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Hopes High for Health Reform as New Congress Opens

For pathologists and other physicians, a key component of reform is creation of a new annual update system for their Medicare fees to avoid a projected cut of at least 15 percent in 2010, and even steeper cuts thereafter under the current SGR update formula.

The 111th Congress convened its first session Jan. 6 as members of the House and the Senate were sworn in amid high expectations that they will make a serious effort this year toward comprehensive reform of the nation's health system.

Support for a sweeping overhaul has already been expressed in broad outline by business, health insurer, and consumer groups and by state and local governments, all squeezed with rising costs. Meantime, with millions of jobs being lost in the nation's economic crisis, the ranks of the uninsured, an estimated 47 million, are growing as more people lose their jobs and turn to public programs for health care coverage or go without it altogether.

While a stimulus package to jump-start the economy tops the legislative agenda, congressional Democrats and president-elect Barack Obama have cast their health care reform plans to control costs, expand insurance coverage, and improve the quality of care as part of their overall economic recovery initiatives. *Continued on p. 6*

INSIDE *NIR*

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New Controversy Erupts Over FDA Regulation of Lab-Developed Tests

The biopharmaceutical company Genentech, a developer of cancer drugs, has reignited concerns within the clinical laboratory industry over how much additional control the Food and Drug Administration should have over laboratory-developed tests (LDTs), including many commonly used genetic tests that currently are not subject to premarket review.

The company wants LDTs, developed by labs for in-house testing, to be subject to the same scientific and regulatory standards, including premarket review and post-market surveillance, that the FDA applies to *in vitro* diagnostic tests developed and sold by device makers as test kits.

Genentech, based in South San Francisco, Calif., has filed a 32-page citizen petition with the FDA, asking it to "initiate rulemaking to exercise regulatory jurisdiction over all LDTs and use its current risk-based classification system to determine the level of regulatory oversight and review that is necessary and appropriate for these tests."

Continued on p. 7

CAP Has Change of Heart on State Licensure of Lab Personnel

The College of American Pathologists will no longer oppose state legislation for the licensure of medical technologists and technicians as long as the legislative language meets model criteria that address specific concerns of CAP's members.

In announcing the change, CAP president-elect Stephen Bauer, M.D., F.C.A.P., said in a Dec. 18 statement that it "reaffirms the college's support for its clinical laboratory partners who desire to raise the standards of their profession through state licensure."

To pass muster with CAP, state licensure legislation would have to:

- ❑ Define the scope of work for medical technologists and technicians to avoid conflict between physicians and nonphysicians.
- ❑ Support creation of limited specialty licenses for personnel who perform specialty services in the lab.
- ❑ Establish minimum educational standards for each licensure category.
- ❑ Specifically ensure that the lab director has control over all personnel in the lab.
- ❑ Incorporate a definition of medical independent judgment that makes clear that in the lab, pathologists alone make independent medical judgments in the diagnosis and treatment related to clinical lab tests.
- ❑ Provide for greater on-the-job training.
- ❑ Restrict the authority of the state licensing board to modify and expand licensing requirements provided by state statute.

While CAP will not oppose any bill consistent with its model approach, "it will not impede any state pathology society from seeking other modifications it deems appropriate," Bauer noted.

CAP's stance is designed to accommodate its concerns that overly stringent licensure rules would exacerbate the shortage of qualified lab personnel and the concerns of licensure proponents that labs will fail to attract qualified personnel if work requirements are not stringent enough. The college supports "qualification requirements that can be met either through college-level course completion and testing or through on-the-job training. Ultimately, licensure may have little to do with the personnel shortage issue, so we should not let it distract us from working together to find a solution."

ASCP Welcomes the Shift

The American Society for Clinical Pathology applauded CAP's revised position, set forth in a letter to society president Barbara J. McKenna M.D., F.A.S.C.P., from CAP president Jared N. Schwartz, M.D., Ph.D., F.C.A.P. In response, McKenna told Schwartz, "Going forward, we look forward to working with you in developing and maintaining high standards for laboratory professionals who are working to ensure patient safety and public health."

According to ASCP's *ePolicy News*, the society has supported state licensure initiatives since 2005 to ensure that lab professionals possess appropriate academic and clinical training, pass competency-based exams conducted by an approved national certifying organization, and participate in continuing education programs. The ASCP Board of Registry certification is the only certification that has approval in all 13 states that require licensure for laboratory personnel, including most recently New York and California.

focus on: Lab Payment Policy

Medicare Lab Fees Get 4.5 Percent Increase for 2009

For the first time in five years, clinical laboratories this year got an increase in their payment rates under the Medicare Part B lab fee schedule. The update, effective Jan. 1, 2009, is 4.5 percent. Congress had blocked an annual update since 2004. In allowing the update, however, Congress required that it be 0.5 percent less than the full Consumer Price Index (CPI) update in 2009 through 2013.

