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FDA Restraint Urged In Regulating Lab 'Home Brew' Tests

Another layer of oversight is not needed since CLIA rules already address concerns about the clinical validity and use of lab-developed tests, say lab and pathology organizations.

Clinical laboratory and pathology groups are calling on the Food & Drug Administration to clarify and limit its draft guidance that would expand agency oversight of lab-developed tests (also known as home brews), including premarket review for new types of gene- and protein-based tests.

In comments to a recent FDA public forum on the guidance, the American Clinical Laboratory Association and the College of American Pathologists said current lab testing requirements under CLIA (the Clinical Laboratory Improvement Amendments) already provide sufficient safeguards for home brew use without impeding genetic testing advances.

ACLA specifically noted that enforcement of the CLIA rules is "consistent with the FDA's emphasis on 'smart regulation' and following the 'least burdensome' approach to tackle the issues raised in the guidance."

In the draft guidance issued last fall, the FDA said it will require premarket review for new types of DNA tests that combine assays and algorithms to produce results tailored to a specific patient—tests which the agency calls In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). *Continued on p. 2*

INSIDE *NIR*

Allied Health Funding Set At $4M Thru FY '07

President Bush has signed into law legislation that would establish, for the rest of fiscal 2007 (which ends September 30), a funding level of $4 million for the Title VII allied health account, which includes training programs for medical technologists and medical laboratory technicians.

The funding was part of a continuing resolution that provides $463.5 billion for federal agencies whose appropriations bills have not been enacted, including the U.S. Department of Health & Human Services. The resolution (H. J. Res. 20) cleared the Senate on February 14 and the House on January 31. The President signed it February 15.

For Title VII health professions programs, the spending package provides $185 million, up $40 million (27%) over FY 2006. The added dollars include $32 million to restore geriatrics training programs to the FY 2005 level and $8 million more for primary care medicine and dentistry programs. *Continued on p. 7*

Lab 'Home Brew' Tests, *from p. 1*

Most of these tests will likely be ranked as medical devices subject to class II and III special controls, the FDA said. Examples include proprietary tests to diagnose and guide treatment for breast and other cancers, cardiovascular disease, and Alzheimer's disease, among others *(NIR, 27, 22/Sep 25 '06, p. 1)*.

The FDA says tighter controls are needed because of the novel technologies involved and the potentially lethal risks. Of particular concern to the agency is the fact that, typically, the algorithm used to derive a patient-specific result is proprietary, making it difficult for the test-ordering physician to know how to interpret the result.

If the agency decides it should provide more stringent oversight, CAP says, it should provide clear guidance on how the FDA requirements would mesh with CLIA rules.

What Is & Isn't An IVDMIA?

ACLA urges the FDA to address IVDMIA issues in a formal rulemaking process, narrow and clarify the IVDMIA definition, and work to strengthen CLIA oversight. ACLA says the following should be part of the IVDMIA definition:

- ❑ Comprises a new, single-source test system.
- ❑ Uses patient and/or clinical data derived from one or more in vitro diagnostic assays together with a proprietary, non-published algorithm.
- ❑ Generates a patient-specific, binary result intended definitively to diagnose a condition or direct behavior for treatment or cure.
- ❑ Presents significant safety and effectiveness risks not present in test systems that have become part of the standard of care.

In ACLA's view, test systems should not be deemed IVDMIAs when they meet one or more of the following criteria: low-risk consequences of invalid or inaccurate test results, independent verification by one or more labs, support of clinical relevance in peer-reviewed literature, transparent algorithms, interpretation support for clinicians, support in clinical guidelines, CPT code assignment, and payer recognition.

Just a few days before the public meeting, the FDA cleared its first IVDMIA test—MammaPrint, designed to determine the likelihood of breast cancer recurrence. The test was developed by Agendia, based in Amsterdam, and has been sold in Europe since 2005. It uses microarray analysis to predict whether existing cancer will spread, based on the activity patterns of 70 genes linked to tumor recurrence in a sample of a surgically removed breast cancer tumor. An algorithm produces a score indicating whether the patient is at low risk or high risk for the cancer spreading to another site.

