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Lab Industry Assails Baucus Plan for $750M Levy on Labs

For the latest on health care reform legislation and the fate of lab and pathology priorities, join us at Lab Institute 2009, Sept. 23-25, at the Crystal Gateway Marriott Hotel, adjacent to Reagan National Airport in Arlington, Va. Details at www.g2reports.com.

While lobbying hard against a Senate Finance committee proposal to require a 20 percent copay for Medicare lab services, the clinical laboratory industry got hit with a bombshell Sept. 8 by a new Finance proposal to levy a fee of $750 million a year on clinical laboratories to help pay for health care reform.

The new fee is part of a series of levies on different parts of the health care industry to help finance health care system overhaul. Medical device makers would have to cough up $4 billion a year, drug companies $2.3 billion, and insurers $6 billion. The fees for these sectors would be allocated by market share.

The proposed fees were presented in the compromise framework for reform legislation released by Finance committee chairman Max Baucus (D-Mont.). The Baucus plan is estimated to cost $900 billion over 10 years. *Continued on p. 2*

Obama Urges Swift Action on Health Care Reform

In his health care reform address to a joint session of Congress on Sept. 9, President Barack Obama sought to explain his vision and buck up nervous Democrats, woo Republicans, and tell the American people what health care changes mean to them.

In a nod to supporters and a challenge to lawmakers, he said, "We came here not just to solve crises, but to build a future" and shaping needed health system reform is an economic and moral imperative for that future. The aim, he said, is "not to disrupt what we have, but to build on what works, not a new system from scratch," and offer more security and stability for all.

In presenting his agenda, Obama noted:

- If you have private health care insurance or insurance through Medicare or Medicaid or the VA, you can keep the physician and coverage you like. Reform will "make coverage work better for you," he said. Insurers would not be allowed to deny coverage for preexisting conditions, deny or reduce coverage when you get sick and need it most, or cap coverage in a given year or lifetime. They also would have to limit out-of-pocket costs and cover screening and other preventive services.
- If you do not have health insurance, you will have affordable quality choices through an insurance exchange where you can shop for coverage at competitive prices. Tax credits will *Continued on p. 7*

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Lab Industry Assails Baucus Plan, *from p. 1*

The Baucus bombshell drew swift return fire from the American Clinical Laboratory Association (ACLA) and the Advanced Medical Technology Association (AdvaMed).

"The plan to impose $750 million in taxes on clinical lab services—on top of other cuts—translates into a disproportionate cut for labs, will damage efforts to enhance prevention and wellness, and raise health care costs," said ACLA president Alan Mertz in a Sept. 8 statement.

The "tax unfairly targets the clinical laboratory industry among providers, which includes about 40,000 labs providing a myriad of critical health services to patients across the nation. When the $750 million in new fees are added to other cuts in the proposal, America's clinical labs could be facing cuts several times that of other providers."

ACLA noted that "everyone has to give" to achieve health care reform goals and that "the laboratory community has demonstrated support and willingness to do its fair share by agreeing to a reduction in future annual updates. However, ACLA strenuously objects to being singled out for additional cuts or taxes that are far beyond those taken by other providers."

Overall, Medicare payments for lab services have been reduced by 40 percent in real, inflation-adjusted terms between 1984 and 2004, Mertz said. "Congress has eliminated the annual update for clinical labs in 10 of the last 12 years. Since 2000, labs have received the smallest cumulative update of any Part B provider, only 5.6 percent compared to 12 percent for physicians and 34 percent for hospitals."

AdvaMed president and CEO Stephen J. Ubl said the devices industry "will vigorously oppose" what it called a "tax on medical devices and diagnostics." It is a form of double taxation, he said in a Sept. 8 statement, "since a portion of the hundreds of billions in cuts aimed at our customers, including hospitals, nursing homes, and home health care agencies, will be passed on to us. Moreover, the tax will fall most heavily on the small and emerging companies that are the backbone of our industry, often driving development of cutting-edge treatments and cures, and that are least able to pay new taxes. Additionally, the fee imposed on clinical labs raises serious concerns in view of other cuts to lab payments."

