G2 INTELLIGENCE

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Congress Urged to Support Lab Personnel Training

The laboratory is a rare place in today's economic climate where job opportunities exist and are projected to grow, but there are not enough qualified personnel available or being trained to fill the slots.

In a wake-up call to Congress, the American Society for Clinical Pathology (ASCP) has urged lawmakers to address the nation's laboratory personnel shortage by reauthorizing the Workforce Investment Act this year with provisions that offer financial assistance to two-year and four-year academic programs that train clinical laboratory professionals.

Despite a growing job market, there are not enough qualified personnel to fill available slots and not enough individuals in the pipeline to meet current, let alone future, demand as hospitals and cash-strapped states shutter training programs.

Federal support is needed to bridge "the disconnect between needed laboratory personnel and available jobs. The missing link continues to be financial resources," ASCP said.

According to the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), the number of accredited medical laboratory technology programs, the programs that train medical laboratory scientists and technicians, dropped from 709 in 1975 to 229 in 2011.

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Major Changes Ahead in CPT Coding for Molecular Pathology Tests

The biggest overhaul in pathology and laboratory CPT coding in 20 years is well under way. The American Medical Association's CPT Editorial Panel met June 2-4 to respond to feedback it received on proposed new code sets for molecular pathology to replace the "stacking codes" (CPT 83890-83914) now used for billing and reimbursement.

Under the new system, there would be two code categories covering more than 90 percent of the volume of current molecular pathology procedures:

- ❏ Tier 1 for high-volume tests coded by specific analyte.
- ❏ Tier 2 for low-volume tests coded by the level of resources required for their performance and interpretation.

The coding overhaul was handled by the AMA Molecular Pathology Coding Workgroup (MPWG), which began its work in December 2009 focusing on molecular assays in cancer, genetics, and histocompatibility.

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Tougher State Self-Referral Law Not Preempted by Federal Law

The federal physician self-referral law does not preempt the state of Florida from enacting more stringent self-referral requirements, a federal district court ruled May 27 in a case brought by a leading provider of renal dialysis services (*Fresenius Medical Care Holdings v. Francois, N.D. Fla.*, 4:03-cv-411).

The Florida case is the latest reminder to labs and other providers that they need to make two analyses of their business arrangements with physician referral sources: Do the arrangements satisfy the federal law? Do they pass separate muster under state and local requirements?

At issue was the state's law regulating physician referrals of patients. The statute makes it unlawful for a physician to refer a patient to clinical laboratory services at an entity in which the physician has a financial interest. In 2002, the statute was amended to delete an exemption for renal dialysis services.

The U.S. District Court for the Northern District of Florida found no indication in the text or history of the federal law, also known as the Stark law, that Congress intended to preempt more stringent state laws. Most states have self-referral regulations, and many have requirements more stringent than the federal law, the court pointed out.

In the opinion by Chief Judge Stephan P. Mickle, the court said there are two types of federal preemptions:

- ❑ Express: when the statute specifically states that the law was intended to displace state law.
- ❑ Implied: when Congress has legislated so pervasively in the field that there is no room for state law.

Only the latter was in dispute in this case, the court said. Fresenius argued for preemption based on the need for uniform standards for patient referrals under Medicare and Medicaid. The federal statute contains an exemption for end-stage renal disease patients. Fresenius argued that Florida's failure to recognize a similar exemption created a prohibited conflict with the federal law.

But the court's analysis of the legislative history of the Stark law found no evidence that Congress intended to preempt state laws that were more restrictive than the federal statute. Additionally, regulations implementing the act specifically recognized that an arrangement that would not violate the federal law could violate state law.

The federal Stark statute applies to physician referrals of clinical laboratory and other designated health services to entities with which the physician (or an immediate family member) has a financial relationship, whether by ownership/investment interests or compensation arrangements, or both. Also outlawed: billing anyone (Medicare, Medicaid, other third-party payers, or the patient) for a service provided pursuant to a prohibited referral. Sanctions for violators include civil money penalties and exclusion from Medicare and Medicaid. There are numerous exceptions that protect ownership/investment interests or compensation arrangements, or both. The Centers for Medicare and Medicaid Services has implemented the regulations through a series of rulemakings—Stark I, II, and III—including defining new exceptions and revising existing ones (such as the safe harbors for space lease and compensation arrangements and for in-office ancillary services).

Health Policy Experts Back New Independent Pay Board

More than 100 health policy experts from across the country have urged Congress to strengthen the controversial Independent Payment Advisory Board (IPAB), a move strongly opposed by many health care provider and business groups as well as congressional Republicans who support eliminating it (*NIR 11, 9/May 12, p. 2*).

In a May 20 letter to House and Senate leaders in both political parties, the experts said the IPAB, created by the health care reform law, would make professional expertise available to lawmakers on ways to evaluate payment reforms.