The FDA says it will soon publish a special controls guidance document describing types of data that should support claims for genetic profiling for breast cancer prognosis.

Meantime, lab and pathology groups are keeping an eye on Sen. Edward Kennedy (D-MA), chairman of the Senate HELP Committee, to see if he moves forward with a bill for tighter FDA oversight. He has expressed an interest in doing so, and a draft, circulated in his office late last year, would make most lab-developed tests subject to class II or III controls.

House Bill Calls For Permanent TC 'Grandfather' Protection

The protection currently is set to expire at the end of this year.

The push to get Congress to make permanent the current "grandfather" protection for certain pathology technical component (TC) billings by independent labs got another boost under a bipartisan bill recently introduced in the House.

The legislation—H.R. 1105, sponsored by Reps. John Tanner (D-TN) and Kenny Hulshof (R-MO)—would permanently allow certain independent clinical laboratories to bill Medicare directly for the TC of pathology services to hospital inpatients and outpatients.

A companion measure was introduced in the Senate January 31 *(NIR, 28, 8/Feb 12 '07, p. 1)*. Key backers of the legislation—entitled the Physician Pathology Services Continuity Act of 2007 in both Houses—include the College of American Pathologists, the American Society for Clinical Pathology, and the American Clinical Laboratory Association.

Similar bills failed to move in Congress last year, but lawmakers did step in to extend the grandfather protection for an additional year, through December 31, 2007, thus blocking the Centers for Medicare & Medicaid Services from going ahead with plans to eliminate the protection at the start of this year.

The grandfather protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end it. The agency contended that Medicare already pays for the TC as part of the hospital's DRG payment, and labs should seek TC reimbursement from the hospital, not from Part B. Congress has repeatedly blocked the agency, however, most recently in the Tax Relief & Health Care Act of 2006, enacted last December.

Under CMS policy, the hospital is the "protected" entity, not the lab. Hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. CMS also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology (Transmittal AB-01-47).

Physician Fee Fix A Priority, Say Key House Leaders

Fixing the Medicare formula for annual physician fee updates to avoid a wave of deep cuts projected over the next decade is a bipartisan legislative priority, House subcommittee health leaders assured attendees at a recent American Medical Association advocacy conference. But how to fix it and pay for it remain to be worked out, they added.

Rep. Dave Camp (MI), the ranking Republican on the House Ways & Means health subcommittee, said the current Sustainable Growth Rate (SGR) system used to calculate fee updates is "unsustainable and unacceptable." But any fix will be difficult, he pointed out, because the price tag for tackling the problem is a projected $252 billion.

Another difficulty, said Rep. Frank Pallone (D-NJ), chairman of the House Energy & Commerce health subcommittee, is that the Democratic leadership has adopted

pay-as-you-go rules, which require that new federal spending be offset by cuts elsewhere.

Pallone said he plans to hold hearings on SGR reform after receiving recommendations due March 1 from the Medicare Payment Advisory Commission, whose report on SGR alternatives was required in the Deficit Reduction Act of 2005.

The Bush administration drew sharp fire from Rep. Pete Stark (D-CA), who chairs the House Ways & Means health subcommittee, for not addressing Medicare physician payment reform in its fiscal 2008 budget request sent to Congress this month. It's "a significant problem that … has been allowed to fester and grow," he said. The President's budget assumes an 8% cut in physician spending next year.

Overhauling The SGR System

Congress blocked a 5% cut in Medicare physician fees scheduled for this year and instead continued a freeze on fees at 2005 levels, while approving a new 1.5% bonus payment to doctors who voluntarily report certain quality measures on their Part B claims *(NIR, 28, 5/Dec 15 '06, p. 1)*. A 10% cut is projected for 2008 unless Congress steps in again, note pathology and other physician groups, which warn that further projected cuts will drive doctors out of Medicare and threaten beneficiary access to care.

The SGR formula in current law is based on a target rate of growth for Medicare spending for physicians' services. It ties reimbursement to a number of factors, including growth in the volume of services relative to growth in the national economy. The SGR compares actual spending to target spending and adjusts the update. When actual spending exceeds a target rate, the update is negative.

