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How Health Reform May Affect Pathology, Laboratory Medicine

Congressional leaders within both chambers of Congress continue efforts to enact health reform legislation. While Democratic leaders in the House of Representatives have essentially completed their work assembling a single bill for consideration by the full House, the Senate is still working to craft a bill from the two separate bills approved by the Senate committees on Finance and Health, Education, Labor & Pensions. ASCP recognizes the need for health care reform, and has been active in shaping legislation under consideration in Congress.

With regard to pathology and laboratory medicine, the House and Senate bills are somewhat similar. Both House and Senate bills contain proposals that would impose a productivity adjustment on the clinical laboratory fee schedule (CLFS). The proposal would reduce annual adjustments to the fee schedule by the increase in annual productivity. Historically, estimates of productivity have averaged about 1.4 percent. The proposal under consideration in the Senate would prevent the productivity adjust-

ment from resulting in a negative update.

Where the two bills differ most significantly is a Senate proposal to cut the clinical laboratory fee schedule by 1.75 percent. Originally, this cut was proposed in the Senate bill as a tax on all clinical laboratory and pathology revenues. However, the tax was eliminated as the result of advocacy by ASCP and others. This adjustment to the fee schedule would go into effect in 2011. In contrast to the clarification that the Senate's productivity adjustment cannot result in a negative annual update, the 1.75 percent negative CLFS update, which would likely be factored into the annual update after the imposition of the productivity adjustment, can result in a negative annual update. The two provisions would cap the maximum negative update that could occur under the Senate bill at 1.75 percent.

More recently, the Senate bill was modified to include a partial fix to the so-called 14 day date of service rule. The amendment would cover certain complex diagnostic tests not furnished by the hospital laboratory. The current rule holds that if a

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test is ordered on a specimen obtained during a patient's hospital stay within 14 days of discharge, the laboratory is reimbursed under the diagnosis-related group (DRG) payment rather than being directly reimbursed by the Centers for Medicare & Medicaid Services (CMS). To pay for the provision, the Senate would increase the 1.75 percent adjustment to the clinical laboratory test to 1.95 percent beginning in 2015. This would maximize any negative annual update at 1.95 percent.

The Senate bill also contains a provision calling on the CMS to submit a report to Congress outlining recommendations for legislative and administrative actions to reform the reimbursement mechanisms for new clinical laboratory tests. The latter proposal would require CMS to hold a public meeting to solicit comments.

Lastly, two provisions common to both bills include an extension of existing legal provisions allowing for technical component billing by independent laboratories performing services for Medicare inpatients and "reasonable reimbursement" for laboratory services provided at small rural hospitals.

Laboratory Screening and Diagnostic Tests: Vital Tools for Health

On September 29, the American Clinical Laboratory Association (ACLA), Advanced Medical Technology Association (AdvaMed), and Results for Life Educational Campaign held a briefing at the National Press Club in Washington, DC, that featured the new report from the Lewin Group entitled "The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement." This session was formed in light of the ongoing debate on health care reform and the Congressional Budget Office's view that prevention could actually increase costs. A panel of experts took part in examining these key issues, along with addressing the question: *Are we counting on what counts?* The participants included Dr. Clifford Goodman, Senior Vice President of the Lewin

Group; Dr. Michael O'Grady, Senior Fellow of the National Opinion Research Center (NORC); Dr. Susan Snyder, Senior Economist, Division of Laboratory Systems, Centers for Disease Control and Prevention; and Neera Tanden, JD, Senior Advisor, HHS Office of Health Reform, Domestic Policy Advisor to the Obama Campaign.

According to the report, the benefits of clinical laboratory screening and laboratory tests are not given full recognition in the current system. Appropriate use of these services is hindered by lack of provider awareness of when to use tests, inconsistencies among clinical practice guidelines, lack of coverage and payment policies, and insufficient evidence regard-

ing the beneficial economic impact of lab testing. Furthermore, certain existing policies limit the contribution of screening and diagnostic tests across the health care spectrum. To validate their findings, the researchers presented four case studies that address, in part, the cost and clinical implications of lab testing. They were: Rapid methicilin-resistant *Staphylococcus aureus* (MRSA) testing for identifying hospital-acquired infections, KRAS gene mutation testing for targeted treatment of colorectal cancer, Hemoglobin A1c (HbA1c) testing for screening and diagnosis of pre-diabetes and diabetes, and Human papillomavirus (HPV) DNA testing to screen and diagnose cervical cancer.

