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Senate Bill Expanding 'Home Brew' Controls On The Fast Track

Under the Kennedy-Smith bill, most lab-developed tests would be class II medical devices, but those used to screen blood or diagnose a contagious disease that is very likely to be fatal would be ranked as class III.

Despite a joint plea from 25 clinical laboratory and pathology groups for "time-out" to allow more deliberation, Sen. Edward Kennedy (D-MA) intends to "fast track" legislation that would vastly expand the Food & Drug Administration's regulation of lab-developed tests (LDTs), also known as home-brew tests.

Kennedy, who chairs the Health, Education, Labor & Pensions Committee, and the ranking Republican, Gordon Smith (OR), are lead sponsors of the bill, S. 736, which would rank most LDTs as class II and III medical devices requiring premarket review (*NIR, 28, 10/Mar 12 '07, p. 1*). Once out of committee, the plan is to attach the measure to FDA user fee reauthorization legislation expected to be considered in mid-April.

The decision to proceed with the "fast track" strategy was confirmed in a recent meeting with Kennedy staffers, Alan Mertz, president of the American Clinical Laboratory Association, told *NIR* at press time.

This is the course advised against in a March 16 letter to Kennedy that was signed by 25 lab and pathology organizations and lab companies at the national and regional level. *Continued on p. 2*

INSIDE *NIR*

Lab Lobbying Blitz Gets Receptive Audience On Capitol Hill

Clinical laboratory professionals from the grassroots level converged on Capitol Hill March 19-20 to lobby Congress against Medicare lab competitive bidding and for increased allied health funding to help address the worsening shortage of clinical lab scientists and medical lab technicians in the workforce.

The two-day Legislative Symposium drew 140 participants from throughout the country, veteran lab lobbyist Don Lavanty told *NIR*. Sponsors included the American Society for Clinical Laboratory Science, the American Society for Clinical Pathology, and the Clinical Laboratory Management Association.

After meeting with senators and representatives from their home state and district and with congressional health committees and their staff to brief them on lab payment and policy issues, participants reported they got "a receptive response," Lavanty said, with lawmakers in both parties signaling interest in backing legislation advocated by the groups. *Continued on p. 6*

Would added federal oversight of lab-developed tests stifle innovations and patient health gains in the fast-growing market for gene- and protein-based testing? That's a big concern for the lab industry, which notes that LDTs already are subject to the highest CLIA test performance standards for analytical and clinical validity.

'Home Brew' Controls, *from p. 1*

The groups said more stakeholder input is needed because of the complex issues surrounding LDTs and the significant expansion of FDA oversight that the bill proposes.

Despite differences over additional LDT oversight, the groups emphasized in the letter, "We are fully united in our request for more time to provide feedback and discuss pathways that will not have unintended consequences on lab services. We are further united in the opinion that any new legislative initiative in this area should be carefully crafted to focus on areas of concern and not be so broad as to encompass lab tests that are clinically established or that are serving a valuable purpose for rare disease groups and public health needs."

An approach more palatable to the groups at this point is the one found in legislation that, at press time, Sen. Barack Obama (D-IL) was reportedly preparing to introduce. Similar to the bill he sponsored in the last Congress, it would take a go-slow approach, calling for an 18-month study by the Institute of Medicine on the need for additional LDT oversight and which tests should be regulated, establishment of a genetic specialty under CLIA, and creation of a task force to coordinate regulatory LDT actions.

By requiring premarket review for most LDTs, the Kennedy-Smith bill would overwhelm both labs and the FDA, Mertz said. LDTs are common among ACLA members, he noted, including in-house developed tests and modifications of FDA-approved test kits. They include a range of tests, not just genetic ones—anything from common routine tests to more complex molecular procedures.

To determine the impact of requiring premarket review, ACLA has been surveying its members over the past few weeks and continues to gather information, Mertz said. One finding stands out already, he pointed out. Seven member labs perform 5,227 LDTs in all, including 3,227 in-house developed tests and 2,000 test modifications. The volume of paper that these labs would have to submit, and the FDA would have to review, on analytical and clinical validity is estimated at 158,394 pages, Mertz said.

