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Senate Bill Would Greatly Expand 'Home Brew' Test Regulation

Lab and pathology groups have raised strong concerns that added federal oversight of lab-developed tests could stifle innovations in the fast-growing field of molecular diagnostics and other gene- or protein-based testing.

Legislation was introduced in the Senate March 2 that would designate laboratory-developed tests (LDTs) as medical devices subject to premarket review by the Food & Drug Administration.The bill's sponsor is Edward Kennedy (D-MA), chairman of the Health, Education, Labor & Pensions Committee; the co-sponsor is Gordon Smith (R-OR), ranking member of the Special Committee on Aging.

Under the bill—S. 736, the Lab Test Improvement Act—LDTs (also referred to as home-brew or in-house developed tests) would generally be categorized as class II devices subject to special controls. LDTs intended to screen donated blood or to diagnose a contagious disease or condition that is highly likely to be fatal would be assigned to class III. The Health & Human Services Secretary would have discretion to assign an LDT to class I (general controls only) if certain safety and effectiveness requirements are met.

The bill would require the Secretary to issue guidance on the special controls to which all LDTs or subcategories of these will be subject. Also, labs that make class II LDTs would generally be exempt from biennial FDA inspection. *Continued on p. 2*

INSIDE NIR

NPI Compliance Deadline: Ready Or Not?

Warned of a lack of readiness in the healthcare industry and delays in vital government guidance, pressure is building for a contingency period to allow providers and health plans to achieve full compliance with National Provider Identifier requirements and still get paid while working toward that goal.

At press time, however, the compliance deadline remains May 23. Thereafter, only NPIs will be recognized; legacy identifier numbers will be rejected. (Small health plans have an additional year.) NPIs were established to facilitate electronic healthcare data exchange under HIPAA (the Health Insurance Portability & Accountability Act of 1996). Every healthcare provider must obtain an NPI, a 10-digit numeric identifier that does not expire or change.

The National Committee on Vital & Health Statistics (NCVHS) has called for a six-month contingency plan, depending on when the Health & Human Services Department releases a key NPI dissemination notice. The NPI data cannot be released until HHS publishes this notice in the *Federal Register*.

The American Clinical Laboratory Association has urged CMS to grant a one-year extension of the NPI deadline, *Continued on p. 6*

The lab-developed test (LDT) legislation, Senate bill 736, would require labeling to indicate intended use and regulatory status, registration of manufacturers and a list of LDT tests, and reporting of adverse events. The bill also calls for a rulemaking to establish a specialty area for LDTs, with standards for proficiency testing, plus "a mechanism for enhanced reimbursement under federal programs for in vitro diagnostics and LDTs."

'Home Brew' Test Regulation, *from p. 1*

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*). Tighter controls are needed for IVDMIAs, the FDA says, because of their novel technologies and the potentially lethal risks. Of particular concern is the fact that the algorithm used to derive a test result is proprietary, making it hard for physicians to know how to interpret the result.

At an FDA public forum last month, lab and pathology groups criticized the agency's draft IVDMIA guidance as a significant departure from the discretionary enforcement approach the agency has followed in the past, limiting itself to regulating only analyte-specific reagents. A separate layer of FDA oversight is not needed, the groups said, because CLIA rules already address concerns over the clinical validity and use of LDTs (*NIR, 28, 9/Feb 26 '07, p. 1*).

Most recently, in a March 5 joint letter to FDA commissioner Andrew Eschenbach, MD, 18 lab and pathology groups said that because the IVDMIA draft represents a substantive expansion of FDA oversight, this new regulatory approach should be proposed through a formal rulemaking process. This would offer full procedural protections, the letter noted, such as "justification and analysis of impact, OMB review, availability of judicial review, and explanations of decisions via publication in the *Federal Register*. These protections are critical when an agency plans to adopt new binding requirements, as the FDA is planning through its IVDMIA initiative."