"The IPAB is a tool designed to help Congress slow the rapid projected increases in health care costs in the federal budget and to improve the delivery of health care. We believe that an independent board is essential to promote, monitor, and implement reforms that improve Medicare and the nation's health care system."

The Board at a Glance

Composition: Fifteen members appointed by the president, subject to Senate confirmation. The secretary of Health and Human Services, the administrator of the Centers for Medicare and Medicaid Services, and the administrator of the Health Resources and Services Administration serve ex officio as nonvoting members.

Terms of Office: First members appointed will be divided into three staggered classes in order to ensure that their terms do not expire simultaneously. A member may not serve more than two full consecutive terms.

Function: Recommend proposals to Congress to curb growth in Medicare spending, including reductions when a target growth rate is exceeded, that would become law unless lawmakers come up with an alternative.

Limits: By law, "proposals shall not include any recommendation to ration health care, raise revenues or Medicare beneficiary premiums under sections 1818, 1818A, or 1839, increase Medicare beneficiary cost sharing (including deductibles, coinsurance, and copayments), or otherwise restrict benefits or modify eligibility criteria."

Beginning in 2014, in any year in which the Medicare per capita growth rate exceeds a target growth rate, the board is required to recommend Medicare spending reductions that would become law unless Congress passes an alternative that achieved the same level of savings.

Opponents argue that the board shifts responsibility for Medicare payment decisions historically made by Congress to an unelected body in the executive branch and short-circuits the current process for a legislative airing of important health care policies. Also, since much of Medicare spending is exempt from the IPAB's purview until 2020 (hospital spending, for example), opponents say this only shifts costs to private payers and consumers.

But the policy experts contend that the IPAB "will not diminish the power of elected officials because Congress may approve, disapprove, or replace the board's proposals with an alternative that achieves the same objectives" and "will force debate on difficult choices that Congress has thus far not addressed."

Bills to repeal the IPAB have been introduced by Republicans in the House (H.R. 452, Tennessee Rep. Phil Roe, with 124 co-sponsors) and in the Senate (S. 668, Texas Sen. John Cornyn, with 28 co-sponsors). G2

Lab Personnel Training, *from p. 1*

NAACLS reports that seven medical laboratory scientist programs and 17 medical laboratory technician programs across 20 states are at risk for closure this year.

The Workforce Investment Act (WIA) offers the best scenario, ASCP said, "to stabilize our nation's clinical education and training programs, fill longstanding vacancies with qualified professionals, and equip the workforce with skills needed to serve an aging population requiring more medical tests."

ASCP made its case in follow-up testimony to the May 11 hearing on removing inefficiencies in the nation's job training programs, held by the House subcommittee on higher education and workforce training.

Demand Outstripping Supply

The U.S. Department of Labor's (DOL) Bureau of Labor Statistics estimates there will be almost 11,000 laboratory technologist/technician job openings annually through 2018. The DOL *Occupational Outlook Handbook* for 2010-2011 lists clinical laboratory scientists as a highly promising career, with "rapid job growth and excellent job opportunities" and describes an appealing career, with an attractive pay scale and employers waiting to hire.

Along with testimony to a key House subcommittee, ASCP held meetings last month with key staffers and members in both houses during the society's annual Capitol Hill day to press home the need to invest in laboratory medicine, which provides the scientific foundation for disease prevention, treatment, and therapy and drives the vast majority of clinical decisions vital to quality care.

In addition, members of ASCP's commission on public policy lobbied for:

- *Repeal of the sustainable growth rate (SGR) formula in Medicare and implementation of a five-year period of stable payments; and*
- *Stable funding for the global health initiative and the president's emergency plan for AIDS relief.*

But programs preparing tomorrow's laboratory workforce train only about a third of what is needed. Fewer than 5,000 individuals graduate each year from accredited training programs.

Hospitals, States Close Training Pathways

Laboratory educational programs prepare people for careers that routinely provide the critical information needed for most medical treatments and therapy, but they are expensive to run and require small classes taught by qualified professionals.

Hospitals, which used to conduct most of the training, have shifted their resources and closed most of their programs. Some state governments have determined that the programs are too expensive to run because of small class size and the investment in laboratory infrastructure needed to adequately train students. Just a few of the programs that have closed in recent years, ASCP noted, include Arizona State University; the University of South Alabama; the University of Wisconsin, Madison; Western Carolina University; and the University of Nevada, Las Vegas.

Lab Staff Workload, Turnover Rates High

Today, increasing numbers of laboratory professionals are working second jobs or extra shifts. With competition for qualified laboratory personnel intensifying, annual turnover rates for some categories exceed 20 percent. Because of the difficulty in finding qualified staff, medical laboratories are increasingly turning to temporary staff (many of whom may already be working full- or part-time clinical lab jobs) to handle the patient testing workload.