Since 2002, Medicare physician spending has been above the SGR target, triggering negative fee updates, but Congress has blocked the cuts. But because the targets have not changed, this has only delayed the negative updates. "As a result, the cumulative SGR formula calculates even larger payment cuts and a longer period of negative updates," MedPAC analyst Dana Kelley has noted in briefings of the panel.

Lawmakers appear anxious to find a long-term solution and avoid having to intervene each year with a short-term fix. But the money for an SGR overhaul would have to come from other segments of the Medicare budget, including other healthcare providers. Comprehensive SGR reform would cost $218 billion over 10 years, the Congressional Budget Office has estimated.

MedPAC chairman Glenn Hackbarth has already said that the Commission's SGR report will not recommend one course of action, but rather will present a series of changes that could be phased in over several years, including the advantages and disadvantages of different options.

Several options were outlined in a draft report discussed by MedPAC earlier this year. One would be to repeal the SGR, not replace it with targets, and develop new approaches such as linking payment to quality. Another option would be to use targets but reconfigure the SGR to apply to all of Medicare, be adjusted by region, and give providers an array of options for sharing in gains that result from their improved efficiency. Congress could also set targets and adjust payments by physician specialty, rather than across-the-board, as is now the case, according to a MedPAC staff analysis.

Bush's Health Budget Gets A Drubbing From Democrats

A day after the President sent his fiscal 2008 budget request to Congress February 5, Health & Human Services Secretary Michael Leavitt was off and running a gauntlet of House and Senate hearings to defend the Bush administration's proposed healthcare spending cuts against Democratic attacks.

Democrats denounced massive Medicare provider cuts while Medicare managed care programs are spared, and questioned the level of funding requested for the State Children's Health Insurance Program (SCHIP). But Democrats also face a major challenge in getting a handle on rising healthcare costs, projected to top $4.1 trillion by 2016 (*see box, p. 6*), while at the same time fulfilling their pledge to reduce federal spending and offset any new spending with cuts elsewhere.

Rep. John Dingell (D-MI), who chairs the House Energy & Commerce Committee, told Leavitt that the growing number of uninsured Americans, now estimated at 47 million, warrants immediate attention, yet "this administration continues to work to shred the health insurance safety net."

President's Proposals For Medicare, SCHIP

To curb Medicare spending growth, the Bush administration has proposed net savings of nearly $76 billion over the next five years, $65.6 billion from legislative changes and $10.2 billion from administrative changes. This would slow the annual rate of spending growth from 6.5% to 5.6%, according to HHS budget documents. Most of the savings will come from freezes or reductions in payments to providers, including hospitals, skilled nursing facilities, hospices, home health agencies, and ambulatory surgical centers. The budget also assumes a savings of $2.38 billion over the next five years by introducing competitive bidding nationwide for Medicare lab services.

The SCHIP funding request of $5 billion over the next five years came under fire from Democrats, who said it was not enough to cover current enrollment. At least $15 billion is needed for that, they said. Democrats also criticized the administration's proposal to narrow SCHIP eligibility to children at or below 200% of the federal poverty level. As of January 1, 16 states covered children above 200% of the level, and as of July 2006, the upper income eligibility limit had reached 350% in some states.

Democrats On The Attack

Rep. Pete Stark (D-CA), chairman of the House Ways & Means health subcommittee, dismissed the Medicare and SCHIP proposals entirely. At a February 13 hearing, he told Leslie Norwalk, acting administrator of the Centers for Medicare & Medicaid Services, that he would set aside the budget blueprint and "create something from scratch." Stark chided the administration for advocating permanent, long-term Medicare spending cuts that, he said, even a GOP-run Congress would not enact.

Senate Finance Committee chairman Max Baucus (D-MT) criticized the squeeze on Medicare providers while Medicare managed care plans are slated for payment increases, and told Leavitt he plans hearings to find out if Medicare managed care plans are overpaid.

Baucus also told Leavitt that his priorities for SCHIP this year include: provide enough funds to maintain coverage for those currently enrolled; get coverage for six million children eligible for SCHIP or Medicaid but not enrolled; support state efforts to use SCHIP to cover more children; improve the quality of care under the program; and not do anything that would increase the number of uninsured.