The groups also noted there are many technical concerns that need further clarification and public input, and asked Eschenbach to consider convening an interactive public workshop on IVDMIA requirements.

House Bill Would Overhaul CLIA Cytology PT Program

Bipartisan legislation has been introduced in the House that would suspend the current controversial program for cytology proficiency testing under CLIA (the Clinical Laboratory Improvement Amendments). The bill—H.R. 1237, introduced February 28 by Reps. Bart Gordon (D-TN) and Tom Price (R-GA)—would replace annual PT of pathologists and lab professionals who perform Pap smear work with annual continuing medical education to improve screening and interpretation skills.

The College of American Pathologists says H.R. 1237 reflects its recommendations to make cytology quality assessment parallel to the approach the Food & Drug Administration uses to oversee mammography facilities. The bill is similar to legislation unveiled in the House and the Senate last year, but not acted on (*NIR, 28, 4/Nov 20 '06, p. 3; 28, 1/Oct 9 '06, p. 3*).

The newly introduced House bill kicks off a renewed push, spearheaded by CAP, for a legislative overhaul of the existing cytology PT program. CAP says the program—which operates under rules written in 1992 but not enforced nationally until 2005—does not reflect current cytology science and clinical practice.

Meantime, the American Society for Clinical Pathology has prodded the Centers for Medicare & Medicaid Services to "fast track" proposed revisions to the cur-

For 2007, cytology PT testing continues under the current CLIA program. CAP and ASCP are the two nationally approved PT providers. The Maryland health department runs an approved program for specimens of state residents.

rent CLIA cytology PT rules. In remarks to the Clinical Laboratory Improvement Advisory Committee during its February 14-15 meeting in Atlanta, GA, Matthew Schulze, ASCP's senior manager for federal and state affairs, noted that despite "initial assurances that the proposed revisions would be expedited, they have yet to be released for public comment and to obtain clearance from the Office of Management & Budget, a process that can take months."

CLIAC last year provided consensus recommendations to CMS for revamping the current rules, including changes to scoring, the number of challenges per testing event, the testing interval, field validation of slides, and allowing for new technologies as an alternative to glass slides. CMS agreed to consider these issues in its proposed revisions and set a target release date of February 2007. That deadline was not met, and agency officials now say the release is planned for "sometime this year." CMS also cautions that finalizing revisions could take several years at least.

To ASCP, the delay in proposing revisions is "unacceptable," Schulze told CLIAC. "It's unclear to us the breadth of the necessary regulatory revisions, but the rules on cytology PT are only a few pages long. When CMS had [to draft] rules to implement the Part D drug benefit, it had to draft over one thousand pages of regulations [and completed the job] in approximately one year."

CMS first agreed to revisit the cytology PT rules in late 2005, not long after the House passed a bill to suspend the current program until certain changes backed by CAP were considered (*NIR, 27, 6/Jan 9 '06, p. 3*). While revisions are in the works, CMS said it would use PT to emphasize improvement vs. punitive sanctions (*NIR, 27, 8/Feb 6 '06, pp. 4-5*).

MedPAC Outlines Options For Physician Fee Fix

Under current law, the physician fee update is scheduled for a 10% cut in 2008 unless Congress decrees otherwise. Lawmakers blocked a 5% cut this year, approved a zero update, and introduced bonus payments of up to 1.5% for doctors reporting certain quality measures.

In its March 1 report to Congress, the Medicare Payment Advisory Commission spelled out the pros and cons of alternatives to the current Sustainable Growth Rate (SGR) formula used to update Medicare physician fees. But the panel did not recommend one over another, due to differences among members over use of spending targets to control program growth, nor did it estimate the costs of replacing the SGR system.

The SGR determines the annual physician fee update in line with a spending target tied to growth in the gross domestic product. When actual spending exceeds the target, negative updates are triggered, as has happened since 2000, though Congress has stepped in repeatedly to block the cuts.

