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Covering Government Policy For Diagnostic Testing & Related Medical Services

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Potential Negative Impact of AHCA on Genetic Testing

While it remains uncertain what the Senate will do with the American Health Care Act (AHCA), alarm is spreading about the legislation's implications for the estimated quarter of Americans under the age of 65 years (more than 50 million people) that have a preexisting condition. One of the more popular features of the Affordable Care Act (ACA) was its guarantee that insurance companies could not deny coverage to people with preexisting conditions. Prior to 2014, when the ACA took effect, private insurers evaluated the health status, health history, and risk factors of applicants for coverage and premium decisions.

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LCD Reform Re-introduced in Senate

Efforts to improve the local coverage determination process have been renewed with the introduction of the Local Coverage Determination Clarification Act of 2017. The proposed bill is the result of bipartisan efforts—sponsored by two democrats and four republican Senators—and revises the process by which Medicare contractors set local policies for Medicare coverage of physician services, creating more transparency and imposing additional procedural requirements.

"The Senate bill would ensure that coverage decisions are made by qualified independent health experts through a transparent process that is based on sound medical evidence," explained College of American Pathologists President Richard C. Friedberg, MD, PhD, FCAP, in a statement praising the legislation and thanking its sponsors for their efforts to fix a "broken" LCD process.

An act by the same name was also introduced last year but didn't make it through Congress. Similar reforms are included in this year's proposed legislation:

- Open, public meetings for the Medicare Administrative Contractor's (MAC) Carrier Advisory Committee to allow input from experts, with minutes of the meetings posted online for public inspection.

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Potential Negative Impact of AHCA on Genetic Testing, *from page 1*

Concern is mounting over the AHCA's provision that allows states to apply for waivers that could allow insurers to charge those with preexisting conditions substantially more, possibly pricing them out of the market to buy individual health insurance.

In just the last few years, genetic testing, including tests that assess hereditary cancer risk, has expanded dramatically. While this has been viewed as a positive development, empowering patients to proactively manage potential health conditions by personalizing screening strategies, the information now may be perceived as liability if the AHCA reverses the ban on preexisting conditions.

According to research from the Kaiser Family Foundation, the preexisting condition exclusion clauses varied state by state prior to the ACA.

- In 19 states, a health condition was considered preexisting only if the individual had actually received treatment or medical advice for the condition during defined period of time prior to the coverage effective date.
- In most states, a preexisting condition could also include one that had not been diagnosed, but that produced signs or symptoms that would prompt most people to seek medical advice or treatment.
- However, in eight states and Washington, D.C., conditions that existed prior to the coverage effective date— including those that were undiagnosed and asymptomatic—could be considered preexisting and excludable from coverage under an individual market policy.

Previously declinable preexisting conditions in the individual market included: infectious diseases (AIDS/HIV, Hepatitis C virus), cancer, and many common diseases that researchers are examining for an underlying genetic cause (heart conditions, diabetes, Alzheimer's, Parkinson's disease, and mental disorders).

While it remains to be seen what will happen regarding preexisting conditions, and whether undiagnosed, asymptomatic conditions will be considered preexisting, there is mounting speculation of how this provision of the AHCA will impact adoption of genetic testing. Presumably the nascent market of preemptive wellness sequencing could be impacted, as could familial genetic testing and even direct-to-consumer genetic testing.

Takeaway: While it remains uncertain what final form AHCA legislation will take, there are increasing concerns over the definition of preexisting conditions in the era of genomic medicine.

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Genetic Test Evaluation Framework to Aid Clinical Usefulness of Testing

A new report by the National Academies of Sciences, Engineering, and Medicine provides a new decision framework for the use of genetic tests in clinical care. *An Evidence Framework for Genetic Testing* provides a seven-step process including defining the genetic testing scenario and a triage process for an expedited provisional decision, as well as a process for evidence review for tests needing further evaluation.

"There are challenges to evidence-based decision making around the use of genetic tests, including the paucity of the types of research studies on which evidence-based medical decisions depend, which are exacerbated by the accelerated development of new tests, variants, and technologic discoveries."

— Alfred O. Berg, M.D.