The 4.5 percent increase affects both local fees and national limitation amounts (fee caps). Payment for a clinical lab test is the lesser of the actual charge billed, the local fee, or the national fee cap. The Part B deductible and coinsurance do not apply for services paid under the clinical lab fee schedule.

The 2009 update for payments made on a reasonable charge basis for all other laboratory services, including blood product and transfusion medicine codes, is 5 percent.

These and other Medicare lab payment policies for 2009 are contained in instructions sent by the Centers for Medicare and Medicaid Services to local contractors (Transmittal 1660, Dec. 31, 2008, *cms.hhs.gov/transmittals*).

Rise in Pap Smear Minimum Payment

The lifting of the lab fee freeze also means a rise in the national minimum payment for certain cervical or vaginal smear codes to $15.42, from $14.76 where it had been frozen since 2004. These tests are paid at the lesser of the local fee or the national fee cap, but never below the national payment floor and never more than the actual charge. Affected codes include:

88142/G0123	88150	88164	88174/G0144
88143/G0143	88152	88165	88175/G0145
88147/G0147	88153	88166	P3000
88148/G0148	88154	88167	

No Change in Setting Fee Caps

Medicare's national fee caps remain set at 74 percent of the national median for those tests on the lab fee schedule that were capped prior to Jan. 1, 2001. For tests whose fee caps were first established on or after Jan. 1, 2001, the caps are to be set at 100 percent of the national median, in accord with the Benefits Improvement and Protection Act of 2000 (BIPA).

This BIPA provision has been applied by CMS, since April 1, 2001, to 12 diagnostic/screening Pap smear codes involving thin-layer preparation and manual or automated screening or rescreening: 88142/G0123, 88143/G0143, 88147/G0147,

88148/G0148, 88174/G0144, and 88175/G0145.

Final Fees Established for New Lab Codes

In setting fees for CPT lab codes new to the fee schedule in 2009, CMS used the crosswalk method; no new test codes were gap-filled (for a look at how the final crosswalks meshed with recommendations from lab and pathology groups, *see table, p. 5*). Below are the new codes and their national fee caps:

Chemistry

83876, Myeloperoxidase (MPO), $18.91

83951, Oncoprotein; des-gamma-carboxy-prothrombin (DCP), $94.04

Hematology and Coagulation

85397, Coagulation and fibrinolysis, functional activity, not otherwise specified (e.g., ADAMTS-13), each analyte, $33.51

Microbiology

87905, Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid), $17.84

In Vivo (Transcutaneous) Lab Procedures

88720, Bilirubin, total, transcutaneous, $7.33

88740, Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin, $7.33

88741, Hemoglobin, quantitative, transcutaneous, per day; methemoglobin, $7.33

CMS Agrees to Higher Fees for Certain New Lab Codes

In establishing the final crosswalks and payment rates for the new CPT lab codes, CMS reversed itself four out of seven times from its preliminary decisions, resulting in higher fees in line with recommendations from leading clinical lab and pathology groups.

Asking CMS to Think Again About Final Fees

Providers who disagree with the final lab fee determinations have another opportunity to ask the Centers for Medicare and Medicaid Services to reconsider. Under procedures adopted in the final 2008 physician fee schedule rule, clinical labs, other providers in the industry, and the public may request a reconsideration of the final fee for a new test, including the method used to derive the fee and the payment amount set.

Providers have 60 days following release of the final rates to request a reconsideration. Those who submit written comments within that period will have the opportunity to present at the next clinical lab public meeting on lab fee-setting, typically held in July of each year. It is up to CMS to decide whether to reconsider and, if so, whether to make the change. Either way, the agency's decision is final. There are no further rights to appeal. CMS's ultimate determination is effective in January of the following year.

Medicare Pricing of New 2009 CPT Lab Codes: *Preliminary vs. Final Crosswalks/National Fee Caps*

Chemistry

83876, Myeloperoxidase (MPO)

Preliminary Decision: 83520, Immunoassay for analyte other than infectious agent antibody or infection agent antigen, qualitative or semiquantitative, multiple step method; not otherwise specified = $18.91

Final Decision: **Same = $18.91**

Lab/Pathology Recommendations
CMS disagreed with:
ACLA: 82045, Albumin, ischemia modified = $49.56
ASCP, CLMA: 83880, Natriuretic peptide = $49.56
CAP: 82553, Creatine kinase (CK) (CPK); MB fraction only = $16.86

83951, Oncoprotein; des-gamma-carboxy-prothrombin (DCP)

