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Professional Orgs Push for State Licensure of Genetic Counselors

The American Society of Human Genetics (ASHG; Bethesda, Md.) joined the National Society of Genetic Counselors (NSGC) in supporting state licensure of certified genetic counselors. The organizations say that licensure helps to ensure both access to genomic services and a uniform level of quality by genetics professionals. Currently, 16 states issue licenses for genetic counselors, and five additional states have passed licensure laws. Connecticut's law is the most recent, with licensure becoming effective as of Oct. 1.

With the rapid expansion of genomic testing, there is anticipated to be increased demand for genetic counseling services. While most envision genetic

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ACMG and AMA Coalition Make LDT Oversight Recommendations to Congress

A coalition of organizations including the American Medical Association (AMA) and American College of Medical Genetics and Genomics (ACMG) have recommended to Congress that oversight of laboratory developed tests (LDTs) be undertaken "primarily through reform of the Clinical Laboratory Improvement Amendments [(CLIA)]," with a more limited role for the Food and Drug Administration (FDA). The coalition's letter, sent to Chairmen and Ranking Members of the Committee on Health, Education, Labor and Pensions and the Committee on Energy and Commerce, says that congressional action is needed to "ensure that high complexity laboratory developed testing services and procedures are accurate, precise, clinically relevant, and monitored for continued quality performance." But, the coalition argues that oversight should occur via updates to CLIA rather than "an entirely new regulatory regime." Utilizing a modernized CLIA framework is "the most streamlined and cost-effective" as well as the "least disruptive and burdensome approach," the coalition asserted.

The recommendations suggest CLIA could be modernized by establishing standards for clinical validity and strengthening existing standards for quality control, quality assurance, personnel standards and regular proficiency

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counselors to have a direct clinical role in pre- and post-test counseling (and the majority do—84 percent report their primary role as clinical care), genetic counselors also work to ensure appropriate ordering of genomic tests.

ASHG says that licensure is also important because it provides counselors with the credentials many hospitals need to approve billing and reimbursement for services. In order for genomic medicine to continue to proliferate, ASHG encourages the remaining 29 states to license certified genetic counselors. In its September statement supporting state licensure, ASHG says that to receive and maintain licensure, providers would need to receive a degree in genetic counseling, pass a national-level exam to receive certification, and fulfill continuing education requirements. These criteria follow closely with NSGC's guiding principles that the organization uses to promote model legislation.

"NSGC supports state licensure of genetic counselors in accordance with our guiding principles, which aim to ensure that licensing laws cover a similar scope across states and maximize flexibility among states in how genetic counselors practice," says Joy Larsen Haidle, NSGC president, in a statement. The guiding principles include a proposed scope of work; qualifications for licensure (having certification with the American Board of Genetic Counseling or the American Board of Medical Genetics, now known as ABMGG-American Board of Medical Genetics and Genomics); reciprocity for "visiting" genetic counselors licensed in other states; and requirements for continuing education.

The calls for state licensure come at a time when there is emerging evidence that in community settings, despite rising genetic testing volumes, utilization of genetic counseling is lagging. For instance, a study published Oct. 1 in *JAMA Oncology* found that most U.S. women undergoing BRCA mutation testing for hereditary breast and ovarian cancer do not receive recommended genetic counseling. It remains unknown why test-ordering physicians failed to recommend genetic counseling. This large study is the first to analyze community-setting data among commercially insured women to evaluate adherence to professional guidelines establishing testing criteria and recommendations for counseling. In the study, just over one-third of nearly 6,500 women undergoing comprehensive BRCA testing received genetic counseling from a genetics clinician prior to testing. Despite the low numbers of referral for counseling, individuals who reported receiving pretest genetic counseling were more than twice as likely to meet guideline-based testing criteria and showed significantly greater knowledge about BRCA and satisfaction with testing.

Takeaway: Expanding licensure of genetic counselors to the remaining 29 states, may expand access to professional genomic service and ensure uniformity in quality of services rendered.