One path Congress could take, says MedPAC, is to repeal the SGR and focus on new incentives to reward quality care. Or Congress could replace the SGR with a new spending target system that would apply ultimately to all providers, though this option should also include rewards to physicians for quality performance.

Release of the report signaled the start of congressional deliberations over SGR reform. The House Ways & Means and the Senate Finance Committees held hearings on the report the same day it was released. In a February 28 joint letter to Ways & Means chairman Charles Rangel (D-NY), 77 medical organizations advocated a new update system reflecting increases in practice costs. If immediate SGR repeal is not possible, the organizations said, Congress should provide transitional positive fee updates until the SGR is eliminated, starting with 1.7% in 2008.

CMS Proposes Switch To Single Medicare ABN

The agency announced the proposed change in the February 23 Federal Register*, with a 60-day comment period, through April 24.*

The two versions of the current Advance Beneficiary Notice (ABN) would be replaced by a new single version that clinical laboratories and other Medicare providers would be required to use, under a recent proposal by the Centers for Medicare & Medicaid Services. No planned effective date was specified, but the draft form has "June 2007" at the bottom, though it is not yet clear if this is a planned implementation or an anticipated regulatory clearance date.

The ABN is used when there is genuine doubt that Medicare will pay for an otherwise covered service due to lack of medical necessity or other limits. The ABN alerts beneficiaries that they are potentially liable to pay for a denied item or service claim. Before the beneficiary can be billed, the provider must obtain a valid ABN signed by the beneficiary (or representative) prior to furnishing the service. (In emergency or urgent care cases, CMS says, ABNs are never required).

Until the ABN change is finalized and approved, CMS says, Medicare providers and suppliers must continue to use currently approved versions—CMS-R-131-G for general use or CMS-R-131-L, which is specific to physician-ordered lab tests. (For lab tests, either form may be used.) CMS has required use of these single-page, standardized ABNs since 2003.

The proposed new ABN (*see p. 5*) is written in more beneficiary-friendly language, CMS says, and meets both general and lab-specific needs. The main changes include:

- ❑ A more precise title: "Advance Beneficiary Notice of Noncoverage"
- ❑ A new grid to identify the item/service, the reason why Medicare payment denial is likely, and the estimated cost to help the beneficiary decide whether or not to receive the item/service.
- ❑ Addition of the 1-800-MEDICARE number and information about the beneficiary's right to demand that Medicare be billed for a coverage decision.
- ❑ Increasing the number of beneficiary choices from two to three to allow them to pay out-of-pocket when they desire.
- ❑ Allowing a place for other insurance information to be recorded.
- ❑ Describing the significance of the signature, which indicates that the beneficiary has received the ABN, understands its contents, and freely assumes financial responsibility.

Of special note for labs, the reasons for noncoverage preprinted on the current lab-specific ABN are still appropriate for use in the grid on the proposed new ABN that matches the reasons for likely denial and estimated service cost with particular services, CMS says. These reasons include:

- ❑ "Medicare does not pay for these tests for your condition."
- ❑ "Medicare does not pay for these tests as often as this (denied as too frequent)."
- ❑ "Medicare does not pay for experimental or research use tests."

ABNs are usually given as hard copy, CMS notes. There is no provision for alternative uses of information technology to deliver ABNs; however, those required to deliver them may store the signed copies electronically.

The draft ABN proposal is posted at *www.cms.hhs.gov/PaperworkReductionActof1995*. At the menu on the left, click on "PRA listing," then scroll down or search for

"CMS-R-131." Comments are due April 24 at: CMS, Office of Strategic Operations & Regulatory Affairs, Division of Regulations Development – C, Attn: Bonnie L. Harkless, Room C4-26-05, 7500 Security Blvd., Baltimore, MD 21244-1850.

(A) Supplier/Provider:

(B) Beneficiary Name: _____ **(C) Identification Number:**_____

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare does not pay for things listed below, you may have to pay.