The FDA already plans to require premarket review for a specific category of lab-developed tests that the agency calls in vitro diagnostic multivariate index assays (IVDMIAs), which use an assay and an algorithm to generate a patient-specific result. Examples include proprietary tests to diagnose and guide treatment for breast and other cancers, cardiovascular disease, and Alzheimer's disease (*NIR, 27, 22/Sep 25 '06, p. 1*).

Lab and pathology groups say the FDA policy in the IVDMIA draft guidance represents a major departure from the discretionary enforcement approach the agency has followed in the past, limiting itself to regulating only analyte-specific reagents. In light of the new binding requirements, they have called on the FDA to propose the policy through a formal rulemaking process, offering full procedural protections, such as justification and analysis of impact, OMB review, availability of judicial review, and explanations of decisions via publication in the *Federal Register*.

Bill Would Boost Medicare Fees For New Testing Technology

The legislation, a top priority for AdvaMed, has been referred to the House Committees on Ways & Means and Energy & Commerce.

A bipartisan bill has been unveiled in the House that its sponsors say would improve payments under Medicare's lab fee schedule and thus widen beneficiary access to diagnostic testing advances that help detect disease earlier and more accurately.

The bill—entitled the Medicare Advanced Laboratory Diagnostics Act (H.R. 1321)—was introduced on behalf of AdvaMed by Reps. Bobby Rush (D-IL), Michael Ferguson (R-NJ), Mike Thompson (D-CA), and Phil English (R-PA). AdvaMed is the leading trade group for companies that produce medical devices, diagnostic products, and health information systems.

Congressman Rush noted that clinical lab tests "account for less than 2% of Medicare spending, but influence 70% of healthcare decisions. Increasing access to new diagnostic technologies and updating their reimbursement scale will contribute to more cutting-edge technology, appropriate diagnosis, prevention strategies, and treatment therapies."

AdvaMed president and CEO Stephen J. Ubl said the bill would make necessary reforms to Medicare policies. "The current Medicare system does not recognize the value that gene-based tests bring to patients and ignores the contributions these tests can make to reducing overall healthcare costs through earlier detection and treatment."

Specifically, H.R. 1321 would:

- ❑ Establish a demonstration project to evaluate a new Medicare payment system for molecular diagnostic tests, with a standing panel appointed to determine the tests to be included and to make recommendations to the Health & Human Services Secretary, based on the findings.
- ❑ Improve fee-setting processes to account for the greater complexity and higher costs associated with genetic testing.
- ❑ Require that regulations be issued on the gap-filling method used to set fees for tests new to the Part B lab fee schedule. Under gap-filling, Medicare initially bases the fee on local prevailing pricing patterns.
- ❑ Correct historic payment errors in fee schedule amounts and national fee caps.
- ❑ Require advance notice of any test fees being considered for adjustment under Medicare's inherent reasonableness authority.

Advisory Panel Advocated To Guide 'Medically Unlikely' Edits

Citing grave concerns about the process being used to develop and implement "medically unlikely" edits (MUEs) of Medicare claims, nine leading pathology organizations are urging the Centers for Medicare & Medicaid Services to establish an advisory committee to guide the project.

The MUEs are limits on the units of service that a healthcare provider can bill a particular CPT/HCPCS code per Medicare beneficiary per day. Claims for services exceeding these limits are automatically rejected. Providers may not bill the beneficiary for MUE-denied claims; this provision can neither be waived nor be subject to an Advance Beneficiary Notice (ABN).

The purpose of the 'medically unlikely' edits, says CMS, is to lower the error rate of Medicare fee-for-service paid claims by flagging billing and typographical errors. The initial anatomic MUEs (for example, one appendectomy per patient) have generated little fuss, but major controversy is brewing over CMS plans to base upcoming MUEs on clinical judgment and medical necessity.

Eight organizations signed on to the March 5 letter from the College of American Pathologists to CMS official Kimberly Brandt, director of the Program Integrity Group, which runs the MUE project. The advisory committee should be composed of the various stakeholders, including CMS physicians and the CMS contractor for the project, representatives of the pathology and lab community, and members of other clinical specialty societies that may be implicated, the letter said.

The panel is especially needed now, the organizations say, since the MUE contractor, Niles Rosen, MD, of Correct Coding Solutions (Carmel, IN), has indicated that future MUEs will be based on clinical judgment as to a procedure's medical necessity as well as additional edits to capture "typographical errors" on a statistical basis.

