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Lab Tax Dropped, But Medicare Fee Update Faces Cuts

Proposed cuts in the lab fee schedule update are among many alternatives to finance health care reform, and with reform legislation before the Senate Finance Committee in flux at press time, it is unclear whether the cuts will survive or in what form.

The proposal to levy an annual fee of $750 million on clinical laboratories to help pay for health care reform, starting in 2010, has been dropped from the modified legislation now being marked up by the Senate Finance Committee.

The fee had been proposed in the bill, released Sept. 16 by Finance chairman Max Baucus (D-Mont.), and drew swift opposition from the clinical laboratory industry and leading Republicans. The fee, based on an entity's relative market share, had been part of a series of levies on different parts of the health care industry to help finance system changes.

But as an offset, the modified bill, known as the chairman's mark, unveiled by Baucus Sept. 21, would reduce the annual update to the Medicare lab fee schedule by instituting a productivity adjustment and, in addition, imposing a five-year cut in the fee update, starting in 2011. *Continued on p. 2*

Report on In-House Molecular Tests Welcomed, But With Some Pointed Barbs

A draft report on the quality and regulation of lab-developed molecular tests (LDMTs) got a generally good welcome from the American Association for Clinical Chemistry (AACC) and the American Clinical Laboratory Association (ACLA) for its summary of this rapidly growing market.

But they took sharp issue with statements in the draft that imply a lack of adequate oversight and want the text revised to note that LDMTs are already subject to stringent federal, state, and professional association standards for quality testing.

The draft from the HHS Agency for Healthcare Quality and Research (AHRQ), released last month for public comment, put the federal spotlight once again on oversight of genetic testing, a highly divisive issue in the lab industry (*NIR, 09, 16/Sept. 14, pp. 3-6*).

Drawing special fire is the report's assertion that "under the current CLIA framework, only the analytical validity of the test is assessed, while the clinical validity and clinical utility of the test are not."

Not so, say AACC and ACLA. They urge AHRQ to change the text to acknowledge that:

- CLIA already subjects LDMTs to high complexity performance standards that address validity and utility, *Continued on p. 7*

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Lab Tax Dropped, *from p. 1*

Currently, lab fees get the full Consumer Price Index update (CPI-U) minus 0.5 percent. This year, it was an increase of 4.5 percent. The bill would leave the current formula in place for 2010, when the update is projected to be a cut of 1.9 percent, the first time the update has fallen into negative territory in the fee schedule's 25-year history.

But beginning in 2011, the 0.5 percent reduction for years 2011 through 2013 would be replaced with a full productivity adjustment for 2011 and subsequent years; however, this adjustment could not reduce the lab fee update below zero. Currently, the adjustment is estimated at a negative 1.3 percent. Applying it to the lab fee update would save an estimated $5 billion over 10 years. On top of this annual reduction, the bill proposes to cut the update by another 1.75 percentage points for five years, from 2011 through 2015.

Pressure on Baucus to keep the bill's costs at or below $900 billion and attract support from colleagues is the driving force behind the host of tax increases and Medicare savings he has proposed. In this climate, one industry source noted, "The committee is looking to all providers to take a haircut to help pay for health care reform."

Going into the deliberations, labs were facing proposed cuts over 10 years of $5 billion for the productivity adjustment and $7.5 billion from the lab tax. Under the Baucus approach, the price for eliminating the permanent tax is that labs would contribute to needed savings by absorbing the productivity cut, plus an additional five-year reduction in their update.

This is "better policy than a permanent tax, which would have hit labs of all sizes hard," Alan Mertz, president of the American Clinical Laboratory Association (ACLA), told *NIR*. ACLA supports the trade-off to pony up the industry's "fair share" to the savings needed to cover the uninsured.

The now-abandoned tax was less of an economic hit to labs than the 20 percent copay option that was not included in the Baucus legislation after intense lobbying by lab groups, industry analysts note. The copay would have saved Medicare an estimated $24 billion over 10 years by shifting the costs to seniors and adding new costs for labs that would have had to collect the copay. But the tax would have been onerous too, these analysts add, accounting for an estimated 2 percent to 2.5 percent of a lab's total revenue.