According to data from the NSGC's 2014 Professional Status Survey

- The number of genetic counselors increased 75 percent between 2006 and 2014 to more than 4,000 practicing certified genetic counselors.
- Prenatal genetics remains the largest specialty area for genetic counselors (35 percent), followed by cancer genetics (29 percent).
- Genetic counselors work in a variety of settings, including university medical centers, private and public hospitals, diagnostic laboratories, and pharmaceutical companies.
- Clinical genetic counselors are primarily employed in university medical centers (34 percent), but 49 percent of non-clinical genetic counselors report working in commercial diagnostic laboratories.

Millennium Settles False Claims Allegations for $256 Million

After winning a procedural victory on appeal in litigation brought by Ameritox claiming unfair competition based on alleged violations of the Anti-kickback statute (AKS) and Stark Law (see "Federal Appeals Court Rebuffed Unfair Competition Claims But Didn't Decide Stark, AKS Liability," *NIR*, Sept. 24, 2015, p. 3), Millennium Health has confirmed it will be paying out three settlements totaling $256 million to resolve False Claims Act and Anti-kickback allegations. It will be paying an aggregate $256 million settlement as follows:

- $227 million settling False Claims allegations of unnecessary urine drug testing between Jan. 1, 2008 and May 20, 2015 through use of custom profiles and standing orders rather than individualized assessment of patient testing needs. The allegations also included claims that free point of care testing cups were provided to physicians in violation of the AKS and Stark Law.
- $10 million for False Claims allegations that genetic testing between Jan. 2012 and May 20, 2015 was routinely performed without regard to individualized need assessment.
- $19.2 million to Centers for Medicare and Medicaid Services with regard to urine drug test billing.

Millennium has also agreed to enter into a five-year Corporate Integrity Agreement with the Office of Inspector General. The settlement of the claims, however, involves no determination of liability and Millennium's Chief Executive Officer Brock Hardaway indicated in a statement the company "may debate some of the merits of the DOJ's allegations" but respects the government's enforcement role and sought closure to a lengthy investigation. Hardaway also stressed the company is a "very different organization" than in the past and the DOJ's settlement announcement acknowledges the company has overhauled its board of directors with mostly new independent members. The company also indicated intentions to pursue restructuring. G2

OIG OK's Health System's Free Shuttle

A program designed to provide transportation within a healthcare system, in the absence of public transportation, won't be subject to sanction according to Office of Inspector General Advisory Opinion 15-13. The free shuttle service would transport patients to medical facilities within an integrated health system, including a medical center, two small community hospitals and an ambulatory surgical center. The system also includes a multispecialty clinic comprised of 1,000 physicians. Limited public transportation and private taxi services were locally available and the health system argued the "lack of affordable transportation … constitutes a barrier to health care access." Transportation would be provided to patients of the system facilities without regard to ability to pay for health care services, health insurance status, or reference to volume of federal health care program business for the system. The OIG also found transport wasn't advertised to the general public, would only serve the system's facilities, didn't bring patients from outside the system's primary service area and wasn't likely to "subsidize the practices of Private Physicians." Therefore, the OIG indicated that the arrangement created only minimal risk of fraud and abuse, so it wouldn't impose sanctions. G2

Industry Experts Highlight Opportunities and Challenges Ahead for the Laboratory Sector

Throughout two and a half days on Capitol Hill, laboratory insiders debated and shared knowledge, insight and concerns about compliance issues, new business challenges and the latest regulatory changes affecting the diagnostic industry, during G2 Intelligence's 33rd Annual Lab Institute (Oct. 14-16).

The opening Keynote address from Steven Brill, author of *America's Bitter Pill: Money, Politics, Backroom Deals, and the Fight to Fix Our Broken Healthcare System*, helped set the tone of the conference discussing the rising cost of the American health care system and how the Affordable Care Act is both changing the industry yet failing to bring enough change. Following Brill, Quest Diagnostics Chief Executive Officer Steve Rusckowski referred to the laboratory industry as America's "Sweet Pill" and emphasized laboratories' influence on 70% of medical decisions for relatively low cost, exhorting the industry to take advantage of the opportunity to be a "part of the transformation of health care."