The MUE process has "morphed from the issue of unbelievability to unlikelihood and now most recently to medical necessity," the letter points out, concluding that "we are very concerned that the level of expertise of the MUE contractor and CMS physicians, who are not full-time practitioners representing the spectrum of potentially implicated specialties, is inadequate to properly set MUE levels based in whole or in part on clinical judgment."

The recommended advisory committee would lend transparency to the process, the letter notes, and would help assure that the edits will be based on appropriate evidence to achieve CMS's objectives without impeding good medical practice.

Given the complexity of the MUEs and their clinical rationale, the letter says the development of these edits does not appear to reflect a broad knowledge base or "even casual familiarity with current standards of patient management found in textbook/literature recommendations, much less appropriate application of new technologies by practicing experts. This has been most evident in molecular pathology …."

The first round of MUEs, involving approximately 2,800 codes, mostly for surgical procedures and based on anatomic considerations, began January 1 of this year. The second round is set to start April 1 and will include, for the first time, several hundred edits for pathology and laboratory services, including Pap smear codes (*NIR, 28, 10/Mar 12 '07, p. 6*).

The third phase, set for July 1, is to include edits based on criteria such as CPT code descriptors, CPT coding instructions, and the nature of the analyte. The fourth phase, set for October 1, will introduce the clinical judgment criterion. CAP says close collaboration with CMS is essential to make sure that non-anatomic edits are arrived at "through an open, transparent process and do not adversely affect provider payments."

CAP's basic position is that MUEs should be set "at a level of unlikelihood such that only exceptional cases would fail to meet the MUE criterion for the service, and that cases would thus properly be adjudicated through a process of individual appeal, obviating the use of override modifiers."

CAP, together with other lab and pathology groups, continues to press the MUE project to provide detailed information on the rationale, criteria, and specific methodology behind the MUEs so it can better understand and comment on the decisions to be made by CMS and the MUE contractor.

HIV-Positive Phlebotomists Protected Under Disabilities Act

The best available medical evidence indicates that healthcare workers in these positions do not pose a direct threat to patient health or safety if they follow universal precautions, says the EEOC. Under universal precautions, workers assume that blood and certain bodily fluids are potentially contagious and protect themselves from exposure by using gloves and other personal protective gear, engineering controls, and work practice controls.

Clinical laboratories and other healthcare employers should review their personnel policies and procedures to make sure that these reflect the recently published view by the Equal Employment Opportunity Commission that HIV-positive phlebotomists are covered by the Americans with Disabilities Act (ADA).

This means a healthcare employer is prohibited from not hiring or from firing an individual as a phlebotomist because of his or her HIV-positive status. HIV infection is considered a disability under the ADA because it limits the "major life activity" of reproduction.

Case Example: No Direct Threat

In a new fact sheet, issued February 26, on how the ADA applies to job applicants and employees in the healthcare industry, the EEOC includes this case: "Ariel, a phlebotomist at a blood bank, is responsible for drawing blood. Lakshmi, a certified nurse's aide in a nursing home, is responsible for dressing and grooming residents, making their beds, and serving their food trays. Both are HIV-positive."

The EEOC concludes that "since the best available medical evidence at the time of the employer's decision indicates that HIV-positive healthcare workers in these types of positions do not pose a direct threat to the safety of patients if they adhere to universal precautions, neither poses a direct threat in their positions based on their HIV-positive status. Therefore, their HIV-positive status would not justify reassigning these employees to different positions or terminating them."

Under the ADA, an employer may exclude an individual with a disability from a particular position if that individual would pose a "direct threat" to health or safety. This is defined as a significant risk of substantial harm to the individual or others in the workplace that cannot be reduced or eliminated through reasonable accommodation. "Direct threat" must be determined on an assessment of the present ability of the job applicant or employee to safely perform the essential functions of the job.

Case Example: Direct Threat

To illustrate when "direct threat" would come into play, the EEOC provided this case summary. A hospital physician who served as chief of the internal medicine department abused both drugs and alcohol. The doctor was out for three months to be treated for alcoholism after a hospital employee found him visibly intoxicated while treating a patient. He then wanted his former position back. The hospital refused, based on information that the physician had relapsed after a six-year period of sobriety and that his prior alcohol abuse and barbiturate addiction had gone undetected by his professional colleagues for many years.

