G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 36th Year of Publication

Vol. 15, Iss. 5, March 9, 2015

INSIDE *NIR*

Health Care Stakeholders Advise FTC/DOJ on Payer Networks, ACOs, and Anti-Trust Concerns

As we reported in our last issue, the Federal Trade Commission (FTC) is concerned about the effects of health care reform on competition. The FTC and Department of Justice (DOJ) held a joint workshop to gain insight from industry experts including economists, lawyers, academics, payer representatives and others about how the market is responding to the integration efforts aimed at improving quality while reducing costs and shifting from fee-for-service to value-based reimbursement. Antitrust lawyer, Dionne Lomax of Mintz Levin, a panelist at the workshop, described the overall tone of the two-day event as one of "learning and gathering of information. The agencies are trying to gather information from the industry participants to inform their thinking. The agencies are obviously going to enforce antitrust law and they understand providers under some circumstances can save costs and recognize potential benefits" from various integration and consolidation strategies, Lomax explains, "but they also recognize there can be harms under certain circumstances."

Continued on page 2

FDA Seeks Stakeholder Feedback on Evaluating Next-Generation Sequencing Tests

Following the U.S. Food and Drug Administration's (FDA) workshop addressing proposed regulation of laboratory developed tests (LDTs) in January (see NIR, Jan. 26, 2015, p. 1), the FDA recently turned to the similar topic of evaluating next-generation sequencing (NGS). Recognizing both the expanding clinical applications of NGS tests and the challenges of overseeing such testing, the FDA held a day-long workshop in February, seeking advice from the industry on how best to regulate NGS. An FDA discussion paper released in anticipation of the workshop explains that oversight of NGS testing can be difficult given the ability to sequence the whole genome and identify a potentially unlimited number of variants. The FDA acknowledges it is impractical to require analytical and clinical performance be demonstrated for every possible variant.

Continued on page 6

■ Payer Networks, ACOs, and Anti-Trust Concerns, *from page 1*

Why the Health Care Industry Raises Antitrust Concerns

Introductory remarks both days of the workshop and presentations from panelists all highlighted the importance of the health care industry and the need for change. Federal Trade Commission Chairwoman Edith Ramirez opened the workshop noting the industry is "one of the most important segments of the U.S. economy" at 17% of the GDP. Many panelists highlighted the high costs associated with health care and the Affordable Care Act's efforts to reform the system and reduce those costs. Certain providers and some commentators think that aggressive antitrust enforcement is counterproductive to what the ACA is meant to achieve, says Lomax. Panelists and agency representatives dispelled this concern throughout the workshop. Ramirez said that the goals of antitrust law are consistent with goals of health care reform.

"While Medicare ACOs still lead the way in the number of ACO contracts, commercial ACOs cover more lives. As of mid- 2014, 60.5 percent of lives served by ACOs were covered under commercial contracts."

— G2 Intelligence, Laboratory Services in Accountable Care Organizations Report

Recognizing the complexity of the issues that are at stake, Ramirez stated: "To say that the health care industry has been changing significantly and rapidly would be a vast understatement." Noting that industry participants are reacting to a new business and regulatory environment, she expressed concern that "their awareness of antitrust law is often in the background."

Thus, she expressed the importance for the FTC and DOJ to understand what is going on in the marketplace and "anticipate" the potential anti-competitive effects of the industry's efforts to adapt to a new environment. Assistant Attorney General William J. Baer from the DOJ's Antitrust Division, echoed her concerns while opening the second day of the conference, explaining that to effectively enforce antitrust law, the agencies need to understand the marketplace and learn about the challenges the industry is facing.

The Importance of Affordable Care Organizations

A major focus of the discussions was the formation of affordable care organizations (ACOs), with an entire panel devoted to discussion of ACOs. Representatives from the Centers for Medicare and Medicaid, private payers and other experts discussed current ACO models, the goals of encouraging more ACO participation and how the CMS is helping entities form ACOs and implement risk-based models.