Baucus has previously welcomed the President's proposals for a tax deduction for healthcare coverage and support for state efforts to cover the uninsured. Baucus says the political climate is shifting toward support for at least the start of a dialogue on national healthcare reform this year. In his view, reform should be guided by the need for universal coverage; shared responsibility in which employers, the individual market, and new pooling arrangements provide coverage; control of rising healthcare costs; high priority for preventive services; and expanded coverage for all Americans.

A bipartisan group of Senators, led by Ron Wyden (D-CA), has held out an olive branch to the President, asking him to work with them on healthcare reform, especially in areas where there is agreement, including coverage expansion through tax code changes, support for state efforts to cover the uninsured, small business and individual purchasing pools, emphasis on prevention, and transparency in the pricing and quality of healthcare services.

National Health Spending To Double In 10 Years

Healthcare spending in the U.S. will nearly double over the next decade to $4.1 trillion in 2016 and will run well ahead of growth in the overall economy, according to a new report from the Office of the Actuary at the Centers for Medicare & Medicaid Services.

And this puts added pressure on Congress to do something to rein in the rising costs.

According to the Actuary's report, by 2016:

- Healthcare will account for nearly 20 cents of every dollar spent, up from about 16 cents today.
- Federal, state, and local governments will be paying half of the national healthcare bill.
- The bill will average $12,782 for every man, woman, and child, an increase from $7,498 this year.

Core hospital and physician services are projected to rise 6% to 7% a year over the coming decade, higher than the forecast for overall economic growth.

And for the first time, the long-term estimates in the Actuary's report factor in the costs of the Medicare prescription drug benefit. The benefit will have a small net effect on aggregate spending, the report says, but it has had a big impact on how drug spending is distributed among payers, with the government absorbing about 40% of the national tab vs. 28% in 2005, before the benefit was implemented.

The Actuary's report is published online by the policy journal *Health Affairs*.

Meantime, the Democratic-controlled Congress is expected to reject the President's request to eliminate Medicare bad-debt reimbursement for unpaid beneficiary cost-sharing. Medicare provides these payments to ensure that hospitals do not use other patients to subsidize their Medicare patients. The budget plan would phase out these payments over a four-year period. Medicare currently pays 70% of unpaid co-pays and deductibles to hospitals and skilled nursing facilities. Eliminating bad-debt payment would save $180 million in FY 2008 and $7.1 billion over 2008-2012, according to HHS budget documents.

Allied Health Funding, *from p. 1*

The $4 million for allied health continues the steep cut imposed in 2006, when funding was slashed from the FY 2005 level of $11.8 million, a cut of 66%, notes an analysis by the Association of American Medical Colleges.

For fiscal 2008, the Bush administration's budget requests only $10 million for Title VII health professions programs and would eliminate allied health funding as well as most other Title VII programs, except scholarships for disadvantaged students.

Clinical laboratory and pathology groups plan to keep lobbying lawmakers to address the growing shortage in the lab workforce, pointing to numerous studies that show demand rapidly outstripping supply *(NIR, 28, 3/Nov 6 '06, pp. 4-6)*. In the last Congress, new spending for allied health was proposed in two major Title VII reauthorization bills—the Allied Health Reinvestment Act, which encompassed all Title VII programs, and the Medical Laboratory Personnel Shortage Act of 2005 (H.R. 1175), which established new scholarship and loan programs to recruit and retain clinical lab personnel *(NIR, 26, 12/Apr 11 '05, p. 2)*. The American Society for Clinical Pathology and the American Society for Clinical Laboratory Science, among others, lined up in support of the legislation. After it was referred to committee, however, no further action was taken.

'Pod' Lab Arrangements Draw Renewed Fire

'Pod' labs are business arrangements by which physician specialty groups—most notably, urologists, gastroenterologists, and dermatologists—seek to increase revenue from pathology referrals.