The effect of the alternative five-year cut in the lab fee update depends on the rate of inflation over this period. For example, assuming an inflation rate of more than 3.1 percent, a productivity adjustment of 1.3 percent, and a reduction of 1.75 percentage points, no reduction in the update is likely. Assuming a lower inflation rate, the worst-case scenario is that the update could be cut by 1.75 percentage points.

The Baucus blueprint does not specify how the lab fee cuts will be allocated, and this concerns the National Independent Laboratory Association (NILA) and the American Association of Bioanalysts (AAB). Mark Birenbaum, Ph.D. who heads these groups, said, "If not done properly, they will put many community laboratories, including those serving nursing home patients, out of business, and give large corporate labs that have a small percentage of Medicare Part B work a huge competitive advantage. These large corporate labs are the same labs that stand to gain from increased enrollment due to health care reform."

Birenbaum says, "The structure of this provision is critical to the future of the community lab. It is simply not fair to have the labs most involved in Medicare sustain another large cut. They will not survive if some adjustment is not made."

focus on: Lab Payment Policy

CMS Sets Preliminary Medicare Fees for New 2010 Lab Codes

The final lab fee decisions will be published in the 2010 Part B lab fee schedule. The schedule is typically released in November.

The Centers for Medicare and Medicaid Services has released its preliminary decisions on payment rates for new codes to be added to the Medicare Part B fee schedule, starting Jan. 1, 2010.

They include 12 CPT codes: three new CPT codes in chemistry, three in immunology, two in tissue typing, three in microbiology, and one for in vivo (e.g., transcutaneous) lab procedures, along with two new G codes for drug screening.

All Crosswalks, No Gap-Fills

In setting initial fees for all the new codes, CMS used a crosswalk to an existing code and its payment rate. No code was gap-filled, a method used when there is no comparable test and the fee is based on local pricing patterns. For each code, CMS presents a rationale and responds to comments received since the fee-setting process began July 14 at an open-door forum (*NIR, 09, 15, August, pp. 3-6*).

The table on pages 4 and 5 compares the CMS CPT crosswalks with industry recommendations. Groups represented include American Association for Clinical Chemistry (AACC), American Clinical Laboratory Association (ACLA), American Society for Clinical Pathology (ASCP), American Society for Microbiology (ASM), College of American Pathologists (CAP), Clinical Laboratory Management Association (CLMA). The American Association of Bioanalysts and the American Society for Clinical Laboratory Science did not submit comments.

Change of Mind on MPO

Responding to a request by Abbott Diagnostics and backed by many industry groups, CMS says it will change the current crosswalk for CPT 83876, Myeloperoxidase (MPO), which was added to the fee schedule this year. The test is a quantitative marker used to predict myocardial infarction in patients with chest pain. Recommended crosswalks were to 82553, Creatine kinase (CK)(CPK); MB fraction only, or 83880, Natriuretic peptide (BNP).

Based on further research on the test method, the agency concluded, the test "appears to have the same level of complexity in the action step process as 83880, Natriuretic peptide (BNP)." The reassigned crosswalk means a boost in payment, with the national fee cap increasing from the current $18.91 to $49.56.

Drug Screening G Codes

CMS also set preliminary fees for new HCPCS drug screening codes on the Medicare lab fee schedule:

- ❑ GXXX1, Drug screen, qualitative; multiple drug classes, any method, each procedure (e.g., multiple drug test kit): Crosswalked to CPT 80100, Drug screen, qualitative; multiple drug classes, chromatographic method, each procedure, $21.23.
- ❑ GXXX2, single drug class method (e.g., immunoassay and enzyme assay), each drug test: Crosswalked to CPT 80101, Drug screen, qualitative; single drug class method, (e.g., immunoassay and enzyme assay), each drug class, $20.11

The CMS announcement of the preliminary payment decisions and their rationale are posted at *cms.hhs.gov/ClinicalLabFeeSched. Click on Laboratory Public Meetings.*