In her opening remarks, Ramirez called the ACO model a "central component of ongoing health care reform efforts." Indeed, *G2 Intelligence*'s report *Laboratory Services in Accountable Care Organizations* indicates that adoption of the ACO model is rapidly growing: "While Medicare ACOs still lead the way in the number of ACO contracts, commercial ACOs cover more lives. As of mid- 2014, 60.5 percent of lives served by ACOs were covered under commercial contracts. "

Panelists throughout the conference expressed a need for more data and that it is too early to tell what benefits ACOs are achieving and what changes in the marketplace can be directly linked to ACOs. G2's report indicates "[e]arly results from Medicare ACO programs were mixed" but that industry experts interviewed for the report "share a positive outlook for ACOs, encouraged particularly by the fact that almost half of the ACOs generated savings."

Lomax indicates that the impact of an ACO on competition is "situational" and really depends on the market in which it operates, the market share held by the participants, and how concentrated the market is. She noted the DOJ/FTC joint guidelines for ACOs released in 2011 "provide guidance regarding the market shares the agencies will find acceptable" to avoid anti-competitive effects but cautioned that failure to meet the parameters of the safety zone enumerated in the 2011 guidelines doesn't necessarily mean the entity is anti-competitive.

"[T]here's always been a sense that providers don't want to give up too much of their autonomy" and we are likely "to see more clinical integration and arrangements short of mergers and consolidations."

— Dionne Lomax, Mintz Levin.

Payer Networks

A panel devoted to the health care exchanges and their potential impact discussed forming payer networks in tiers and what factors make it easier for customers to compare health care insurance. On this subject, as with ACOs, there was some agreement that it is too early to tell the true effect of new network models for payers and the impact of the ACA-spurred health care insurance exchanges.

The potential value of tiered and narrow networks was discussed throughout the workshop. One panelist predicted narrow networks are inevitable if true integration is achieved. Participants noted the need for providers to compete on price and quality and some panelists promoted narrow networks as drivers of such competition.

Lessons for the Agencies

Lomax indicates the agencies learned from the workshop that there is still a lot of movement in the industry toward consolidation but noted that many panelists highlighted the lack of sufficient metrics or information about the efficiencies and cost savings resulting from these consolidations. "Obviously somebody is getting it right – it just takes time to get that type of metrics and information" to explain how and why, she adds. Lomax indicates that "there's always been a sense that providers don't want to give up too much of their autonomy" and we are likely "to see more clinical integration and arrangements short of mergers and consolidations."

While public comments are being accepted until April 30 it is unclear what will happen after that. Lomax notes that while the agencies indicated the workshop may result in further study, reports, or new guidelines, she doesn't see immediate revisions to existing guidance as likely.

In their summations, the participants of the final panel offered a mixture of caution and encouragement to the agencies. Noting the need to protect the market from anti-competitive behavior and to carefully watch behavior in the marketplace, several panelists cautioned against overly aggressive enforcement of antitrust law and promoted keeping an open mind to how this changing environment affects competition.

Panelists noted the recent St. Luke's case in which a court found a hospital acquisition of a medical group violated antitrust law and discussed the court decision's impact on the likelihood of efficiencies being a viable defense to antitrust allegations. Lomax in particular predicted "very stringent efficiency defense standards will apply in the wake of" the St. Luke's decision. She expressed concern that it's unclear what the FTC and the courts would find persuasive in terms of quality

and efficiencies in an antitrust analysis and that "certain providers may have reduced incentive to pursue certain transactions if they see antitrust as an insurmountable barrier." Lomax's summation encouraged the agencies to be "measured" in their enforcement efforts and indicated a concern that agencies not "chill innovation" but rather support good faith efforts by providers to enter into risk-based contracting and partner with others to help control costs.

Sources

G2 Intelligence, *Laboratory Services in Accountable Care Organizations* (2014).

Federal Trade Commission/Department of Justice, Examining Health Care Competition Workshop, Feb. 24-25, 2015; slide presentations, transcripts and video of the workshop are available on the FTC website under News & Events, Events Calendar.