Panelists and attendees throughout the conference reiterated a consistent message: the laboratory industry needs to work together to demonstrate their value and make their voices heard by their legislators as well as other health care organizations, payers, potential partners, and patients.

While emphasizing the need for laboratories to voice their concerns about issues such as the Centers for Medicare and Medicaid Services' Proposed Rule implementing the Protecting Access to Medicare Act (PAMA), Rusckowski asserted that changing reimbursement systems are also creating opportunity for the laboratory sector. "We're seeing more and more organizations that want to partner with our industry," said Rusckowski, who also serves as Chairman of the American Clinical Laboratory Association.

Impact of PAMA and Changing Reimbursement Debated

An overwhelming concern throughout the conference was how laboratories will be paid for their services. The Centers for Medicare & Medicaid's recently proposed rule implementing PAMA served as the focal point of a heated panel discussion that addressed the impact of proposed changes to how the clinical laboratory fee schedule is determined. The proposed rule requires specifically defined Applicable Laboratories prepare to report by March 31, 2016, private payer reimbursement data for the period July 1, 2015 through Dec. 31, 2015. Debate centered on whether the interests of all stakeholders in the industry have been adequately considered, with particular concern raised about the exclusion of hospital laboratory payment rates from the proposed data collection and the impact of the resulting Medicare rates on smaller and independent laboratories.

PeaceHealth Laboratories Chief Executive Ran Whitehead described his experiences meeting with Capitol Hill members to educate them on the realities that laboratories are facing and indicated the need for others to similarly inform their representatives. Panelists and attendees throughout the conference reiterated a consistent message: the laboratory industry needs to work together to demonstrate their value and make their voices heard by their legislators as well as other health care organizations, payers, potential partners, and patients.

PAMA was not the only reimbursement related topic generating spirited discussion. The dramatic cuts being faced by the toxicology labs and the proposed crosswalking for several molecular codes were also topics raising significant concern among attendees.

Regulatory and Enforcement Concerns Highlighted

In addition to reimbursement, sessions addressed other weighty regulatory issues affecting the industry—recent fraud and abuse enforcement initiatives and pending changes in oversight of laboratory developed testing dominated several discussions throughout the conference. A pre-conference workshop focused on compliance addressed recent cases highlighting top compliance issues such as arrangements with and provision of free items and services to referring providers, potential kickback risks of marketing and promotion efforts, client billing arrangements and the lack of clarity concerning the "usual charge" issue, and of course, surviving in a world of exclusive contracts and dealing with provision of out of network services.

Other sessions focused on compliance issues raised by business strategies, partnerships and ventures being undertaken or considered by laboratories and pathology groups to survive in and adapt to the new value-based environment. Attendees were advised to consult legal counsel earlier rather than later in developing a transaction or arrangement to avoid surprises that can delay a deal and to engage third party valuation consultants to provide guidance on fair market value for all compensation to avoid running afoul of fraud and abuse laws.

Several speakers noted that patients are increasingly paying a larger portion of their health care bills as a result of high-deductible plans or those with higher co-pays and as a result are beginning to question health care costs, including the need for and price of laboratory tests.

Finally, the status of laboratory developed testing oversight raised questions and concerns about how regulation may be implemented and what steps laboratories need to be taking in anticipation of increased scrutiny and new standards. Panelists discussed the potential for Congressional action and the various proposed alternatives to FDA regulation and offered practical advice for steps to take now to prepare laboratories for the changes ahead.

The Future of Laboratory Medicine: Engaging the Patient

The conference closed with a view to the future of laboratory medicine with a focus on the increasing involvement of patients in the diagnostic process. Presenters emphasized the value laboratories can bring to health care delivery by engaging patients and empowering them with information gained through diagnostics. Several speakers noted that patients are increasingly paying a larger portion of their health care bills as a result of high-deductible plans or those with higher co-pays and as a result are beginning to question health care costs, including the need for and price of laboratory tests. But, speakers also asserted that patients aren't just looking for lowest cost tests, but also to gain better understanding of the need for tests and the meaning of their test results.