Aging Workforce, Fewer Replacements in the Pipeline

Another concern is the aging laboratory workforce, reflecting the slowing pace at which younger, newly trained laboratory professionals are entering the laboratory

workforce. Approximately 40 percent of the laboratory workforce is within 10 years of retirement. Many are in fact delaying retirement because of the dismal economy and the need to sustain that source of income.

Some Bright Spots

With funding streams drying up, states and individual universities have made use of WIA dollars and stimulus money in the economic recovery bill to keep valuable programs afloat.

Minnesota got two Labor Department grants totaling $5 million through WIA, which has allowed a local educational institution and a health care system to build a cohesive structure that led from training to employment, as shown below:

- ❏ During 2006-2008, 308 students graduated from medical laboratory technician (MLT) and medical laboratory science (MLS) programs.
- ❏ During 2009-2011, the number of graduates from MLT and MLS programs rose to 423.
- ❏ From the initial period of 2006-2008 through the 2009-2011 cycle, there was an increase in the number of graduates: 115 or an increased graduation rate of 137.4 percent.

In California, San Jose State University's clinical laboratory scientist training program, part of the department of biological sciences, won a $5 million grant through the American Recovery and Reinvestment Act of 2009 to train future health care professionals.

"To fill the needs in California alone, we need to be training 850 people a year," said Michael Sneary, professor and chairman of the department. "At this point, we are training 300."

The picture in California distills the problems facing other states as the shortage drags on, ASCP said. "There are 34 clinical lab scientists for every 100,000 Californians compared to the national rate of 54 such workers for every 100,000 people. Vacancies of nearly one-third of the jobs now occupied are predicted for coming years because the average age of workers in the field is above 50, as possibly up to one-third of staff could be lost to retirements over the next four or five years."

Minnesota and the San Jose programs are just two examples of the synergy and partnership that other states could replicate, ASCP noted. In reauthorizing the WIA, Congress should include provisions that make institutions of higher learning partners in job creation initiatives, with medical lab personnel training programs as one of a group of preferred programs where a large number of job vacancies exist.

National Commitment Needed to Fill Gap

In conclusion, ASCP pointed out that these model programs rested on local resourcefulness in tapping new revenue streams from the government to bridge the gap from education and training to employment. But funding from the WIA and the economic stimulus bill will eventually dry up and need to be replaced if programs are to survive and grow. Local and state program models, no matter how successful, are no substitute for a national commitment to invest in clinical lab education and training to prepare for an aging population and new service delivery models, the society concluded. G2

Major Changes Ahead, *from p. 1*

"Our goal was to have a specific CPT code for a large majority of the clinically useful molecular pathology procedures performed," said Mark Synovec, M.D., co-chair of the MPWG, in an interview in the April issue of *CAP Today*.

Given the scope of the changes, the AMA took an unusual step this March by releasing for the first time the coding descriptions for the proposed codes to allow stakeholder input through April 15. The AMA also invited comments on future coding for lab-developed multivariate index assays.

The Tier 1 and Tier 2 codes, not yet available for reporting nor recognized by payers, are scheduled to be published in the CPT update for 2012 and will be submitted to the Centers for Medicare and Medicaid Services (CMS) for its review.

Unanswered Questions

When it comes to Medicare coverage and reimbursement, CMS has its own final say on recognizing the coding changes and when to do so. A key question is where the agency would place those it recognizes:

- ❏ On the clinical laboratory fee schedule, where pricing is set using the crosswalk or gap-fill method and there is no beneficiary cost sharing for tests; or
- ❏ On the physician fee schedule, where pricing is set using relative value units (RVUs) subject to adjustments under the sustainable growth rate (SGR) formula and periodic CMS review of the relative values. Beneficiary cost sharing is required.

The CPT molecular pathology coding changes do not affect molecular microbiology tests or most cytogenetic assays, the AMA said.

Another issue is the implementation timeline. The AMA feedback request targeted the Tier 1 and Tier 2 changes to take effect Jan. 1, 2012. Tests that have new analyte codes assigned and are listed in these tiers must be coded with the most specific CPT code available and not with stacking codes. Some industry sources are hoping for more flexibility in the timing to allow providers sufficient time to comment on and digest final changes before the full rollout of the new codes.

For tests not in either tier, the current stacking codes will apply for 2012 but are likely to be retired in 2013, AMA said in the feedback request. But industry sources speculate they might be retired earlier, depending on payer and provider readiness. No one will miss these codes for analysis of nucleic acids. They have been outpaced by technology advances, are cumbersome to bill, and payers have been loath to cover them because they are unsure of what was actually done. They are coded by procedure, rather than analyte, and each procedure used in an analysis is coded separately, including, where appropriate, use of a modifier to specify the probe type or condition tested.

