laboratories," CAP president Gene N. Herbek, MD, said in a March 27 statement.

HR 4302 is not the only thing that will put the squeeze on labs, Michel said in his talk. The federal budget and state budgets are likewise running short on cash, meaning the pressure will intensify for legislators and government health officials to look for other places to cut costs.

"When it comes to health care, there is no additional money available to increase funding for Medicare and Medicaid programs," Michel said.

Meanwhile, the massive shift toward physician employment will make it harder for labs to win new clients as the buyers are mostly hospitals and managed care companies. In 2000, Michel noted, 57 percent of physicians practiced independently. By 2013, that share had dwindled to 33 percent.

Yet another trend that will challenge labs is the move away from fee-for-service, Michel said. Many Executive War College sessions focused on how labs can adjust to the landscape of what is called value-based care.

"We're entering a world of budgeted care," Michel said.

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FDA clears Omnyx Manual Read of Digital HER2

The Food and Drug Administration in April cleared the Manual Read of the Digital HER2 Application made by Omnyx, a joint venture of GE Healthcare and UPMC, the Pittsburgh-based health system and insurer. The device is based on the Omnyx Integrated Digital Pathology System.

"Pathologists will see this as validation that they can make similar decisions when using this system versus glass. … This is a stepping stone toward more and more adoption," says Jonhan Ho, MD, director of dermatopathology at UPMC. Dr. Ho sits on the Omnyx board of advisors and has a personal consulting agreement with the company.

"The real reason I'm interested in this technology is to improve the way I work," he says. "I read 500 or so slides a day. Basically, I have to be in a specific room fairly close to the lab if I want to read my cases. But I have meetings all over the city and all over the country, and it's very difficult for me to take care of my patients when I'm not near the microscope. This technology basically breaks the physical connection between me and my microscope."

In one example of the tool's potentially broad application, the Omnyx device lets pathologists use microscopy images displayed on a computer monitor to detect and semiquantitatively measure HER2/neu in formalin-fixed, paraffin-embedded normal and neoplastic tissue that has been immunohistochemically stained for HER2 receptors with the Dako HercepTest. The Omnyx results can be used to help manage and predict therapy outcomes in breast

cancer, but the device cannot be marketed for use as a general diagnostic tool.

Omnyx's is not the first such device to win the FDA's approval. The agency also gave the nod to similar tools from Aperio Technologies, Ventana Medical Systems, and Royal Philips.

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Direct Strep goes to market

Quidel received FDA clearance, via the de novo request process, to market its Lyra Direct Strep assay, a multiplex real-time PCR assay. It detects and differentiates between pyogenic group A and pyogenic C or G streptococcal throat infections.

The Lyra Direct Strep assay kit includes an extraction-free, three-step sample preparation process that does not require automated extraction. The direct-to-amplification procedure allows the assay to generate a result in just over an hour.

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From IDL, prostate blood test now available

Beckman Coulter Diagnostics has made its Prostate Health Index available to physicians nationwide through Innovative Diagnostics Laboratory.

Results of a multicenter clinical study found a 31 percent reduction in unnecessary biopsies due to false-positives as a result of using what the company calls the "phi" test.

"The phi test helps physicians distinguish prostate cancer from benign conditions by utilizing three different PSA markers—PSA, free PSA, and p2PSA—as part of a sophisticated algorithm to more reliably determine the probability of cancer in patients with elevated PSA levels," Kevin Slawin, MD, who performed some of the key research that led to the development of the phi test and who began using the test in February, said in a statement. He is director of the Vanguard Urologic Institute at Memorial Hermann Medical Group, clinical professor of urology at Baylor College of Medicine, and director of urology at Memorial Hermann Hospital-Texas Medical Center.

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What report says about PQRS and pathologists in 2012

Sixty-nine percent of eligible pathologists participated in the Physician Quality Reporting System in 2012, according to a Centers for Medicare and Medicaid Services report released April 3 on the 2012 PQRS reporting year.

Pathology's participation rate was higher in 2012 than for the other participating specialties. Emergency medicine was a close second, at 68 percent. Three new quality measures developed by the CAP for pathologists were in place in 2012.

Pathology's 69 percent participation rate compares favorably to the total eligible professional participation rate of 36 percent.

Also in the CMS report:

- 6,192 pathologists out of 7,050 who participated successfully in the PQRS reported on 50 percent of their relevant claims. The success rate of 87.8

percent for pathologists was an improvement over previous years' success rates for participating pathologists and similar to the overall 2012 success rate for eligible professionals of 85.6 percent.

- The average bonus for pathologists who participated successfully was $398 (range $0.06–$26,505). The average bonus for all physicians who participated was $548 ($457 for all eligible professionals).