"Under these circumstances, the physician would pose a direct threat even with reasonable monitoring," the EEOC concluded. "Moreover, even if the 'direct threat' standard was not satisfied, the employer could discipline the physician, up to and including termination, in accordance with any uniformly applied conduct rule consistent with business necessity, for example, a rule prohibiting drinking alcohol before or during a shift."

The EEOC fact sheet is posted on the Commission's Web site, *www.eeoc.gov/facts/health_care_workers.html*.

Lab Lobbying Blitz, *from p. 1*
Blitz participants urged a halt to the Medicare lab bidding pilot planned by the Centers for Medicare & Medicaid Services. Virtually all lab groups oppose competitive bidding, saying it treats lab services as a commodity, rather than as complex medical services essential for accurate diagnosis and treatment. Alan Mertz, president of the American Clinical Laboratory Association, which is pushing hard to get the bidding demo repealed, told *NIR*, "we're close to getting a sponsor" for legislation to do just that.

CMS planned to launch a bidding demo for independent lab services (excluding Pap smears and colorectal cancer screening) by April 1 in at least one of two sites. At press time, however, the sites had yet to be identified and other project details had yet to be finalized. The CMS media office confirmed to *NIR* that there is no official word yet beyond what has been previously reported—namely, the project is awaiting clearance from the Office of Management & Budget.

The lobbying blitz also drummed up support for the Allied Health Reinvestment Act (S. 605), introduced in the Senate last month by Maria Cantwell (D-WA), with eight co-sponsors, including Edward Kennedy (D-MA), chairman of the Health, Education, Labor & Pensions Committee. A sponsor is being sought to introduce a companion bill in the House.

Lab groups have coalesced around S. 605 because, while addressing all allied health professions, it would authorize support targeted to critical personnel shortage areas, and the lab workforce is already identified as one of those areas, Lavanty said. Under the bill, schools for clinical lab scientists and medical lab technicians would be eligible for grants and contracts and students would be eligible for scholarships and loans. In defining allied health, S. 605 specifically includes—at the certificate, associate, baccalaureate, or graduate level—clinical laboratory sciences, medical technology, and cytotechnology. If allied health increases are authorized this year, the next step is to lobby for the necessary appropriations next year, Lavanty said.

FDA Okays 1st Fully Automated WNV Donor Screening Test

The test has been used on an investigational basis by select blood centers to screen for WNV since August 2004. The FDA estimates that one million to three million people in the U.S. have been infected. The virus is typically transmitted to humans by mosquito bites.

The Food & Drug Administration this month announced approval of the first fully automated West Nile Virus (WNV) nucleic acid test for donor screening. The Procleix WNV Assay on the Procleix TIGRIS system is licensed to detect the virus's genetic material in plasma specimens from individual donors of blood, tissue, and organs, the FDA said. It is not intended for use on cord blood specimens or as an aid in the diagnosis of WNV infection.

The Procleix TIGRIS system is manufactured by Gen-Probe Inc. (San Diego) and is marketed by Chiron Corp. (Emeryville, CA), a Novartis business. It can be used to test individual donor samples or to test pooled samples from up to 16 individual donations of whole blood and blood components. This allows for flexibility, the FDA said, in testing individual donor samples more extensively during periods of high WNV activity. The system's high-throughput, Novartis said, allows blood centers to process 1,000 blood samples in under 14 hours.

What distinguishes the new assay system from the previous FDA-approved semi-automated platform is the capability for full automation, "reducing the potential for human error while accelerating donor screening to enhance the safety of the blood supply," said Jesse Goodman, MD, director of the FDA Center for Biologics Evaluation & Research.

New CPT Lab Codes Subject To CLIA Edits

Effective April 2, local Medicare contractors will implement CLIA edits for HCPCS codes new in 2007, including the 11 new codes added to the CPT 80000 series on this year's Part B lab fee schedule. The new lab codes include tests for conditions such as liver cancer, heart disease, West Nile virus, and staphylococcus.