CMS will invite public comment this summer on these issues in its annual lab public forum for pricing new and revised CPT codes or the proposed 2012 physician fee schedule rule or in both venues.

Indiana Enacts Direct Billing Law for Anatomic Pathology

Indiana is the 18th state to enact a direct billing law for anatomic pathology services (*see box*). Signed May 13 by Gov. Mitch Daniels (R), the measure (H.B. 1071) takes effect July 1. The measure was supported by the College of American Pathologists (CAP) and the Indiana Association of Pathologists.

Just one month earlier, Washington became the 17th state to enact a similar direct billing law, which takes effect July 1 as well (*NIR 11, 9/May 12, p. 8*).

States With AP Direct Billing Laws

Arizona	Montana
California	Nevada
Connecticut	New Jersey
Indiana	New York
Iowa	Ohio
Kansas	Rhode Island
Louisiana	South Carolina
Maryland	Tennessee
Massachusetts	Washington

CAP, along with various other state pathology societies, supports direct billing laws like the one in Indiana because they protect patients from "mark-up charges" added by an ordering physician. These laws ensure that patients are billed for anatomic pathology services only by the physician performing or supervising the service.

CAP and state societies have long opposed the practice of client billing, in which a treating physician realizes a profit by charging a patient full price for a laboratory service the physician received at a discount. In some cases, a physician marks up the price of the service to widen the profit margin. This practice gives providers an incentive to choose a test based on price, rather than quality, critics say. It also creates an incentive to order more tests than necessary since each service ordered results in an incremental increase in profit.

Policymakers in the News

Two new members have been appointed and three commissioners reappointed to the influential Medicare Payment Advisory Commission, the Government Accountability Office (GAO) announced May 31.

The new members are **Willis D. Gradison Jr.**, a scholar-in-residence in the Health Sector Management Program at Duke University's Fuqua School of Business, and **William J. Hall**, a geriatrician and professor of medicine at the University of Rochester. Their terms expire in 2014.

"Given the challenges facing Medicare, the commission will be more important than ever," Gene L. Dodaro, comptroller general of the United States and head of GAO, said in a statement.

Gradison, a Republican, was part of the Ohio delegation in the House of Representatives from 1975 to 1993. He served on the Budget Committee and the Committee on Ways and Means.

Hall is a member of the board of directors of AARP. He helped establish the Program of All-Inclusive Care for the Elderly and many senior prevention and wellness programs, according to GAO.

The two replace Jennie Chin Hansen, chief executive officer, the American Geriatric Society; and Nancy M. Kane, professor of management in the Department of Health Policy and Management and associate dean of education, Harvard School of Public Health.

Reappointed commissioners are **Peter W. Butler**, executive vice president and chief operating officer, Rush University Medical Center; **Michael Chernew**, professor of health care policy, Harvard Medical School; and **George N. Miller Jr.**, chief operating officer, First Diversity Management Group and managing partner of First Diversity Healthcare Group.

CMS Announces National Version 5010 Testing Days: Wednesday, June 15 and Aug. 24

CMS also is holding its 17th national provider call on Medicare implementation of Version 5010 and D.0 transactions on June 29 from 1:30 p.m. to 3 p.m. (Eastern). For more information on HIPAA Version 5010, go to http://www.cms.gov/Versions5010andD0.

The Version 5010 compliance date—Sunday, Jan. 1, 2012—is fast approaching, and the Centers for Medicare and Medicaid Services is urging all entities covered under the Health Insurance Portability and Accountability Act (HIPAA) to get ready, including conducting external testing to ensure timely compliance.

Medicare fee-for-service trading partners—providers, clearinghouses, and vendors—are encouraged to contact their Medicare Administrative Contractors (MACs) now and gain a better understanding of MAC testing protocols and the transition to Version 5010.

To assist in this effort, CMS will hold National 5010 Testing Days on June 15 and Aug. 24 to help trading partners test compliance efforts already under way with real-time help desk support and direct and immediate access to MACs. More details concerning transactions to be tested are forthcoming from your local MAC. Also, several state Medicaid agencies will be participating in the testing days; more details will follow from them as well.

G2 Conference Calendar

Upcoming Conferences

June 15-17
Laboratory Outreach: Repositioning Your Program for the New Normal
Caesars Palace
Las Vegas

Sept. 22
Molecular Diagnostics-Fall 2011
W San Francisco
San Francisco

Oct. 19
Lab Leaders Summit 2011
Come for the summit and stay for Lab Institute
Ritz-Carlton Pentagon City
Arlington, Va.

Oct. 19-21
Lab Institute 2011
Arlington, Va.

Dec. 12-14
LabCompete: Laboratory Sales & Marketing
Sheraton Wild Horse Pass Resort
Chandler, Ariz.

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