Preliminary Decision: 82491, Chromatography, quantitative, column (gas liquid or HPLC); single analyte not otherwise specified, single stationary and mobile phase ($26.37) plus 83520, Immunoassay, analyte, quantitative; not otherwise specified ($18.91) = $45.28

Final Decision: **83950, Oncoprotein; HER-2/neu = $94.04**

Lab/Pathology Recommendations
CMS agreed with:
AACC, ACLA, ASCP, CAP, CLMA

Hematology and Coagulation

85397, Coagulation and fibrinolysis, functional activity, not otherwise specified (e.g., ADAMTS-13), each analyte

Preliminary Decision: 85230, Clotting; factor VII (proconvertin, stable factor)= $26.14

Final Decision: **85245, Clotting; factor VIII, von Willenbrand factor, ristocetin cofactor = $33.51**

Lab/Pathology Recommendations

CMS agreed with: CAP

Disagreed with:
ACLA: 85246, Clotting; factor VIII, VW factor antigen = $33.51
ASCP, CLMA: 85247, Clotting; factor VIII, VW factor, multimetric analysis = $33.51
AACC, ASM: n/c

Microbiology

87905, Infectious agent enzymatic activity other than virus (e.g., sialidase activity in vaginal fluid)

Preliminary Decision: 82657, Enzyme cell activity, nonradioactive substrate, each specimen minus 87176, Homogenization, tissue, for culture = $17.84

Final Decision: **Same = $17.84**

Lab/Pathology Recommendations

CMS agreed with: ASM, CAP

Disagreed with:
ASCP, CLMA: 82657, Enzyme cell activity, nonradioactive substrate, each specimen = $26.37
AACC: 87808, Trichomonas vaginalis assay with direct optical observation = $17.52
ACLA: 87810, Chlamydia trachomatis assay with direct optical observation = $17.52

In Vivo (e.g., Transcutaneous) Laboratory Procedures

88720, Bilirubin, total, transcutaneous. This code replaces **88400**, which has been deleted from the CPT 2009 and renumbered as part of a subsection for in vivo lab procedures. **It is priced at the same rate as the old 88400 = $7.33.**

88740, Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin (For in vitro carboxyhemoglobin measurement, use 82375)

Preliminary Decision: ½ of payment for 88720 = $3.665

Final Decision: **88400, Bilirubin, total, transcutaneous = $7.33**

Lab/Pathology Recommendations
CMS agreed with: ASCP

Disagreed with: CAP: ½ of 88400 = $3.665
AACC, ACLA, ASM, CLMA: n/c

88741, Hemoglobin, quantitative, transcutaneous, per day; methemoglobin

Preliminary Decision: ½ of payment for 88720 = $3.665

Final Decision: **88400, Bilirubin, total, transcutaneous = $7.33**

Lab/Pathology Recommendations
CMS agreed with: ASCP

Disagreed with: CAP: ½ of 88400 = $3.665
AACC, ACLA, ASM, CLMA: n/c

 Acronyms: AACC-American Assn. for Clinical Chemistry, ACLA-American Clinical Laboratory Assn., ASCP-American Society for Clinical Pathology, ASM-American Society for Microbiology, CAP-College of American Pathologists, CLMA-Clinical Laboratory Management Assn.

The agency ran into sharp challenges from the lab industry when it unveiled its preliminary decisions last fall. Their overarching criticism was that CMS disregarded the public input it sought, ignored the clinical and technical information the groups submitted to back up their recommendations, and thus failed to value most of the new codes properly (*NIR, 30, 2/Oct. 27, '08*).

The biggest CMS turnaround in the final fees involved new chemistry code 83951, Oncoprotein; DCP, and hemoglobin codes 88740 and 88741. In these cases, the agency agreed to payment rates more than double those it had proposed.

But CMS held fast to its initial decision for 83876, Myeloperoxidase, resulting in a significantly lower fee than advocated by most of the lab and pathology groups that submitted comments. (For details on the CMS rationale for the final fee determinations, go to *www.cms.hhs.gov/ClinicalLabFeeSchedule* and click on "Laboratory Public Meetings.")

Trip Fees

The travel allowance for the following codes used to bill for collecting specimens from nursing home and homebound beneficiaries is:
—P9603, $1.035 per mile trip basis (round to $1.04 if necessary)
—P9604, $10.35 per flat rate trip basis

The rates are effective for dates of service from July 1, 2008 through Dec. 31, 2009. The rate for P9604, CMS notes, corrects the dollar figure in Change Request 6195 (Sept. 5, 2008).

The lab fee schedule also includes codes with a QW modifier to identify codes and determine payment for tests performed by a lab registered with only a CLIA certificate of waiver.