The controversy over "pod" or "condo" lab arrangements has reignited in the wake of calls from pathology and laboratory organizations for government agencies to crack down on these ventures. The Centers for Medicare & Medicaid Services, citing the potential for service overutilization, proposed new pod lab curbs last year, but yanked them from the final 2007 physician fee schedule rule.

The American Society for Clinical Pathology is mobilizing its members to get lawmakers to write to CMS urging prompt release of proposed rules, Matthew Schulze, ASCP senior manager for federal and state affairs, told *National Intelligence Report*. The American Clinical Laboratory Association has asked the HHS Office of Inspector General to issue a Special Fraud Alert on pod lab arrangements, warning of potential violations of the federal anti-kickback statute. The OIG began scrutinizing pod labs in 2004 *(NIR, 25, 17/Jun 21 '04, p. 1)*.

The College of American Pathologists wants the OIG to investigate allegations that some pod labs are offering free or deeply discounted software to referring physicians and defending this as allowed under the new safe harbor for electronic health records. CAP considers pushing for legislative curbs on pod labs premature for now, since CMS officials have said they plan to issue a proposed rule on the issues sometime this year, Gretchen Schaefer, director of communications advocacy at CAP, told *NIR*: "We'll wait and see what comes out from CMS, then decide." Since 2004, CAP has opposed pod lab proliferation on both regulatory and legislative fronts.

CMS had proposed tightening the Medicare benefits reassignment rule and the Stark safe harbor for in-office ancillary services to control the spread of pod labs, but in the end, opted to delay any final regulations to allow further consideration of the issues. Said acting CMS head Leslie Norwalk, "We want to be careful not to interfere with legitimate group practice arrangements that enable beneficiaries to get medical services at one location." This is essentially the argument that the American Medical Association made to CMS against the proposed controls.

Genetic Anti-Discrimination Bill Moves In The House

Prospects for enactment of genetic anti-discrimination legislation are promising in the Democratic-controlled Congress, say Capitol Hill watchers. The Senate has unanimously passed such a measure on two occasions, in 2004 and 2005, but further action stalled in the House under the previous GOP-run Congress.

Close on the heels of action by a key Senate health panel, the House Education & Labor Committee approved by voice vote February 14 a bill that would ban discrimination by employers and health insurers against individuals based on genetic information. Similar legislation (S. 358) cleared the Senate Health, Education, Labor & Pensions Committee on January 31 *(NIR, 28, 8/Feb 12 '07, p. 8)*.

The House bill, H.R. 493, would bar group health plans and other health insurers in the group and individual market from using genetic information to deny coverage or determine premium rates and from requiring individuals to undergo genetic testing. Medicare supplemental policy plans also would be prohibited from discriminating on the basis of genetic information.

Employers would be barred from using genetic information when making decisions on hiring, firing, job placement, or promotion.

The legislation, sponsored by Reps. Louise Slaughter (R-NY) and Judy Biggert (R-IL), has widespread support, with more than 205 other House members signing on to it. The bill now goes to the full House, where it is expected to pass, though some Republicans have raised concern that it does not explicitly protect embryos and fetuses. But Biggert disputes this, saying, "Let's just make perfectly clear that they are protected."

washington WATCH

New Web Site For Physician Quality Reporting Measures

Medicare has a new Web page, *www.cms.hhs.gov/pqri*, for its 2007 Physician Quality Reporting Initiative (PQRI), which replaces the Physician Voluntary Reporting Program (PVRP) established in 2006.

The PQRI program, authorized by the 2006 Tax Relief & Health Care Act, authorizes financial incentives to doctors who voluntarily report quality measures from July 1 through December 31, 2007. Those who are eligible may earn a bonus, subject to a cap, of 1.5% of total allowed charges for services covered under the Medicare fee schedule. Pathologists are not yet eligible, but the College of American Pathologists is working to get pathology quality measures implemented in 2008 *(NIR, 28, 7/Jan '29 '07, p. 1)*.

The initial PQRI list for 2007 includes testing for blood glucose and LDL cholesterol in patients with Types 1 and 2 diabetes, as well as quality measures for osteoporosis, melanoma, and end-stage renal disease. Thus far, 66 quality measures have been finalized, CMS says, adding that the list will be updated regularly on the new Web page.

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