After assessing the value of lab screening and tests, the researchers concluded “innovation, demonstrated clinical benefit, and appropriate use of laboratory screening and diagnostic tests are essential for achieving the goals of health system reform,” because early detection and diagnosis would result in better health outcomes for the patients and greater savings for the health system. The value of laboratory medicine should be realized because it plays a very important role in patient care, formation of clinical guidelines, and improvements in clinical practice.



For report and briefing materials go to:

www.labresultsforlife.org/briefing

or

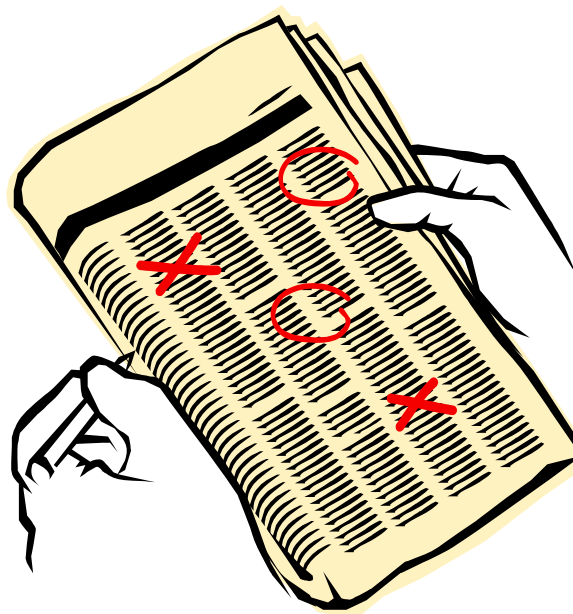
www.advamed.org.

HELP WANTED

Will Recent Legislative Efforts Help Fill Gaps in Laboratory Workforce?

Discussions about overhauling the nation's healthcare system have traditionally drawn closer attention to all areas of health care. The current debate surrounding health care reform is no exception; as Congress wrangles over particulars, there has been an increased focus on those who provide health care services. In fact, there is some mention of the health care workforce in all the proposed major health care reform bills. The nursing shortage is widely known as is the lack of primary care physicians, but does this new emphasis on the health workforce signal the need for allied health workers or laboratory professionals in particular?

Included in the American Recovery and Reinvestment Act passed earlier this year, monies were allocated for health professions training programs through the Health Resources and Services Administration (HRSA). Millions of dollars were made available through these agencies in an effort to counter health workforce shortages by expanding training and educational opportunities. According to HRSA, this investment reflects President Obama's historic commitment to attract and retain more nurses, doctors, and other health care professionals. The new funds are expected to train 8,000 students and credentialed health professionals by the end of fiscal year 2010. Additionally, looking forward to 2010, the President's proposed budget targets more than \$715 million for health professions programs. However, in what has been proposed



thus far, there is absolutely no mention of laboratory professionals; the emphasis on training is restricted to nurses, nursing assistants and physician assistants.

HRSA

Despite these efforts, the fate of the laboratory workforce still seems tenuous at best. At a recent Friends of HRSA Coalition meeting attended by ASCP staff, agency Administrator Mary Wakefield, RN, PhD, provided an overview of many of the agency's initiatives, including health professions training. A question from ASCP and the American Society for Microbiology spoke to the laboratory workforce shortage and whether there would be training for laboratory professionals counted in this emphasis on allied health. An HRSA staffer responded that there was no activity in

the FY 2010 budget and that there were no earmarks that addressed such training. There could be a possibility of funding in FY 2011; however, training for laboratory professionals has not been funded since 2005.

Funding for Title VII (allied health) and Title VIII (nursing) have received marginal increases. Most recently, Congress approved a continuing resolution to fund at the FY 09 levels through October 31, while Congress continues to work on the FY 2010 spending bills. In addition, the Medicare Payment Advisory Commission (MedPAC) has discussed support for funding for the two programs.

Hope From Department of Labor

It appears that the laboratory workforce remains somewhat in the shadows as training and replenishing the health care workforce are addressed. The Department of Labor seems to offer the broadest scope and most hope to secure money for laboratory training programs. The Department announced that funds are authorized for projects that provide training and placement services to help workers pursue careers within the health care sector. Eligible applicants include public entities and private nonprofit organizations. The grants are intended to fund projects that provide workers with training that will prepare them to enter and

advance in the health care sector.