Takeaway: Industry experts advise FTC and DOJ to temper antitrust enforcement with a recognition of the unique challenges facing providers due to current health care reforms. G2

Cybersecurity Gets Presidential Attention

Information security isn't just about HIPAA. As the Sony movie studio hacking and the recent Anthem data breach demonstrate, any industry or organization can be affected by deliberate hacking as well as inadvertent breaches and disclosures of protected information. Multiple news agencies including the New York Times, Wall Street Journal and Privacy Rights Clearinghouse reported a major breach occurred at Anthem, Inc. due to a cyber attack on the system, exposing millions of individuals' records. Anthem notified potentially affected members that cyber attackers gained unauthorized access to personal information and explained how to sign up for free identity theft repair and credit monitoring services. In addition to the exposure of personal information and personal emails that garnered so much attention in the mainstream press, Reuters is also reporting that Sony now faces a civil lawsuit against the company by affected individuals.

Laboratories aren't safe either. BioReference laboratories reported a breach in 2014 and explains on its website that it believes a test server was inadvertently rendered accessible for a short period of time exposing personal information, including in some cases, social security numbers. While this wasn't an instance of intentional hacking, BioReference's response demonstrates the costs associated with any data breach. BioReference's website indicates it had to undertake the costs of an "extensive internal investigation, hired an independent security firm to conduct a forensic investigation, … retained a company to regularly monitor our servers, and implemented enhanced security measures." It also offered to provide a year of credit monitoring, identity theft and other security services to those whose information was involved.

While data breaches got a lot of attention in Hollywood this past year, every industry needs to focus on cybersecurity. A White House press release highlighted

President Obama's comments this past December calling for legislative security proposals: "[I]f we don't put in place the kind of architecture that can prevent these attacks from taking place, this is not just going to be affecting movies, this is going to be affecting our entire economy in ways that are extraordinarily significant." Recent Presidential orders and actions have therefore made cybersecurity a national priority, calling for coordinated efforts to protect sensitive information.

In February, the President issued an executive order calling for the private sector to "share information related to cybersecurity risk and incidents and collaborate to respond in as close to real time as possible." While emphasizing the need to share information, and encouraging voluntary formation of organizations that will share such cybersecurity information, the order also cautions that information sharing must be accomplished in a way that protects "privacy and civil liberties of individuals, that preserves business confidentiality, that safeguards the information being shared, and that protects the ability of the Government to detect, investigate, prevent, and respond to cyber threats to the public health and safety, national security, and economic security of the United States." The order discusses formation of Information Sharing and Analysis Organizations (ISAOs), including both public and private sector organizations. The National Cybersecurity and Communications Integration Center (NCCIC) will coordinate with ISAOs in sharing information, addressing cybersecurity risks and incidents and improving information security. An ISAO Standards Organization will establish voluntary standards for information sharing and ISAO activities.

The President also issued a memorandum Feb. 25, 2015, directing the Director of National Intelligence to establish the Cyber Threat Intelligence Integration Center. That Center will provide "analysis and intelligence" regarding foreign cyber threats or threats "affecting U.S. national interests." It will also assist other government entities focused on information security and cybersecurity risks and "oversee the development and implementation of intelligence sharing capabilities" and support efforts to coordinate response to cyber threats.

A January White House press release notes that "public and private networks are facing an unprecedented threat from rogue hackers as well as organized crime and even state actors" and announces proposed cybersecurity legislation that "promotes better cybersecurity information sharing between the private sector and government and … enhances collaboration and information sharing amongst the private sector." The release states the proposed legislation will encourage private entities to share cyber threat information with the Department of Homeland Security's NCCIC which will in turn share that information "in as close to real-time as practicable" with other federal agencies and ISAOs. The proposed legislation also provides law enforcement with tools to investigate and prosecute cyber crimes, including prosecution of insiders who "abuse their ability to access information to use it for their own purposes." Finally, the proposal also addresses state laws requiring reports of data breaches by standardizing these reporting requirements in a federal statute with a "clear and timely notice requirement" for security breaches.