We think Medicare will not pay for the "**Item(s)/Service(s)**" listed below because of certain rules for coverage described under "**Reason.**" You still can receive this care, since you or your health care provider may have good reason to think you need it, but it is likely you or other insurance will have to pay. We have estimated about how much you may have to pay under "**Estimated Cost**" to help you decide whether or not to receive the care listed.

(D) Item(s)/Service(s):	(E) Reason:	(F) Estimated Cost:

- **Medicare wants us to be sure you make an informed choice**. Read this whole notice, which explains our opinion that Medicare won't pay. **This is not an official Medicare decision**. Ask us for more explanation if you need it. For questions on this notice or on Medicare billing, you can also call **1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048)**.
- **You need to make a choice about receiving the care listed above**. You must choose **only one** of the three options below. **We cannot choose for you.**
- **We must bill Medicare when you ask us to.** We may help you with billing other insurance if you choose Option 2 or 3 below, though Medicare cannot require us to do this.

(G) OPTIONS

❑ **1. Do not provide me with anything listed above.** With no care provided, there is no billing. I understand that **I cannot appeal** to Medicare when choosing this option.

❑ **2. Provide me with what is listed above. I do not want Medicare billed. I agree to be responsible for payment.** I understand that **I cannot appeal** to Medicare when choosing this option.

❑ **3. Provide me with what is listed above. I want you to bill Medicare for an official decision on payment. You can ask for payment now that will be refunded if Medicare pays.** I understand that if Medicare does not pay, **I can appeal that decision.**

(H) Other insurance to consider for billing: _____

Your signature below means that you have received this notice and understand it. You will also get a copy.

(I) Signature:	(J) Date:

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NPI Compliance Deadline, *from p. 1*

during which legacy identifier numbers could continue to be used in both electronic standard and paper transactions until NPI compliance is achieved. This would avoid serious disruptions to claims processing and the potential loss of millions in reimbursement, says ACLA, which will post a White Paper on the NPI impact on labs on its Web site at *www.clinical-labs.org*.

Both ACLA and the NCVHS warn that HHS delay on the NPI dissemination is hampering the ability of trading partners to exchange NPI data and allow sufficient time to test the software among themselves. Many health plans need the data to crosswalk legacy numbers to NPIs, the NCVHS noted, and providers need to obtain the NPIs of other providers, since claims require the number of both the primary billing provider and the ordering or referring provider.

In addition, full compliance is not feasible by May 23, the groups say, because many providers still do not have an NPI. More than 1.7 million NPIs have been issued, the NCVHS noted, but many providers have yet to sign up, including many who don't yet realize they must.

Granting a contingency period for NPI compliance is not unprecedented. CMS did so when implementing standards for electronic transactions / code sets and remittance notices, giving most providers up to two years to become compliant.

For more NPI information, go to *www.cms.hhs.gov/NationalProviderStand.* Providers can apply for an NPI online at *https://nppes.cms.hhs.gov* or by calling the NPI enumerator at 1-800-465-3202, CMS says.

Next MUE Round Hits Pathology, Lab Codes For First Time

As of April 1, Medicare is scheduled to begin the second round of "medically unlikely" edits, and it will include, for the first time, several hundred claims processing edits for pathology and laboratory services, including a controversial set of Pap smear codes.

The MUEs limit 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.

The Centers for Medicare & Medicaid Services launched the first round of MUEs on January 1 of this year. The edits encompassed approximately 2,800 codes, mostly surgical procedures, the agency said, and were based on anatomic considerations considered non-controversial (for example, one appendectomy per patient per day). But the agency said it would allow an appeals process for claim line items denied because of an MUE edit.

The April round of MUE implementation and the third phase, set for July 1, will include edits based on other criteria such as CPT code descriptors, CPT coding instructions, and the nature of the analyte.