ASCP has encouraged laboratory professional training programs, schools at risk of closure, and programs seeking to expand to proactively examine this grant money from the stimulus package. These dollars are specifically available for health care professions training and for projects that provide training and placement services to help workers pursue careers within the high-growth health care sector. The purpose of the high-growth and emerging industries grants is to teach workers the necessary skills for, and help them pursue careers in, health care. The DOL intends to fund 45-65 grants ranging from approximately \$2 million to \$5 million. The Society has been contacted by a number of schools with laboratory professional training programs that intend to seek funds through the department.

ASCP's Office of Public Policy will continue to monitor the health care workforce from all vantage points, will advocate for legislative and regulatory initiatives that will replenish the pool of laboratory professionals, and will be available to assist those who are interested in pursuing training dollars.

FOR MORE INFORMATION . . .

Visit the Advocacy section of the ASCP website at . . .

www.ascp.org/Advocacy

ASCP Looks to the Future of Pathology and Laboratory Medicine



From left to right: **Jeff Jacobs**, **John Ball**, **Cyril M. Hetsko**, **Ronald A. Paulus**, **Arl Van Moore**, **Ronald L. Weiss**, **Lee H. Hilborne**, **Julie L. Gerberding**, **Mark Sobel**, **Robert Martin**, **Robert H. Brook**, **Steven J. Bernstein**, **John H. Spearman**, **E. Blair Holladay**. Not pictured: **John E. Tomaszewski**.

As the country moves toward a new chapter in healthcare driven by reform, ASCP recently assembled a panel of leaders in the field to examine the role pathology and laboratory medicine will play in its delivery. *Pathology's Future: A View from Leaders in Health Care*, courtesy of a grant from the Abbott Fund, brought together a distinguished cadre of individuals with expertise in different areas of healthcare delivery.

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Julie L. Gerberding and **E. Blair Holladay**

Conference Participants

John Ball, MD, JD, FASCP, Executive Vice President, ASCP

Steven J. Bernstein, MD, MPH, Director, Quality Management Program, University of Michigan Health System

Robert H. Brook, MD, ScD, Vice President of the RAND Corporation and Director of RAND Health

Julie L. Gerberding, MD, MPH, Immediate Past Director, Centers for Disease Control and Prevention

Cyril M. Hetsko, MD, FACP, Chief Medical Officer, COLA, and Member of the Board of Trustees, American Medical Association

Lee H. Hilborne, MD, FASCP, MPH, DLM(ASCP)^{CM}, Past President of ASCP, and Medical Director, Quest Diagnostics, Southern California

E. Blair Holladay, PhD, SCT(ASCP)^{CM}, Vice President for Scientific Activities, ASCP, and Executive Director, Board of Registry

Jeff Jacobs, Vice President, Public Policy and Government Affairs, ASCP

Robert Martin, MPH, DrPH, Laboratory Science Officer, Coordinating Office for Global Health, CDC

Arl Van Moore, Jr., MD, FACR, Chairman of the Board, American College of Radiology

Ronald A. Paulus, MD, MBA, Executive Vice President, Clinical Operations and Chief Innovations Officer, Geisinger Health System

Mark Sobel, MD, FASCP, Executive Officer, Association for Molecular Pathology

John H. Spearman, MBA, Senior Vice President, External Affairs, University of Maryland Medical Center

John E. Tomaszewski, MD, FASCP, Interim Chair and Professor, Department of Pathology and Laboratory Medicine, Hospital University of Pennsylvania, Vice President, ASCP

Ronald L. Weiss, MD, MBA, Executive Vice President, Health Policy, External Affairs and Corporate Communication, ARUP Laboratories

Future of Pathology... (Continued from previous page)

The objective of the conference was to evaluate the role of pathology and laboratory medicine in the practice of medicine and identify innovative services that will complement patient care and improve patient outcomes.

The panel was composed of clinicians, researchers, government officials, hospital administrators, IT specialists, experts in quality and public health, as well as pathologists. Discussion centered on the role of pathologists and laboratory professionals in a number of areas, including the development and impact of new technologies, increased involvement in patient

care delivery and guideline development, personalized medicine, employing laboratory data to prevent overutilization, and global efforts to ensure international standards and quality. The discussions initiated at the conference mark the beginning of what will be continued dialogue on how pathology and laboratory medicine must evolve to meet the needs of tomorrow's patients.