'Visit the Hill' Lobbying Day Set for Sept. 23

On the opening day of Lab Institute 2009, the American Association of Bioanalysts and the National Independent Laboratory Association will conduct "Visit the Hill" trips for all attendees who want to meet with their senators or representatives to discuss their priorities on pending legislative issues.

The morning program includes breakfast at 8, orientation at 8:30, and departure for Capitol Hill at 9:30. The second program will start at 12 noon and wrap up around 12:30 for departure.

If you wish to participate, contact Denise Hurt at AAB (aab@aab.org).

Lab Copay Threat

Clinical labs appear to have been spared the proposed copay for Medicare services that the Finance committee had been considering. The copay would save Medicare an estimated $24 billion over 10 years, according to the nonpartisan Congressional Budget Office. The Clinical Laboratory Coalition said it amounts to a massive cost shift to seniors and added administrative costs for labs to collect the money.

The Baucus framework does not include the copay, and it is absent from reform bills passed by House committees and the Senate HELP committee. Still, industry

sources caution, labs should not be confident it has been dropped until a final bill is written. The lab industry fended off a proposed lab copay in 2003 (while absorbing a freeze on lab fee updates for five years) and again in the fall of 2005 (*NIR, 27, 1/Oct. 17 '05, p. 1*).

Showdown Looming on Medicare Physician Fee Fix

Congress is expected to block a 21.5 percent cut in Medicare physician fees scheduled for next year, but it is uncertain whether lawmakers will approve a short-term fix to, or a fundamental overhaul of, the current Sustainable Growth Rate (SGR) formula.

The Senate is expected to go with a short-term patch. The framework for health care reform legislation released Sept. 8 by Finance committee chairman Max Baucus (D-Mont.) would cancel the cut under the SGR and grant an increase of 0.5 percent in 2010.

In the House, key committees have approved reform legislation that approves a basic overhaul. H.R. 3200, America's Affordable Health Choices Act of 2009, includes a provision to cancel the cumulative SGR cuts and base the fee update in 2010 on the Medicare Economic Index. Starting in 2011, the update would allow for growth based on the gross domestic product (GDP) plus 1 percent (2 percent for evaluation and management and preventive services).

Pathology 'Grandfather' Protection for TC Billings

H.R. 3200 also would extend the pathology "grandfather" provision for another two years through 2011. It expires at the end of this year. This provision allows independent clinical laboratories to bill Medicare Part B separately for the technical component (TC) of pathology services to hospital inpatients and outpatients.

The 'grandfather' protection affects hospital-lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare and Medicaid Services (CMS) first proposed to end the pathology TC billings. CMS said the TC is reimbursed as part of Medicare's Part A inpatient payment, and labs should seek TC payment from the hospital, not Part B. Since CMS proposed the payment policy change, Congress has repeatedly blocked it by granting temporary extensions of the protection, most recently in the Medicare Improvements for Patients and Providers Act of 2008.

The 'grandfather' protection applies to the hospital, not the lab, CMS says. 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.

Physician Quality Reporting Initiative

Also extended for another two years: the Physician Quality Reporting Initiative (PQRI), but not with the changes to the measures review process that the College of American Pathologists advocated. Of the 11 measures developed by the college for the PQRI, only two (for breast and colorectal cancer) have been approved, while nine developed in 2007 are stuck in the review pipeline (*NIR, 09, 13/July 13, p. 4*). Pathologists are entitled to an incentive payment of 2 percent of total allowed charges for successfully participating in the PQRI.

focus on: Genetic Testing

Lab-Developed Tests Back in the Federal Spotlight

In all, the report catalogues 1,442 molecular tests, of which 813 were clearly identified as LDMTs and 629 were tests that used commercially available full testing systems or ASRs (meaning that some are still lab-developed if they use commercial ASRs, the researchers noted).

Regulation of laboratory-developed tests—a highly controversial issue for the industry—is back in the federal spotlight in a new draft report that the HHS Agency for Healthcare Research and Quality (AHRQ) released for public comment.