Takeaway: Laboratories need to be concerned about information security not just for HIPAA compliance but also due to broader data security purposes as evidenced by recent cyber attacks. G2

FDA Issues Guidance Affecting Digital Pathology Whole Slide Imaging

Whole slide imaging systems are the subject of newly proposed guidance from the FDA addressing "technical performance assessment data that should be provided for regulatory evaluation of digital whole slide imaging (WSI) systems." WSI involves "digitization of the stained entire tissue specimen on a glass slide" which allows a pathologist to see the slide image on a computer monitor rather than through a microscope. The draft guidance doesn't focus on clinical submissions but only technical aspects of WSI performance. Before non-technical analytical studies with clinical specimens and clinical studies, the guidance says manufacturers "should first determine the technical characteristics that are relevant to such performance" and provides recommendations for evaluating those technical characteristics.

The guidance is "applicable for surgical pathology tasks performed in the anatomic pathology laboratory." It doesn't address the non-technical analytical studies or clinical studies that are used to support safety and effectiveness or interpretation of WSI images via mobile platforms.

The draft guidance provides a description and test methods for each component of the WSI device—that is, the hardware and/or software that "processes the image signals flowing through the imaging chain." Such components include the slide feeder, light source, imaging optics, mechanical scanner, digital imaging sensor, image files formats, image processing software, image review manipulation software, and the computer workstation at which the image is displayed. For each component, the guidance lists what information or specifications should be supplied. The guidance also makes suggestions for the system-level assessments and evaluation of other aspects of the system including color reproducibility, labeling, and quality control.

Comments must be submitted within 90 days of the Feb. 25, 2015 issue date for the guidance.

Source

U.S. Food and Drug Administration, Draft Guidance for Industry and Food and Drug Administration Staff, *Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices*, Feb. 25, 2015.

FDA Seeks Stakeholder Feedback, *Continued from bottom of p.1*

Panel presentations consumed most of the workshop with far fewer individual public comments than occurred during the January LDT workshop. As with the LDT comments, some commenters asserted that regulation of NGS could stifle innovation and delay access to critical testing capabilities. The bulk of the discussion, however, focused on the issues raised by the unique nature of NGS and difficulties concerning demonstration of analytical and clinical performance. During three sessions, panels of individuals representing a broad spectrum of stakeholders addressed development of standards for evaluating NGS tests, implementation of such standards, evidence and database curation for demonstrating clinical performance, communication of results and test reliability to providers and patients, and other factors to consider regarding the FDA's regulatory approach.

An often cited challenge to evaluating NGS was the fact that it can have different clinical utility in different contexts—for example, whether utilized for cancer treatment or identification of hereditary disease. Reference was made to the FDA's authorization of Ilumina's MiSeqDX testing based on demonstration of the analytical test performance for a "representative subset of types of variants in various sequence contexts." In its discussion paper, the FDA expressed an intent to continue that subset-based approach to analytical performance evaluation but welcomed suggestion of other methods.

With regard to demonstrating clinical performance of NGS, attendees were asked to comment on the use of "highly curated genetic databases that provide information on genetic variants and their association with disease." Several attendees supported the use of shared databases, with some suggesting participation in publicly shared databases should be mandatory.

The FDA moderators asked panelists whether they thought standards were feasible and, if so, who should develop them, who should implement them, and how compliance with the standards could be verified. Panelists advised the FDA to involve multiple stakeholders in crafting any standards and pressed for flexibility in the standards to accommo-

date the rapidly developing nature of the technology. More than one speaker emphasized the urgency of these issues noting that NGS is already in use and significant numbers of patients are already relying on this testing. Attendees agreed that patients and physicians need to know about the reliability of these tests to make informed decisions. Panelists also discussed issues concerning informed consent and the need to understand how much the patient does and doesn't want to know about their genetic information.

A transcript of the workshop will be available on the FDA's website. Written comments should respond to the questions raised in the discussion paper and must be submitted by March 20, 2015. For instructions with regard to submission of written comments, see the FDA's announcement of the workshop in the Dec. 29, 2014 *Federal Register*.