Pricing of New CPT Codes on 2010 Medicare Lab Fee Schedule
CMS Preliminary Decisions Versus Industry Recommendations

CODE/DESCRIPTOR**	CMS PRELIMINARY CROSSWALK	CURRENT NATL. FEE CAP
CHEMISTRY		
839XX, pH; exhaled breath condensate	**82800**, Blood gases, pH only + **87015**, Concentration, any type, for infectious agent	**$22.12**
Industry Recommendations		
AACC, ACLA, ASCP, CAP, CLMA	Same	Same
ASM	No comment	N/A
841XX, Procalcitonin (PCT)	**84146**, Prolactin	**$28.30**
Industry Recommendations		
ASCP, ASM, CAP, CLMA	Same	Same
AACC, ACLA	83880, Natriuetic peptide	$49.56
844XX, Thromboxane metabolite(s), including thromboxane if performed, urine	**83520**, Immunoassay, analyte, quantitative; not otherwise specified	**$18.91**
Industry Recommendations		
AACC, ACLA, ASCP, CAP	Same	Same
CLMA	83520 + 82570, Creatinine; other source	$26.47
ASM	No comment	N/A
IMMUNOLOGY		
863XX1, Human epididymis protein 4 (HE4)	**86316**, Immunoassay for tumor antigen, other antigen, quantitative (eg, CA 50, 72-4, 549), each	**$30.38**
Industry Recommendations		
ACLA, ASCP, ASM	Same	Same
AACC, CAP, CLMA	86304, Immunoassay for tumor antigen, quantitative; CA-125	Same
863XX2, Cellular function assay involving stimulation (eg, nitrogen or antigen) and detection of biomarker (eg, ATP)	**86353**, Leukocyte transformation, mitigen or antigen induced blastogenesis + **82397**, Chemiluminescent assay	**$92.21**
Industry Recommendations		
AACC, ACLA, ASM	Same	Same
ASCP, CAP	86353 + 82397 + XX (gap-fill if advised)	$92.21 + XX
CLMA	No comment	N/A
867XX, Antibody, Treponema pallidum	**86781**, Treponema pallidium, confirmatory test (eg, FTA-abs.)	**$19.34**
Industry Recommendations		
AACC, ACLA, ASCP, ASM, CAP, CLMA	Same	Same
TISSUE TYPING		
868XX1, Human leukocyte antigen (HLA) crossmatch, non-cytotoxic (eg, using flow cytometry); first serum sample or dilution	**86356** ($39.03) **x 3**, Monoclonal cell antigen, quantitative (eg, flow cytometry), not otherwise specified, each antigen	**$117.27**
Industry Recommendations		
CAP	Same	Same
AACC	86361, T cells; absolute CD4 count x 3	Same
ACLA, ASCP	87536, HIV-1, quantification	$124.24