Thus, presenters demonstrated how laboratories can provide added value by educating and engaging patients. For example, a case study discussed Boston Heart Diagnostics, a laboratory recognized for creating value through individualized patient management. Chief Executive Officer Susan Hertzberg explained how Boston Heart creates a "virtual hub" around the patient, seeking to improve treatment adherence and health literacy among high-risk patients. The company provides "personalized" and "contextualized" laboratory results that will provide an overall risk statement as well as simple explanations of results with visual supports. The company also uses a proprietary algorithm to provide customized lifestyle management counseling to patients based on their diagnostic results.

Following Hertzberg's presentation, 23andMe's Chief Medical Officer Dr. Jill Hagenkord detailed for attendees how use of genetic information can inform and personalize health care decisionmaking and improve patient outcomes, using examples of specific customers who gained life changing insight from genetic information. She explained current and potential uses for genetic information and research conducted using 23andMe's database of genotyped and phenotyped participants, supplemented with questions and surveys directed to its customers.

Takeaway: While the laboratory industry faces significant regulatory and compliance challenges as it moves into a value-focused future, as an influencer of the majority of medical decisionmaking, the sector enjoys considerable opportunities as well.

Scholarship and Industry Awards Recognize Current and Future Leaders

Amidst discussions about industry challenges and opportunities, G2 Intelligence presented three awards recognizing individuals for their achievements in academia and industry and their current and future contributions to the sector:

G2 Intelligence Laboratory National Leadership Award

Sponsored by Kellison & Company, the G2 Intelligence Laboratory National Leadership Award was presented to Khosrow Shotorbani, president and chief executive officer of TriCore Reference Laboratories. The award recognizes singular accomplishments that directly enhance patient care and the laboratory profession in one or more specific areas: basic and applied research, business creativity and innovations, public policy, and lifetime achievement. Shotorbani leads TriCore in its efforts to improve health outcomes and lower health care costs by using laboratory medicine and the information and data gained in the diagnostic process to improve utilization of health care services.

Laboratory and Diagnostic Innovation Award

Sponsored by Halfpenny Technologies, the Laboratory and Diagnostic Innovation Award was presented to HealthTap and accepted by the company's co-founder and Chief Medical Officer Geoffrey Rutledge, M.D., Ph.D. This award celebrates individuals and organizations defining the future of diagnostic medicine, with cutting-edge technologies that have the potential to transform the way lab testing is performed and novel business models that respond to the challenges and opportunities of the industry's changing market. HealthTap is an interactive health care company using technology and the prevalence of smartphones and tablets to virtually connect providers and patients.

G2 Intelligence Scholarship Awards

Sponsored by McKesson for more than 10 years, the G2 Intelligence Scholarships are awarded to students who show leadership promise in the field of laboratory sciences. This year scholarships were awarded to Ashley Archambault-Winn and Harry Ryan Roderick. Nominated by several members of the Department of Laboratory Medicine at Lahey Hospital & Medical Center in Burlington, Massachusetts, Ashley is a senior technologist in the Hematology Laboratory at Lahey, where she has worked since 2009, after graduating from the University of Massachusetts Lowell's Medical Laboratory Science Program. She was recently accepted into the UMass Lowell Graduate Certificate in Health Management Program and will apply her scholarship to this next step in her professional development.

Harry Ryan Roderick, a graduate of Arkansas State University Beebe's division of Advanced Technology & Allied Health's MLT program, is now pursuing a bachelor's degree as a Medical Laboratory Scientist at the University of Central Missouri. He is also a member of the 139th Medical Group, Air National Guard Missouri, and uses his knowledge in the clinic's lab and in aerospace medicine as an aerospace technician.