Takeaway: Like LDTs, next-generation sequencing tests raise unique challenges for regulators charged with protecting patient safety. Recognizing these challenges, the FDA is again soliciting industry comment on how best to protect safety without stifling innovation. G2

CMS Releases New CLIA-Waived Tests, Billing Codes

CMS notified contractors of new CLIA-waived tests effective April 1, 2015. There are 30 newly waived complexity tests, the latest approved by the FDA—which are again dominated by drug testing related items. The tests, listed in the table below, all require the QW modifier be attached to the CPT code for recognition as a waived test.

The following table provides a listing of the new CLIA-waived tests with their CPT Code, effective date and description.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	Sept. 18, 2014	CLIAwaived Inc. Rapid Drug Test Cup (Cassette Dip Card format)
86308QW	Sept. 23, 2014	AimStep Mono (Whole Blood)
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Marijuana Panel Dip
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Marijuana Quick Cup
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Marijuana Strip
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Marijuana Turn-Key Split Cup
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Methamphetamine Panel Dip
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Methamphetamine Quick Cup
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Methamphetamine Strip
G0434QW	Sept. 26, 2014	Polymed Therapeutics FaStep Methamphetamine Turn-Key Split Cup
G0434QW	Oct. 9, 2014	Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests
G0434QW	Oct. 9, 2014	Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests

CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	Oct. 9, 2014	Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card Tests
G0434QW	Oct. 9, 2014	Chemtron Biotech, Inc. Chemtrue Multi-Panel Drug Screen Dip Card with OPI 2000 Test
G0434QW	Oct. 17, 2014	Healgen Oxazepam Test Strip
G0434QW	Oct. 17, 2014	Healgen Oxazepam Test Dip Card
G0434QW	Oct. 17, 2014	Healgen Oxazepam Test Cup
G0434QW	Oct. 17, 2014	Healgen Oxazepam Test Cassette
G0434QW	Oct. 17, 2014	Healgen Morphine Test Strip
G0434QW	Oct. 17, 2014	Healgen Morphine Test Dip Card
G0434QW	Oct. 17, 2014	Healgen Morphine Test Cup
G0434QW	Oct. 17, 2014	Healgen Morphine Test Cassette
G0433QW	Oct. 29, 2014	Chembio Diagnostic Systems, Inc. DPP HIV ½ Assay (Oral Fluid)
87389QW**	Dec. 5, 2014	Oregenics, Alere Determine HIV-1/2 Ag/Ab Combo (fingerstick Whole Blood)
G0434QW	Dec. 10, 2014	Transmetron Invitro Pro Drug Test Cups
G0434QW	Dec. 10, 2014	Coastline Medical Management Coastline Explorer Cup (Cassette Dip Card Format)
86780QW	Dec. 15, 2014	Diagnostics Direct LLC Syphilis Health Check (FingerStick Whole Blood)
G0434QW	Dec. 19, 2014	On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card Tests
G0434QW	Dec. 19, 2014	On-Site Testing Specialists, Inc. On-Site Testing Specialist Single/Multi-Panel Drug Screen Dip Card with OPI 2000 Tests
87502QW	Jan. 5, 2015	Alere i Influenza A & B Test (Direct Nasal swab only)

Source: CPT Codes are Copyright American Medical Association

**Note that CPT code 87389QW is applicable from Dec. 5, 2014 to Dec. 31, 2014 for detecting "antigen to HIV-1, and antibodies to HIV-1 and HIV-2 performed using the Oregenics, Alere Determine HIV-1/2 Ag/Ab Combo (fingerstick Whole Blood)." Effective Jan. 1, 2015 the appropriate CPT code is 87806QW.

The CMS Transmittal announcing the latest FDA approved waived tests is Transmittal 3207, Change Request 9072, Pub. 100-04, dated Feb. 27, 2015. The Transmittal and a complete list of CLIA waived devices is available on the CMS website at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3207CP.pdf.

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

Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Stephanie Murg, Managing Director, Conferences & Events;
Kim Punter, Director of Conferences & Events; Myra Langsam, Corporate Licensing Manager; Michael Sherman, Director of Marketing; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.