ASM	88184, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker	N/A. Code payable via physician fee schedule. Mean of limiting charge: $86.02
CLMA	88184, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker + 88185, each additional marker (list separately to code for the first marker)	N/A. Paid on the physician fee schedule, $124.79 pure fee, unadjusted for locality.
868XX2, Human leukocyte antigen (HLA) crossmatch, non-cytotoxic (eg., using flow cytometry, each additional serum sample or dilution (list separately in addition to primary procedure)	**86356**, Mononuclear cell antigen, quantitative (eg, flow cytometry), not otherwise specified, each antigen	**$39.09**
Industry Recommendations		
AACC, CAP	Same	Same
ACLA, ASCP	86361, T cells; absolute CD4 count	Same
ASM	88185	N/A. Mean of physician fee schedule limiting charge: $51.10
CLMA	88184, Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker + 88185, each additional marker (list separately to code for the first marker)	N/A. Paid via physician fee schedule, $124.79 pure fee, unadjusted for locality.
MICROBIOLOGY		
871XX1, Culture, typing; identification by nucleic acid (DNA or RNA) probe, amplified probe technique, per culture or isolate, each organism probed	**87798**, Infectious agent antigen detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique	**$51.25**
Industry Recommendations		
AACC, ACLA, ASCP, ASM, CAP, CLMA	Same	Same
871XX2, Culture, typing; identification by nucleic acid sequencing method, each isolate	Molecular diagnostics codes **83891, 83898, 83904, 83912,** and **87900** (at ½)	**$155.79**
Industry Recommendations		
AACC, ACLA, ASCP, ASM, CAP	87902, Infectious agent genotype analysis; hepatitis C virus	$375.88
CLMA	83890-83912 range; no specific code recommended.	N/A
874XX, Infectious agent antigen detection by nucleic acid (DNA or RNA); Clostridium difficile, toxin gene(s), amplified probe technique	**87798**, Infectious agent antigen detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique	**$51.25**
Industry Recommendations		
AACC, ACLA, ASCP, ASM, CLMA	Same	Same
CAP	87500, Infectious agent detection by nucleic acid (DNA or RNA); vancomycin resistance (eg, enterococcus species van A, van B), amplified probe techniques	Same
TRANSCUTANEOUS LAB PROCEDURES		
887XX, Hemoglobin (Hgb), quantitative, transcutaneous	**88740**, Hemoglobin, quantitative, transcutaneous, per day; carboxyhemglobin	**$7.33**
Industry Recommendations		
AACC, ACLA, ASCP, CAP, CLMA	Same	Same
ASM	No comment	N/A

**CPT codes © American Medical Assn. Last two digits to be finalized.

CMS Proposes Medicare Coverage of HIV Screening

The Centers for Medicare and Medicaid Services is proposing to expand the Medicare preventive services benefit by adding coverage of voluntary HIV screening for beneficiaries. The agency earlier this year announced that it was considering this step (*NIR, 09, 6/March 30, p. 8*).

This is the first time CMS has exercised its new authority to expand the Part B benefit without first obtaining congressional approval. Since Jan. 1 of this year, CMS has had this power, if certain requisites are met, under provisions of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275).

In its proposed decision memo, CMS said, "The evidence is adequate to conclude that screening for HIV infection, which is recommended with a grade of A by the U.S. Preventive Services Task Force for certain individuals, is reasonable and necessary for early detection of HIV."

Current Medicare Preventive Services Benefit

- ❑ "Welcome to Medicare" initial preventive physical exam
- ❑ Screening tests/procedures for:
  - — Abdominal aortic aneurysm
  - — Breast cancer: mammograms, Pap smears
  - — Cervical or vaginal cancer: pelvic exam, plus clinical breast exam
  - — Cardiovascular disease (lipids)
  - — Colorectal cancer, including fecal occult blood test
  - — Diabetes and diabetes self-management training
  - — Prostate cancer: prostate-specific antigen test, digital rectal exam
  - — Glaucoma
  - — Osteoporosis: bone mass measurements
- ❑ Medical nutrition therapy
- ❑ Smoking and tobacco-use cessation counseling
- ❑ Vaccinations: influenza, pneumococcal, hepatitis B

A guide to eligibility, frequency limits, coinsurance, coding/billing and other requirements for the above is available at *cms.hhs.gov/MLNProducts/35_PreventiveServices.asp*.

Therefore, CMS proposes to cover HIV screening with an FDA-approved enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA), or rapid HIV antibody test, as follows:

1. Annual voluntary HIV screening of Medicare beneficiaries at increased risk for HIV infection under guidelines of the U.S. Preventive Services Task Force:

- ❑ Men who have had sex with men after 1975
- ❑ Men and women having unprotected sex with multiple partners
- ❑ Past or present injection drug users
- ❑ Men and women who exchange sex for money or drugs or have sex partners who do
- ❑ Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users
- ❑ Persons being treated for sexually transmitted diseases
- ❑ Persons with a history of blood transfusion between 1978 and 1985
- ❑ Persons who request an HIV test despite reporting no risk factors, since this group is likely to include individuals not willing to disclose high-risk behaviors.

2. Voluntary HIV screening of pregnant Medicare beneficiaries.

The proposed decision is posted at *www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=229*.