The report, by the National Academies' Committee on the Evidence Base for Genetic Testing, came from a request by the Department of Defense (DoD) to create recommendations for decision-making regarding the use of genetic tests in clinical care. DoD's Office of Health Affairs, which is responsible for developing cost-effective, high-quality health benefit for 9.6 million active-duty uniformed service members, retirees, and their families through the Military Health System, recognized the challenges posed by dramatic growth of genetic testing in the health care system, including the need for rigorous evaluation of not just their validity, but also their clinical utility and cost effectiveness, as well as the best ways to incorporate them into clinical practice.

"There are challenges to evidence-based decision making around the use of genetic tests, including the paucity of the types of research studies on which evidence-based medical decisions depend, which are exacerbated by the accelerated development of new tests, variants, and technologic discoveries," writes the committee, chaired by Alfred O. Berg, M.D., professor emeritus from the University of Washington, Seattle. "Randomized controlled trials to establish clinical utility are expensive and of long duration, so decisions about the clinical value of genetic testing are often based on lower levels of evidence. Policy making is often hampered by the lack of objective methods for setting decision thresholds."

While the committee's development of the framework intended to address general principles of clinical usefulness relevant to any genetic technology, it focused on germline DNA-based tests, including diagnostic genetic testing; predictive genetic testing (e.g., hereditary cancer, pharmacogenetic testing, newborn screening); and reproductive genetic testing (e.g., carrier, prenatal, and preimplantation testing).

The National Academies' committee recognized the "numerous" existing efforts to assess genetic tests by ad hoc groups, regulatory agencies, organizations, and professional societies. As such, they adapted existing frameworks to create a hybrid decision framework consisting of seven components to guide an evaluator through evidence-based decision-making. The steps include:

- Defining the genetic test scenario (e.g., population, clinical purpose, desired outcome, alternative methods);
- Triage whether the test should be covered, denied, or subject to additional evaluation – Is the test worthwhile? Is there evidentiary support for the test? What are the contextual factors (costs, ethical, legal, and social implications);

- Conduct evidence-based systematic reviews, if necessary;
- Reach a decision regarding whether or not to support the use of a genetic test;
- Track decisions and supporting information in a repository;
- Regularly review and revise decisions;
- Identify evidence gaps.

In addition to developing the framework, the National Academies committee recommends that the DoD advance the evidence base on genetic testing through independent and collaborative research. For instance, the National Academies suggests the DoD could undertake or support prospective studies of clinical utility or the DoD could implement processes for data collection and analysis of its own experience with genetic testing. Contributions of the large DoD TRICARE population to data repositories (e.g., ClinVar) could "substantially" advance the evidence base on clinical validity of genomic tests.

Takeaway: The National Academies' new decision framework for the use of genetic tests in clinical care may be widely applicable for evaluation of genetic tests. Additionally, the National Academies' encouragement may prompt DoD to substantially contribute to and grow the evidence base for genetic tests.

FDA Exempts Certain Class I Devices, Test Kits from 510(k) Filing

The FDA has determined that 71 device types, including some diagnostic test kits, should be exempt from 510k filings. These devices are deemed "sufficiently well understood and do not present risks that require premarket notification to provide a reasonable assurance of safety and effectiveness," the FDA said in a statement regarding the determinations. Generally, devices introduced to market after 1976 require either FDA notice under 510(k) or premarket approval, depending on their risk classification. Class 1 devices are the lowest risk devices, for which the agency has determined general controls will be "sufficient to assure safety and effectiveness." A 510(k) filing gives the FDA notice of the intent to market the device and allows the FDA to decide if the new device is "substantially equivalent" with a device already on the market that doesn't require full premarket approval.

The FDA announced the 71 class I device types in a notice published in the April 13, 2017 Federal Register. It is the result of efforts to streamline agency review under the 21 Century Cures Act, which was signed into law in December 2016. That Act requires the FDA to announce in the Federal Register within 120 days of enactment those devices that don't require 510(k) reporting to give the agency assurance of safety and effectiveness. The FDA must also publish similar determinations at least once every five years.

The FDA considered the following in creating this list: a) "risk inherent with the device and the disease being treated or diagnosed (e.g., devices with rap-

idly evolving technology or expansions of intended uses)" b) history of adverse event reporting regarding the device type; and c) history of product recalls related to the type of device. The list currently includes some diagnostic devices including test kits. Limitations to the exemption are included in some cases, however. For example, some test kits are only partially exempt with the exemption not applicable to use of the kit for donor screening tests.