Hopes High for Health Reform, *from p. 1*

House Ways and Means health subcommittee chairman Pete Stark (D-Calif.) is the latest lawmaker to put his health care reform ideas on the table. On Jan. 6, he introduced bills that would offer coverage to all adults modeled on Medicare and including a new public plan option alongside employer-based coverage, and that would cover children from birth through age 23, though parents would have a choice of enrolling their children in private or public plans.

In the Senate, Finance Committee chairman Max Baucus (D-Mont.) has already unveiled his comprehensive reform plan, with a controversial mandate that all people must obtain health care coverage. At the Health, Education, Labor, and Pensions Committee, chairman Edward Kennedy (D-Mass.) has assigned members to three working groups to write their version of health care overhaul (*NIR, 30, 4/Nov. 24 '08, pp. 4-6*).

While Obama has yet to unveil legislative proposals to carry out his health care change agenda, his team has been busy with outreach to get the public involved in the debate via a series of grass-roots events to mobilize local support for reform. At one such open forum held Dec. 29 in Dublin, Ind., Health and Human Services secretary-nominee Tom Daschle, whom Obama has designated as his lead architect for reform, told the audience that the administration is determined "to get out of Washington and hear directly from you about your concerns and ways you think our system can be made to work better."

ACLA and the College of American Pathologists oppose further expansion of the FDA's authority over LDTs, saying CLIA standards assure the analytical and clinical validity of these tests.

Lab-Developed Tests, *from p. 1*

Further, Genentech wants the FDA to simultaneously initiate enforcement action against "any clinical laboratory or any other company that is selling an LDT or making claims about its potential indication for use, effectiveness or value, or that otherwise impacts patient safety without having sufficient analytical and clinical evidence to support such claims."

The American Clinical Laboratory Association, which represents national and regional labs as well as test manufacturers, assailed Genentech's move as posing a "chilling effect on innovation in patient care while stifling the promise of personalized medicine," which tailors a particular treatment and therapy to an individual's genetic profile. LDTs include commonly used tests for breast and colon cancer, AIDS, and other diseases that have a history of being safe and effective, ACLA said. "All health care-related lab tests are already either cleared by the FDA or are performed in a lab regulated by the Centers for Medicare and Medicaid Services under CLIA, or both. Also, labs that perform genetic tests must meet the most stringent level of CLIA complexity oversight, often are also regulated by states, and most have further oversight via lab accrediting bodies."

More FDA regulation would threaten rare and low-volume tests for genetic diseases, such as spinal muscular atrophy, Gaucher disease, Tay Sachs disease, and Canavan disease, among others, ACLA warned. "Because of small populations for clinical trials, [these tests] would not be able to meet FDA requirements and, with limited markets, could disappear."

The FDA currently regulates analyte-specific reagents used in LDTs and a category of LDTs known as IVDMIAs (*in vitro* diagnostic multivariate index assays) that use a proprietary algorithm to produce a patient-specific result. Legislation to require premarket review of all LDTs (S. 736) was introduced in the previous Congress by Sen. Edward Kennedy (D-Mass.); hearings were held, but no action was taken.

ASCP Joins in Asking Obama's Help on Health Professions Funding

The American Society for Clinical Pathology and other medical groups in the Health Professions and Nursing Education Coalition (HPNEC) have written to president-elect Barack Obama, citing his previous support for Title VII and VIII health professions programs and urging him to back their full funding as part of his health care reform initiative, ASCP reported in the Jan. 1 *ePolicy News*.

The programs, run by the Health Resources and Services Administration, are designed to train providers to meet the needs of special and underserved populations, as well as increase minority representation in the health care workforce. Title VII in particular has been hit hard, ASCP noted, due in large part to a funding cut of 51.5 percent ($155 million) in fiscal 2006, and the amount channeled to allied health, including training of medical technologists and medical lab technicians, is miniscule.

ASCP believes that Title VII funding is an avenue to address the growing severity of the lab workforce shortage, noting that the Clinical Laboratory Curriculum at the University of South Alabama is but the latest training program to close its doors due to lack of funding and dwindling enrollment.

Notice to Subscribers: Change in *NIR* Volume, Issue Numbers

Beginning with this issue, the *National Intelligence Report* is changing to a calendar year system for numbering volume and issue in accord with a new standardized IOMA format for all Washington G-2 Reports newsletters.

In the new system, the volume number represents the last two digits of the year, followed by the issue number for the year. Accordingly, the masthead for this issue reads Vol. 09, Iss. 1.

There is no change in the number of issues (22) that you will receive during a subscription year, twice each month except August and December, which are one-issue months.

Previously, the *NIR* volume and issue year ran from October through September, reflecting the launch of the publication in October 1979. Citations to stories covered in *NIR* prior to the start of 2009 will continue to use this numbering scheme for reference.

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