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testing. The coalition argues "in light of the extraordinary progress in diagnostic medicine, including large-scale genetic sequencing and the application of information technology, the existing CLIA requirements should be enhanced to ensure the quality of high complexity testing services and procedures based on risk." Similarly, the Association for Molecular Pathology (AMP) issued a proposal earlier this year calling for updating CLIA provisions with a tiered, risk-based structure. (See "AMP Offers Proposal for Regulation of Laboratory Developed Tests," *National Intelligence Report*, Aug. 20, 2015, p. 6). The organizations signing this most recent letter include the AMA, ACMG, AMP, American Association of Bioanalysts, American Society for Clinical Pathology, Bioreference Laboratory, Infectious Diseases Society of America, and the National Independent Laboratory Association.

Reiterating common objections to the FDA framework, the coalition claims opting for the new FDA framework rather than updating CLIA's existing structure would stifle innovation by limiting the number of new tests being developed and would hamper access to testing because "public health, community and academic laboratories" could find the new regime "cost-prohibitive." "In short, legislative and regulatory proposals that shoehorn clinical laboratories into an entirely new regulatory agency and set of requirements will interject tremendous instability and unpredictability that will harm access and innovation," the coalition warns. Previously, in November 2014, ACMG joined in a coalition letter to the FDA requesting the FDA withdraw its proposed framework, arguing the framework "would impose substantial new requirements on clinical laboratories" and other health care providers without notice and comment periods required for traditional rulemaking.

Genetic Testing is Different

In connection with the current letter, ACMG also released a statement on the issues, explaining how genetic tests are different—"highly complex tests based on recently acquired and rapidly evolving knowledge" and LDTs used for genetic testing should be treated differently than "routine diagnostic tests." Noting that genetic tests don't provide "individualized results on their own but require expert interpretation informed by medical and family histories to ensure their safe and effective use by providers" the ACMG echoed arguments made by other stakeholders that LDTs involve the practice of medicine and thus shouldn't be pigeonholed into a framework similar to that used for medical devices.

The ACMG further explained there are two types of genetic tests—those that target specific variations known to be linked to specific conditions versus "more open test platforms that sequence the entire genome and provide a comprehensive look at known and previously undescribed potential contributors to a disease." The first category, says ACMG, are "more amenable to test validation and direct oversight of laboratory performance in detecting the target." It is the open testing of the entire genome that requires professional determinations

and judgment calls based on knowledge of genetics and pathology. Both types require a "unique base of specialized medical knowledge and training to ensure both that the proper test is ordered as well as interpreted in the context of individuals and their families." ACMG suggests that for open forms of testing an oversight model similar to that used for radiologic imaging would be more appropriate in acknowledging that the machine is the regulated device but the interpretation services are professional services.

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Proposed Keys to Efficient, Effective Oversight

ACMG's position is that any oversight of LDTs must include four key features:

1. Enhanced CLIA regulations that are tiered and risk-based, with a third-party review system, public reporting of test performance, coordinated oversight between CMS and FDA, grandfathering of tests based on prior assessment of clinical validity, and adverse event reporting.
2. Increased role for third-party genetic testing laboratory accreditors that assesses analytical and clinical validity of new tests but without requiring laboratories to "provide separate clinical validity details of tests already accepted as clinically valid." If data regarding validity is privately held rather than publicly available, third party-reviewers could review validity if the developers reveal algorithms and proprietary information; or more formal/traditional regulatory oversight would apply if trade secrets are not shared. Third-party reviewers could pre-certify moderate risks tests and low risk tests could be subject to oversight via third party accreditation inspections. Test kits and devices "for broad clinical laboratory use" would be subject to FDA processes.
3. Low and moderate risk genetic tests could be pre-certified as to clinical validity under CLIA via third-party accreditors. High risk tests would be subject to oversight under joint CLIA/FDA third-party review system. Utilize Federal Trade Commission and State Attorneys General to address marketing and sale of tests with insufficient clinical validation.
4. NIH support for common sharing of data regarding clinical significance of rare genetic variations through an Information Commons, facilitating not only test validation but also postmarket surveillance and support clinical interpretations by increasing availability of data.

Takeaway: The debate concerning LDT oversight continues and intensifies as the industry looks for Congressional action to supplant the FDA's previously proposed framework. G2

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