Look for follow-up from *Pathology's Future: A View from Leaders in Health Care* in future editions of *ePolicy* and on the ASCP website.

GAO Report on High-Containment Laboratories *A Single Entity is Needed to Provide Government-Wide Strategic Oversight*

The expansion of high-containment laboratories, triggered by the anthrax incident in 2001, has taken place throughout the federal, state, academic and private sectors of the United States. While these facilities play an important role in discovering ways to combat the effects of dangerous biological pathogens and emerging infectious diseases, the accidental or intentional release of the microorganisms they possess can have detrimental effects to the workers and the public. There is a growing concern that biosafety level (BSL)-3 and BSL-4 laboratories are not being properly monitored. As a result, the US Government Accountability Office (GAO) conducted a study on high-containment lab expansion and management. The report was released in September 2009, stating that a national strategy for oversight is needed.

According to GAO, a proper assess-

ment of national needs for BSL-3 and BSL-4 laboratories is a tremendous challenge. At present, no single entity oversees the expansion of these facilities or has the knowledge of existing capacity. Information on the number, location, activities and ownership of high-containment labs are only available for those who are registered to the Division of Select Agents and Toxins (DSAT) and Animal and Plant Health and Inspection Service (APHIS). The number of BSL workers by type of laboratory and type of worker (lab staff and support staff) are not included in the DSAT database, making it difficult to monitor workforce need. Therefore, aggregate risks are not properly measured and effective safety guidelines are not in place.

The report also reviewed four highly publicized incidents that feature some of the risks associated with the expansion of high-containment laboratories. They are (1) alleged insider misuse of a select agent and laboratory;

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(2) Texas A&M University’s failure to report to CDC exposures to select agents; (3) power outages at CDC’s high-containment labs; and (4) the release of foot-and-mouth disease virus at the Pirbright facility in the United Kingdom. GAO suggests that DSAT and APHIS examine the key issues that stemmed from these events so that proper guidelines on high-containment laboratory design, training of workers, personnel reliability programs, definition for exposure and inventory control measures may be formed. As part of GAO’s recommendation for executive action, they call upon the National Security Advisor to collabo-

rate with the Secretaries of Health and Human Services (HHS), Agriculture (USDA), Defense (DOD) and Homeland Security (DHS), the National Intelligence Council and other executive departments to form a single entity responsible for the government-wide strategic oversight of high-containment laboratories. In doing so, the nation can utilize these laboratories to its maximum potential.

For access to the full report, go to: www.gao.gov/new.items/d09574.pdf

ASCP Appeals to MedPAC on Self-Referral of Anatomic Pathology

ASCP recently appealed to the Medicare Payment Advisory Commission (MedPAC) to increase its recent focus on physician self-referral arrangements pertaining to anatomic pathology services, urging the Commission, an advisory body to Congress, to recommend closure of the Stark law loopholes enabling ordering physicians to markup anatomic pathology services. ASCP’s comments were provided as part of MedPAC October meeting in Washington, DC.

Over the years, MedPAC has published several reports detailing and providing policy recommendations to Congress about self-referral arrangements. These reports have focused on imaging services and physician-owned hospitals. This time, however, anatomic pathology was on the commission’s agenda. The addition of anatomic pathology service is the direct result of ASCP’s work to inform MedPAC about some of the abusive arrangements that ordering physicians have used to profit from the pathology and laboratory services they or-

der on they patients. ASCP, along with the American Clinical Laboratory Association and the College of American Pathologists, met with MedPAC staff earlier this year about this issue.

The commission’s deliberations marked the first time in recent years that MedPAC considered whether the in office ancillary services exception needs reconsideration. In its comments to MedPAC, ASCP noted that one of the goals of health care reform to obtain “meaningful control of health care expenditures can [not] be achieved without stronger safeguards against physician self referral.” “If the federal government is serious about trying to control unnecessary health care spending,” ASCP argued, “there may be no better place to start than reforming the Stark self-referral law.”

To obtain a copy of ASCP’s comments to MedPAC, visit www.ascp.org/MedPAC.