The report, requested by the Centers for Medicare and Medicaid Services (CMS), looks at lab-developed molecular tests (LDMTs) using either FDA-regulated or self-developed analyte-specific reagents (ASRs) and intended for use solely in the test developer's lab. These tests are not actively regulated by the Food and Drug Administration (FDA), although the agency asserts it has jurisdiction over them.

'Horizon Scan' for Medicare

The draft technology assessment is a "horizon scan" summarizing scientific evidence, available as of Oct. 31, 2008, on the quality of "home brew" or "in-house" molecular tests of potential clinical relevance to the Medicare population age 65 and older. CMS requested evidence on molecular tests used for diagnostic purposes in symptomatic individuals, as prognostic indicators, to monitor response to therapy, and to choose therapies for a known disease entity or adjust medication dosing.

The study identified 1,442 molecular tests relevant to the Medicare population offered by 95 different laboratories. It further reviews the methods and processes developed to assess the analytical and clinical performance of molecular tests and summarizes the federal regulatory role and the quality standards developed by the industry and professional groups within the medical community. The AHRQ assigned the study to the ECRI Institute Evidence-Based Practice Center. The authors caution that the findings are their own and do not necessarily reflect the views of the AHRQ.

The report uses the term "molecular test" interchangeably with "molecular genetic test." It adopts the definition recommended by the Clinical Laboratory Improvement Advisory Committee: "an analysis performed on human DNA or RNA to detect heritable or acquired disease-related genotypes, mutations, or phenotypes for clinical purposes."

Excluded from the report are molecular tests used primarily for blood supply screening, tissue typing, epidemiological surveillance, pure research, and forensic purposes. Tests used to screen the pediatric population for inherited diseases of metabolism or other conditions are also outside the scope of this report.

'Red Flag' Warnings

The report, while mainly descriptive, said Vince Stine, government affairs program director for the American Association for Clinical Chemistry (AACC), has raised some concerns. Any use of the findings to suggest more federal oversight would be controversial, he told *NIR*. Added regulatory costs could push certain tests, such as "orphan" tests that are not cost-effective, out of the market to the detriment of patients, he noted.

The American Clinical Laboratory Association (ACLA) also has "a keen interest in this topic," David Mongillo, vice president for policy and medical affairs, told *NIR*. "We want to make sure that a report of this nature incorporates all the information that should be considered in a review like this."

Expanded federal regulation of molecular and other lab-developed tests (LDTs) remains highly divisive in the industry. Earlier this year, biopharmaceutical giant Genentech and AdvaMed, the trade group representing test manufacturers, separately petitioned the FDA to require that LDTs meet the same premarket review requirements that apply to commercial test kits (*NIR, 09, 1/Jan. 12, p. 1; 09, 7/Apr. 13, p. 1*).

Summary of Molecular Tests

Test Category	Number of LDMTs	Number of Tests Using Commercial Kits or ASRs	Total Number of Tests
Infectious disease tests, bacterial	153	151	304
Infectious disease tests, viral	259	214	473
Infectious disease tests, parasitic or fungal	35	0	35
Solid tumor tests	145	97	242
Hematopathology tests	221	167	388

ACLA and the College of American Pathologists strongly oppose expanded FDA oversight, arguing that requirements under the Clinical Laboratory Improvement Amendments (CLIA) are sufficient and thus CMS should have the lead role, with the FDA serving in a consultative capacity (*NIR, 09, 4/Feb. 23, p. 3*).

ACLA said the petitions, if accepted, would impose a "new, unnecessary regulatory framework on all LDTs," hindering the ability of clinical labs "to incorporate medical innovations quickly and effectively into patient care, provide rapid response to disease outbreaks, and provide treatment guidance for patients with rare diseases or in other situations where no FDA-cleared test exists."

To date, the FDA has applied its regulatory enforcement discretion over genetic testing only to ASRs and to a category of tests known as IVDMIAs (In Vitro Diagnostic Multivariate Index Assays) that use a proprietary algorithm to produce a patient-specific score that the ordering physician often cannot verify independently.