The devices in the list will still be required to satisfy general controls and remain subject to other statutory or regulatory requirements for which an exemption hasn't been expressly issued.

Takeaway: 21st Century Cures Act leads to streamlining path to market for some diagnostics.

FDA Sends 14 Warning Letters Regarding Cancer Products

The U.S. Food and Drug Administration (FDA) continues to focus on direct-to-consumer marketing and sale of products and has issued warning letters in an effort to protect vulnerable cancer patients from suspect products. "Unfortunately, rogue operations exploiting those fears [relating to cancer] peddle untested and potentially dangerous products, particularly on the internet," said Donald D. Asley, J.D. and Douglas Stearn, J.D. in a recent FDA Voice blog post announcing the agency's enforcement efforts concerning cancer related products.

In late April, the FDA issued a series of warning letters to 14 manufacturers of over 65 products the agency claims are being illegally sold without FDA approval because they "fraudulently claim to prevent, diagnose, treat or cure cancer."

"Consumers should not use these or similar unproven products because they may be unsafe and could prevent a person from seeking an appropriate and potentially life-saving cancer diagnosis or treatment, warned Stearn, the FDA's Office of Regulatory Affairs director of the Office of Enforcement and Import Operations. The FDA warned consumers to be "vigilant" when shopping online or in a store and be wary of products marketed for cancer "without any proof they will work." "Patients should consult a health care professional about proper prevention, diagnosis and treatment of cancer." It also encourages patients to report adverse reactions to these or other products to the MedWatch program.

The 65+products included pills, creams, oils, drops, syrups, teas and diagnostics and the FDA's warning letters request that the companies respond with a plan for correcting the violations. If they don't, the FDA could take legal action such as seizure, injunction or criminal prosecution. The violations are also grounds for a one-year prison sentence, five years probation and a fine equal to $100,000 or two times the gain from the offence.

Among the 14 companies, one company was alleged to be illegally selling a diagnostics product—a telethermographic camera system, "intended for adjunctive diagnostic screening for detection of breast cancer." The FDA said the company was improperly marketing the device for use as a sole screening device. Such systems are Class I devices requiring 510(k) premarket clearance before marketing and are not intended to be used alone as a diagnostic screening device—which would make it a class III device requiring premarket approval.

Takeaway: The FDA continues to monitor and take action to protect consumers by challenging manufacturers of products advertised or sold direct to consumers.

Do No Harm: Diagnostic Errors and the Lab

By Jennifer (McMahon) Dawson, MHA, DLM (ASCP)

Do no harm" is the mantra that health care providers live by. Doctors, nurses and laboratory professionals alike enter into the business of health care because they are motivated to help people.

"In order for the laboratory to have a positive impact on diagnostic errors, it is necessary to become part of the interdisciplinary patient-centered care team."

— Jennifer (McMahon) Dawson, MHA, DLM (ASCP)

Why then do 5% of adults in the United States experience diagnostic error annually in outpatient settings at the hands of these well-meaning providers?[1] Humans work in health care. Where humans are involved, there will be mistakes.

There is also a certain level of trial-and-error that is acceptable in the diagnosis of patients. Laboratory professionals often feel removed from the actual diagnosis of the patients that they serve.

Laboratories play a critical role as lab testing is often used to confirm initial impressions or rule out differential diagnoses. It is estimated that 70% of all health care decisions affecting diagnosis or treatment involve lab testing[2] and at least 10% of all diagnoses are not considered final until lab testing is complete.[3,4]

We can all agree that the identification of diagnostic errors in medicine is critical to improving patient safety; however, it is easier said than done. Historically, the laboratory industry has focused its quality improvement efforts within boundaries of the laboratory. We have been lab-centric in this respect and have not focused on collaboration with other members of the care team or patient outcomes. The laboratory has been very good at detecting and eliminating errors in the analytical phase. Less focus has been placed on identifying and remedying errors outside of the analytical phase, particularly those that occur outside the boundaries of the lab (pre-pre and post-post-analytical).

In order for the laboratory to have a positive impact on diagnostic errors, it is necessary to become part of the interdisciplinary patient-centered care team. Laboratory professionals need to view their services as contributing to patient outcomes, not just generating results.