But the fourth phase, scheduled to start October 1, will introduce a significant change to the criteria—a key point noted during a recent LABline audio conference sponsored by the American Clinical Laboratory Association, said

Liability Alert: MUE-Denied Claims

Excess charges due to units of service greater than the MUE may not be billed to the beneficiary—this is a provider liability, CMS has noted—and this provision can neither be waived nor subject to an Advance Beneficiary Notice.

David Mongillo, ACLA's vice president for policy and medical affairs. The session featured CMS project official Lisa Zone and MUE project contractor Dr. Niles Rosen of Correct Coding Solutions, LLC (Carmel, IN).

"To date, none of the proposed MUEs are based on clinical judgment," Mongillo told *NIR*. "But Phase IV of the edits, comprising about 40% of the total to be proposed, will be based on clinical judgment," injecting a degree of "professional judgment subjectiveness." The current criteria are more objective, he said, for example, anatomic and logistical considerations such as urine collection issues.

The College of American Pathologists said the introduction of clinical judgment as a criterion requires close collaboration with CMS to make sure that the non-anatomic edits are set "through an open and transparent process and do not adversely affect provider payments."

Both CAP and ACLA submitted comments to CMS on the April round of MUEs and are reviewing for comment the list of codes proposed for Phase III. Both organizations recommended that the Phase II edits for Pap smear codes allow for three units of service, rather than one, to account for specific cases. But the MUE project contractor responded that if a provider needs to use an MUE of greater than one in these instances, the additional specimens may be reported with a modifier 59. CAP argues that "the MUE should be set at the appropriate level, rather than rely on a modifier for those cases that might fall below the stated MUE. If CMS does not publish the MUEs for provider use, a provider will not know when to use a specific modifier. Also, not all private payers use or recognize modifiers, and should they adopt MUEs, providers could face denials of claims in the cases above."

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."

Lab Groups Lobby Against Medicare Competitive Bidding

At press time, the Medicare competitive bidding demonstration for independent lab services remained in regulatory limbo, while clinical laboratory groups are stepping up their lobbying to get Congress to halt and even repeal the demo project altogether.

The official word on the demo to date is that the project is awaiting final clearance by the Office of Management & Budget. Nor has the Centers for Medicare & Medicaid Services said anything official about extending the previously announced April 1 start of the demo, even though the agency has yet to propose demo sites and solicit bids.

The legislative vehicle to block the demo would not likely be a stand-alone bill, but rather a broader piece of legislation, Jason DuBois, vice president for government relations at the American Clinical Laboratory Association, told *NIR*. The lobbying blitz is targeting key lawmakers whose districts include metropolitan statistical areas that are potential demo sites, DuBois said, noting that briefings have already been held with senators and representatives from Washington, Tennessee, Colorado, Texas, and New York, among others.

Are Medicare Managed Care Plans Overpaid?

About eight million Medicare beneficiaries are enrolled in managed care plans.

A key Democratic health leader and the Medicare Payment Advisory Commission think so, though some Republicans and managed care groups dispute this, saying the pay rates go toward offering additional benefits and lower out-of-pocket costs that are not available under traditional Medicare fee-for-service (FFS).

Medicare pays 12% more to Medicare Advantage plans than to FFS plans, even though most FFS plans deliver care more efficiently, MedPAC chairman Glenn Hackbarth told a March 1 hearing of the House Ways & Means health subcommittee. MedPAC recommends that managed care payment benchmarks be pegged at 100% of FFS costs. Though noting that beneficiaries should have the option to enroll in managed care, Hackbarth said Medicare needs plans that deliver care efficiently to keep the program sustainable financially.

Subcommittee chairman Pete Stark (D-CA) has made no secret that he would consider reducing managed care pay rates to help pay for other Medicare initiatives, including, for example, a fix to the physician fee update system. Paying Medicare Advantage plans at the same level as FFS would save $65 million over five years, the Congressional Budget Office has estimated. But some Republicans on the Ways & Means panel warned that cutting managed care rates could force MA plans to cut back on benefits for seniors or increase cost-sharing, or both.

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