New 'Good Practices' Guidance for Molecular Diagnostics

Also in the federal spotlight is new "good laboratory practices" guidance to help clinical labs ensure the quality of the molecular genetic testing they provide for heritable diseases and conditions. Published by the Centers for Disease Control and Prevention (CDC), it contains recommendations from the Clinical Laboratory Improvement Advisory Committee (CLIAC).

The recommended practices address the total testing process (including the preanalytic, analytic, and postanalytic phases), lab responsibilities regarding authorized persons, confidentiality of patient information, personnel competency, considerations before introducing molecular genetic testing or offering new molecular genetic tests, and the quality management system approach to molecular genetic testing.

Of special note:

- Errors are more likely to occur during the preanalytic and postanalytic phases of the testing process, with most errors reported for the preanalytic phase. In the preanalytic phase, inappropriate selection of laboratory tests has been a significant source of errors.
- Labs should be sure that in addition to complying with federal and professional

rules governing patient confidentiality, they meet any state law requirements, including those more stringent.

- ❑ Labs should provide users with information on performance specifications and limitations before test selection and ordering to prepare users to make the appropriate choice and understand test results and implications.
- ❑ For each molecular genetic test, the following information should be provided:
  - — Intended use, including the nucleic acid target of the test (*e.g.*, genes, sequences, mutations, or polymorphisms), the purpose of testing (*e.g.*, diagnostic, preconception, or predictive), and the recommended patient populations.
  - — Indications for testing.
  - — Test method to be used, presented in user-friendly language in relation to the performance specifications and the limitations of the test.
  - — Specifications of applicable performance characteristics, including analytic and clinical validity and limitations of the test.
  - — Whether testing is performed with an FDA-approved or FDA-cleared test system, with a laboratory-developed test or test system that is not approved or cleared by FDA, or with an investigational test under FDA oversight.
  - — Information on appropriate collection, handling, transport, and submission of specimens.
  - — Patient information necessary for the laboratory to perform the test and report test results.
  - — A statement indicating that test results are likely to have implications for the family members of the patient.
  - — Availability of lab consultations regarding test selection and ordering, specimen submission, results interpretation, and implications of test results.
  - — Where possible, estimated costs for the testing.

More Controversy Brewing

Molecular diagnostics will also come into the federal spotlight this fall when a top HHS advisory panel takes up the highly charged issue of gene patents and licensing. The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is scheduled to consider a draft report and recommendations on the issue and its impact on research and clinical practice at its Oct. 8 meeting.

The issue flared into the headlines in May when the American Civil Liberties Union and a long list of pathology organizations and other plaintiffs filed suit charging that patents on two human genes associated with breast and ovarian cancer, BRCA1 and BRCA2, are unconstitutional and should be invalidated because genes are "products of nature." The suit is the first to apply the First Amendment to a challenge to gene patenting (*NIR, 09, 10/May 25, p. 2*).

The patents give Myriad Genetics the exclusive right to perform or license testing for BRCA1 and BRCA2 gene mutations. The company uses its BRCAnalysis test to assess a woman's risk of developing breast or ovarian cancer based on detection of BRCA1 and BRCA2 gene mutations.

New AHRQ, CDC Reports

- ❑ *Quality, Regulation, and Clinical Utility of Laboratory-Developed Tests.* Technology assessment report. ECRI Institute Evidence-Based Practice Center under contract to the Agency for Health Care Research and Quality, Rockville, Md. www.ahrq.gov/clinic/ta/tareview.htm.
- ❑ *Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions.* Prepared by the CDC Division of Laboratory Systems, National Center for Preparedness, Detection, and Control of Infectious Diseases, Coordinating Center for Infectious Disease. *Morbidity and Mortality Weekly Report*, June 12, 2009/ Vol. 58/No. RR-6. www.cdc.gov/mmwr.

To restrain costs, Obama proposed requiring spending cuts if expenses become to large.

Health Care Reform, *from p. 1*

be available to help individuals and small businesses purchase coverage. The exchange would take effect in four years, but "we will immediately create low-cost coverage if you cannot afford other plans," he said.