Research on diagnostic errors and the laboratory's role has found that failure to order appropriate diagnostic tests, including lab tests, makes up 55% of missed and delayed diagnoses in the ambulatory setting and 58% of errors in emergency departments.[5] We know that health care providers don't understand our tests as well as we do. This statistic underscores the need for Clinical Lab Scientists to interact with and provide education to ordering providers on the proper use of the testing we provide.

One way that clinical laboratory professionals can affect positive change is by collaborating with other health care providers to establish evidence-based decision-making guidance for ordering tests. Providing feedback to providers detailing improper test utilization patterns, both over- and under-utilization, is another way that laboratory professionals can help to reduce diagnostic errors. Other ways the laboratory can help reduce diagnostic errors include reflexive testing, consultative services and improved test reporting.

Unfortunately, standardized feedback systems and reliable evidence-based decision support mechanisms do not yet exist on a large scale. In the meantime, we are reliant largely on our non-conforming event management systems to capture diagnostic errors. The success of these systems, whether you choose a manual or electronic option, is contingent on the establishment of a reporting culture.

A reporting culture is a culture of trust where employees feel safe, supported and comfortable pointing out errors, which may include their own, in the interest of patient safety and continuous improvement. The types of errors captured will include laboratory errors, errors generated outside the confines of the laboratory, and near misses. A near miss is "any event that could have had an adverse patient consequence, but did not, and was indistinguishable from a full-fledged adverse event in all but outcome."[6] A near miss is the perfect quality improvement opportunity, as we have the opportunity to eliminate the root cause before a patient is harmed. It is only after we are made aware of an event or near miss that a root cause analysis and corrective action can be formulated to prevent the event's recurrence.

The identification of diagnostic errors to which the laboratory has contributed is a crucial piece of the puzzle in our effort to improve patient safety and outcomes. The lack of comprehensive information on the incidence of diagnostic errors should not prompt us to conclude that these errors are uncommon or unavoidable.[7]

In addition to the patient safety benefits, the shift from fee-for-service to value-based purchasing is already requiring us to become more patient-centric and outcomes-focused. This way of thinking is in line with the way we will be reimbursed in the future. The lab can help to reduce diagnostic errors by focusing on becoming more patient-centered, educating providers on lab testing, providing consultative services, initiating feedback loops that extend beyond the walls of the lab and ensuring that we have an effective non-conformity management system.

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Another Decision in the HDL Case Highlights Kickback Risks of Patient Responsibility Waivers Involving Private Payers

The Health Diagnostics Laboratory, Inc. (HDL) and Singulex saga continues. The latest chapter involves not the labs themselves but BlueWave Healthcare Consultants, their marketing firm. And it raises new and potentially troubling implications for labs that waive copayments and deductibles for patients covered by private payers.

"This is an important moment for people who want to know their genetic health risks and be more proactive about their health."

— Anne Wojcicki, CEO and Co-founder

A Quick Recap

The HDL case has been described as the mother of all clinical lab fraud schemes because of the massive dollars involved. For those of you unfamiliar with it, the case began as a *qui tam* lawsuit accusing HDL, Singulex and one other lab (Berkeley Heart Lab) of working with BlueWave to induce blood testing referrals, including medically unnecessary large multi-assay panels, by paying physicians sham specimen processing and handling fees of between $10 to $17 per referral and routinely waiving copayments and deductibles.

In 2015, HDL paid $47 million to settle False Claims Act (FCA) charges against it; Singulex settled for $1.5 million. Both labs also entered into corporate integrity agreements with the government. The settlement forced HDL into Chapter 11 but the embattled lab giant's legal woes continued. In addition to its creditors, HDL is being sued by Cigna for $84 million in damages the private payer allegedly suffered as a result of the scheme. Adding insult to injury, BlueWave has also sued its former partner for millions in unpaid consulting fees.

The Newest Case

Now BlueWave is in the hot seat. The most recent case centers on the waiver of copayments and deductibles by HDL and Singulex. In the case it was argued that the waivers were kickbacks to induce referrals even though they applied to patients of private insurers. BlueWave disagrees and asked the South Carolina federal court to throw out the charges without a trial.

Ruling: The court refused.

Reasoning: Waivers of private insurance copays and deductibles may amount to kickbacks under the Anti-Kickback Statute (AKS). And there was evidence suggesting that the waiver arrangements in this case did cross the line:

- BlueWave's agreement with HDL and Singulex allegedly required the labs to agree not to charge patients for copays and deductibles; and
- BlueWave then leveraged the labs' no-balance billing practices to induce referrals by highlighting those practices in the marketing pamphlets it gave to physicians.