The agency will accept public comments on the proposal through Oct. 9 and issue a final coverage decision in December.

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and this information must be available to inspectors.

- ❑ The College of American Pathologists, one of the leading accrediting bodies in this area, requires labs in its Laboratory Accreditation Program to demonstrate the analytic validity of these tests as well as document how they are clinically validated.
- ❑ The New York State program, which covers 75 percent of all LDMTs performed in the United States, requires laboratories to demonstrate that a test is clinically validated prior to being introduced.

Both AACC and ACLA say a revised version should incorporate the findings of the Centers for Disease Control and Prevention guidance on good laboratory practice for molecular testing for heritable diseases and conditions (*NIR, 09, 16/Sept. 14, p. 5*). The guidance takes particular note, they point out, of CLIA requirements to ensure clinical validity.

The AHRQ draft technology assessment, requested by the Centers for Medicare and Medicaid Services (CMS), looks at LDMTs, using either FDA-regulated or self-developed analyte-specific reagents (ASRs) and intended for use solely in the test developer's lab. It offers a "horizon scan" summarizing scientific evidence, available as of Oct. 31, 2008, on the quality of LDMTs of potential clinical relevance to the Medicare population age 65 and older. The report, prepared by the ECRI Institute Evidence-Based Practice Center, 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.

CLIA and Genetic Testing

AACC notes that the draft frequently mentions that there is no separate specialty or subspecialty for genetic testing under CLIA and that proficiency testing (PT) is not required for LDMTs. "We suggest that the report include CMS's rationale for not creating a specific genetic testing category, including:

- ❑ New standards for this fast-evolving field would be outdated by the time they were implemented.
- ❑ LDMTs are already subject to the most stringent standards under CLIA rules.
- ❑ Requiring PT would not increase the number of labs conducting PT on LDMTs, since there were only 16 proficiency tests available for more than 1,000 different genetic tests (as of 2007)."

Also, it should be noted, says AACC, that CMS is currently working on a proposed rule that would require PT for genetic tests, when available, and developing alternative mechanisms for assessing genetic tests.

FDA Jurisdiction over LDMTs

ACLA takes exception to the draft's unqualified reiteration of the Food and Drug Administration's claim that it has the authority to regulate LDMTs. This is an unresolved legal question, the association contends, and the report should note this. ACLA says these tests neither constitute "medical devices" nor are they distributed commercially in interstate commerce, both requirements for FDA oversight. "The components of the test processes are not marketed as kits or test systems, and they are not physically distributed or delivered outside the lab that developed the test. Instead, labs provide written reports of the results to ordering physicians after the labs have performed the tests in their facility. Thus, clinical labs that develop and perform LDMTs are selling services to outside entities; they are not selling any identifiable medical device."

FDA Clears Test for Ovarian Cancer

Primary care physicians or gynecologists should use the IVDMIA test to complement, not replace, other diagnostic and clinical procedures, the FDA cautions.

The Food and Drug Administration has approved a test that can help detect ovarian cancer in a pelvic mass known to require surgery. The test, called OVA1, helps patients and health care professionals decide what type of surgery should be done and by whom, the agency noted.

The test is developed by Vermillion Inc. (Fremont, Calif.), in conjunction with researchers at The Johns Hopkins University in Baltimore. Quest Diagnostics (Madison, N.J.) has a three-year exclusive agreement to offer it to the U.S. reference lab market.

The test uses a blood sample to assay levels of five proteins: transthyretin, apolipoprotein A-1, beta2-Microglobulin, transferrin, and cancer antigen 125. It combines the five separate results into a single numerical score between 0 and 10 to indicate the likelihood that the pelvic mass is benign or malignant.

OVA1 is intended only for women, 18 years and older, selected for surgery. It is not intended for screening or diagnosing ovarian cancer. Interpreting the result requires knowing whether the woman is pre- or post-menopausal.

G-2 Conference Calendar

Webinar

Oct. 20
Increasing the Market Value of Pathology: How Technology and Practice Trends are Driving Business Growth
2:00 p.m. (Eastern)

Conferences

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
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