- ❑ Individuals would be required to have coverage, and employers would have to offer affordable coverage to their workers or chip in to pay for the uninsured. A hardship waiver would be allowed for individuals and about 90 percent of small businesses that cannot meet this requirement.

On the public option, Obama said his guiding principle is, "Consumers do better when there is choice and competition." In 34 states, one company controls 75 percent of the market, he noted, so it is a good idea to have a nonprofit option in the insurance exchange. It would not be funded by taxes but would be financed from premiums.

But Obama signaled some flexibility on the issue by noting that other models have been proposed, such as putting a public plan in effect in markets where the private sector has failed to deliver or expanding choice through consumer co-op alternatives. But his bottom line is: "If you can't find affordable coverage, we will provide you with a choice."

Health care reform would cost an estimated $900 billion over 10 years, he said, but it will not add to the deficit now or in the future. Much of that money is "already being spent in the health care system, but badly," he noted, adding that additional savings would come from rewarding quality and efficiency. Medicare benefits would not be cut, he assured seniors.

Obama concluded by saying he is open to work on medical malpractice reform, a GOP priority. The Bush administration proposed demonstration projects in this area, and Obama said he has directed HHS to move forward on these now.

Medicare to Limit Coverage of Warfarin Response Testing

The decision memo is available at www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=224.

Medicare will not cover warfarin response testing unless the beneficiary is in a randomized clinical trial that meets specific guidelines, the Centers for Medicare and Medicaid Services (CMS) has announced. The agency concluded there was not enough evidence to show that pharmacogenomic testing of two different alleles (gene variants) to predict responsiveness to the anticoagulant drug improves health outcomes in Medicare beneficiaries. Thus, it "is not reasonable and necessary," two criteria for coverage.

Warfarin is a self-administered oral blood thinner and affects vitamin K dependent clotting factors. It has a trade name of Coumadin, but also is marketed by various manufacturers under different names. Testing is used to monitor and adjust dosage.

The final decision, effective Aug. 3, endorses the warfarin coverage policy that CMS proposed in May for public comment. But the agency left the door open to reconsider based on further evidence development. CMS said a clinical study seeking Medicare payment for testing of CYP2C9 or VKORC1 gene variants must compare "the frequency and severity of major and minor hemorrhaging, different thrombolic events, and mortality to patients whose warfarin therapy management does not include pharmacogenomic testing." CMS also listed 13 "standards of scientific integrity and relevance to the Medicare population" that had to be met by a clinical trial, including a written protocal that explicitly discusses subpopulations affected by the treatment.

Should Medicare Payments Be Set by an Independent Entity?

A proposal to transfer Medicare payment decisions from Congress to an independent body, dead in the House, has surfaced in the Senate in the framework for health care reform issued Sept. 8 by Finance committee chairman Max Baucus (D-Mont.). His plan calls for a Medicare Commission to make proposals to Congress on program solvency and quality that would take effect unless lawmakers overrode them.

Also in the Senate, John Rockefeller IV (D-W.Va.) has backed legislation that would transform the Medicare Payment Advisory Commission (MedPAC) into an entity that would set provider rates, subject to congressional oversight.

The Obama administration has backed the idea of an independent entity, such as MedPAC or a newly established Independent Medicare Advisory Council (IMAC) to set rates and depoliticize the process. Seventy-five members of Congress registered opposition to the idea, which would limit them to an up-or-down vote on recommendations.

The College of American Pathologists has urged congressional leaders to retain power over payment rates, allowing "physicians who are on the front line of diagnosis and treatment to collectively debate and discuss with their representatives how Medicare policies affect their practice."

G-2 Conference Calendar

Sept. 23-25
27th Annual Lab Institute: Advancing in the Eye of the Storm
Crystal Gateway Marriott Hotel
Arlington, Va.

Nov. 12
Lab Leaders Summit Driving Growth in Your Business
The Princeton Club of New York
New York City

Dec. 7-9
Laboratory Sales and Marketing Conference: Scaling New Heights in a Volatile Market
Sheraton Wild Horse Pass Resort and Spa
Chandler, Ariz.

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