Bottom Line: BlueWave will have to stand trial for its role in the kickbacks scheme. And remember that committing a kickback violation can make a defendant guilty of FCA violations if it submitted false claims for services

provided as a result of those illegal referrals.

What It Means

The concept of finding a kickback violation based on an arrangement involving services paid by private insurers is nothing novel, notes Baker Donelson attorney Robert Mazer. For example, the OIG has stated that improper physician discounts on private pay business can be used to unlawfully induce referrals of Medicare tests.

But, Mazer suggests, the relationship between forgiveness of a private patient's cost sharing responsibility and financial benefit to a physician related to his referrals of federal health care program appears much more attenuated.

Takeaway: Be mindful that waiver arrangements can raise kickback red flags even when they involve private payers.

Value of Price Transparency Questioned

Publishing testing prices in electronic ordering systems for inpatients may not lead to significant changes in clinician ordering behavior or associated fees, according to a study published April 21 in *JAMA Internal Medicine*. However, small changes were seen in ordering for patients in the intensive care unit and in higher fee tests. The authors say this suggests that more targeted price transparency interventions may have more impact.

"The price transparency intervention in this study was always displayed regardless of the clinical scenario," explain the authors led by Mina Sedrak, M.D., from the City of Hope Cancer Center in Duarte, Calif. "The presence of this information for appropriate tests may have diminished its impact when tests were inappropriate."

The study was conducted as part of the Pragmatic Randomized Introduction of Cost data through the Electronic health record (PRICE) trial. It assessed the effect of displaying Medicare allowable fees for 30 inpatient laboratory tests on clinician ordering behavior over a one-year period at three Philadelphia hospitals, representing 98,529 patients and 142,921 hospital admissions.

The 30 tests in the intervention were selected from a list of 30 high volume and 30 more expensive tests based on 2014 charges. Tests were then grouped by tests that could be ordered individually, as a panel, or as tests with similar alternatives in order to avoid situations where clinicians would have price transparency for only a part of a group. (For example, basic metabolic panels of varying sizes, as well as the individual tests they comprised, were grouped together.) Finally, stratified randomization occurred with the top quartile of higher volume tests followed by the top quartile of the more expensive tests followed by the remaining tests. At implementation, clinicians were told this was part of a health system–wide initiative to improve high value care and they were required to acknowledge a 1-time message within the electronic health record system.

> *"Because health care decisions are changing more rapidly in this [ICU] setting, clinicians may be less likely to rely on repeating orders and therefore may have been exposed to the intervention more often."*
>
> — Mina Sedrak, M.D.

The researchers found that there were no significant changes in overall test ordering behavior. In the intervention period, the mean number of tests ordered per patient-day was 2.34 in the control group and 4.01 in the intervention group versus 2.31 and 3.93, respectively in the one-year pre-intervention period. However, a small but significant decrease in test ordering was seen in patients with ICU stays and amongst the top quartile of the most expensive tests.

"Because health care decisions are changing more rapidly in this [ICU] setting, clinicians may be less likely to rely on repeating orders and therefore may have been exposed to the intervention more often," write the authors. "Future efforts might also consider pairing price transparency information with changing the default setting in the EHR so clinicians cannot order repeating laboratory testing for an extended duration."

Takeaway: Overall, studies examining price transparency's effect on test ordering remain inconclusive. This study suggests future efforts examine interventions without standing orders and targeting pricing information to clinical situations where a test may be unnecessary.

CORRECTION: Molecular Assays Stave Off Big Cuts in 2017 Clinical Laboratory Fee Schedule

Editor's Note: *The lead story in the November 25, 2016 issue of LIR is about changes to the 2017 Clinical Laboratory Fee Schedule affecting reimbursement for clinical laboratory tests. The first section of the story discusses new molecular tests added to the CLFS in 2017, specifically the seven tests that were in line for major price cuts. The punchline was that the price cuts CMS proposed were never made. The Problem: Although the analysis was correct, the article listed the wrong pricing information for these and other molecular tests contained in the CLFS. Here is a revised version of the affected parts of the article listing the correct prices, including a chart providing a clearer comparison between the CMS proposed and final National Limitation Rate for each test. G2 apologizes for the error and thanks our loyal and attentive users for bringing it to our attention.*

Clarifies and corrects data and shows more clearly comparison between proposed final limitation amount and proposed.