To receive payment, clinical laboratories performing these tests must have a CLIA registration certificate, a certificate of compliance, or an accreditation certificate. Otherwise, payment will be denied, said the Centers for Medicare & Medicaid Services (CMS Change Request 5457). The edits do not include HCPCS codes for waived tests or provider-performed microscopy, the agency said.

New lab codes subject to CLIA edits are:

Chemistry

82107 Alpha-fetoprotein; AFP-L3 fraction isoform and total AFP (including ratio)
83698 Lipoprotein-associated phospholipase A2 (Lp-PLA2)
83913 Molecular diagnostics; RNA stabilization

Immunology

86788 Antibody; West Nile virus, IgM
86789 Antibody; West Nile virus

Microbiology

87305 Infectious agent antigen detection by enzyme immunoassay technique, qualitative or semiquantitative, multiple-step method; Aspergillus
87498 Infectious agent detection by nucleic acid (DNA or RNA); enterovirus, amplified probe technique
87640 Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, amplified probe technique
87641 Infectious agent detection by nucleic acid (DNA or RNA); Staphylococcus aureus, methicillin resistant, amplified probe technique
87653 Infectious agent detection by nucleic acid (DNA or RNA); Streptococcus, group B, amplified probe technique
87808 Infectious agent antigen detection by immunoassay with direct optical observation; Trichomonas vaginalis

New HCPCS Code Added To Fecal Occult Blood NCD

Effective April 1, the new HCPCS code G0394 for occult blood test (e.g., guaiac), feces, for single determination for colorectal neoplasm (i.e., patient was provided three cards or single triple card for consecutive collection) is added to the list of covered codes for the National Coverage Decision (NCD) for the Fecal Occult Blood Test. The change will be included in the April 2007 release of the edit module for the lab NCDs (CMS Change Request 5514).

The lab NCDs encompass 23 of the most frequently ordered lab tests and establish uniform payment rates, eliminating previous carrier variations in fee amounts based on local medical review policies. They were developed in a negotiated rulemaking and published as a final rule on November 23, 2001. The NCD edit module is updated quarterly as necessary to reflect coding and other substantive changes to the NCDs.

Genetic Anti-Discrimination Bill Advances In The House

House floor action on the legislation, which has broad bipartisan backing, is expected soon, possibly by the end of this month. In the Senate, a similar bill (S. 358) cleared the HELP Committee on January 31 (NIR, 28, 8/Feb 12 '07, p. 8).

Bipartisan legislation that would make it unlawful for health plans and employers to discriminate against individuals based on genetic information (H.R. 493) was approved by the House Ways & Means Committee March 21, and at press time, the House Energy & Commerce Committee was expected to quickly follow suit.

The legislation contains the key health plan and employer provisions of H.R. 493 that the House Education & Labor Committee approved February 14 (*NIR, 28, 9/Feb 26 '07, p. 8*), but was amended to also provide for enforcement against health plans that violate the law and fines for an employer that sponsors the plan.

Under the bill, employers would be prohibited from using genetic information when making decisions on hiring, firing, job placement, or promotion. Group health plans and other health insurers in the group and individual market would be barred from using genetic information to deny coverage or determine premium rates and could not require individuals to undergo genetic testing. The prohibitions apply as well to employment agencies, labor unions, and Medicare supplemental policy plans.

As noted in a summary of the bill, "genetic information" can include various data, such as genetic tests of an individual or family member, the occurrence of a disease in family members when applied to a person other than the one with the disease, and requests for genetic services, such as counseling.

Get Ready To Celebrate

National Medical Laboratory Professionals Week
April 22-28

This year's theme:
Quality Care from Quality Professionals.

Sponsors:
- American Society for Clinical Pathology
- American Association for Clinical Chemistry
- American Association of Blood Banks
- American Medical Technologists
- American Society for Clinical Laboratory Science
- American Society for Cytopathology
- Association of Public Health Laboratories
- Clinical Laboratory Management Association
- College of American Pathologists
- National Society for Histotechnology

This annual event aims to increase recognition among the general public and in the healthcare community of the vital role that medical lab professionals play in assuring quality care and patient safety. Many members plan displays, open houses, radio and TV spots, and other activities in their locale. Planning guides, posters, and promotional materials are available on the Web home pages of the sponsoring organizations.

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