1. Seven Molecular Assays Stave Off Big Cuts

[For many labs, the most significant aspect of the 2017 CLFS is reimbursement for] the 15 CPT codes for molecular tests that CMS added to the CLFS this year. The question: How much should Medicare pay for these esoteric and pricey assays? In June, CMS proposed interim gapfill prices at a discount from their regionalized prices. Led by providers of the assays highlighting the inconsistencies between the proposed gapfill rates and the rates established by the Medicare Administrative Contractors who approved the tests, the industry asked CMS to reconsider the interim rates. "The proposed gapfill rates are inconsistent with rates established by commercial payers and the

Protecting Access to Medicare Act of 2014," contended The Coalition for 21st Century Medicine.

CMS apparently took heed, dropping the rate cuts and restored or increasing the regional prices for seven of the tests listed increased by the annual CLFS modifications. Companies benefiting from the change of course included:

- **CareDx**, which instead of a 77 percent cut got its rate restored to the original rate on its AlloMap test to identify heart transplant recipients at low risk of rejection (CPT 81595);
- **Biodesix**, which got the rate restored for its VeriStrat lung cancer aggressiveness test (81538);
- **Genomic Health**, which got the rate restored on its Oncotype DX colon cancer recurrence test (81525);
- **BioTheranostics**, which got the rate restored for its metastatic tumor origins diagnostic test (81540);
- **Invitae**, which avoided a 33 percent cut on its hereditary breast cancer panel (81432);
- **CardioDx**, which instead of a 28 percent cut had its rate almost completely restored on its coronary artery disease risk test Corus CAD (81493); and
- **Veracyte**, which instead of a 22 percent cut got its rate restored on its thyroid nodule assessment assay Affirma (81545).

2017 Medicare Rate for New Molecular Diagnostic Tests

(**Boldface** tests are those for which discounts were proposed but not adopted)

CPT Code	Test	Proposed National Limitation Rate	Final National Limitation Rate
81412	9-Gene Ashkenazi Jewish Screen	$602.10	$602.10
81432	**Hereditary Breast Cancer Panel, 14 Genes**	**$622.53**	**$931.48**
81433	Hereditary Breast Cancer, Duplications/ Deletions Panel	$602.10	$602.10
81434	Hereditary Retinal Disorder Screen	$602.10	$602.10
81437	Hereditary Neuroendocrine Tumor	$602.10	$602.10
81438	Hereditary Neuroendocrine Tumor, Duplications/ Deletions	$602.10	$602.10
81442	Noonan Gene Screen	$602.10	$602.10
81490	Vectra Screen	$590.61	$590.61
81493	**Corus CAD**	**$741.01**	**$1,042.35**
81525	**Oncotype DX**	**$848.86**	**$3,125.73**
81538	**Veristrat**	**$283.00**	**$2,126.78**
81540	**bioTheranostics**	**$1,522.17**	**$2,920.30**
81545	**Affirma**	**$2,240.16**	**$3,222.40**
81595	**AlloMap**	**$732.00**	**$2,840.75**
0009M	VisibiliT	$602.10	$602.10

LCD Reform Re-introduced in Senate, *from page 1*

- Opportunity for public comments regarding draft LCDs, at least a 30-day comment period required.
- Disclosure online of the evidence and rationale underlying local policy decisions to deny coverage. "If this information is not provided until the final LCD, it hinders meaningful stakeholder exchange and makes the MAC's decision to deny coverage almost a foregone conclusion," the College of American Pathologists said in a statement applauding the proposed bill.
- Sets procedural requirements for the reconsideration and appeal processes that include establishing an ombudsman.
- Preventing a single MAC from making express or de facto national determinations by requiring MACs that want to adopt LCDs from a different geographic region to first independently evaluate the evidence supporting the LCD and make its own determination. "The CAP has witnessed the carbon copy adoption of MAC LCDs by other MACs without the benefit of meaningful solicitation or independent assessment of comments and concerns from the public or medical community of the adopting MAC," the CAP said in a statement. "The policy then can become of such geographic magnitude it approaches becoming a NCD in practical terms without having followed more rigorous requirements."

Takeaway: Congress tries once more to make improvements to the local coverage determination process.