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Stakes Are High for Pathologists, Labs in Health Care Reform

Congressional Democratic health leaders have told the president they plan to have their committees pass health care reform bills by the August recess, paving the way for House and Senate floor action later this year.

Congress returned the week of April 20 from a two-week Easter recess, with Democratic health leaders vowing to enact health care reform legislation this year, but a more immediate task for lawmakers is reconciling differences between House and Senate budget blueprints for fiscal 2010.

Both House and Senate budget plans approve President Obama's request for a $634 billion, 10-year reserve fund as a "down payment" on reform, including a Medicare physician fee fix, but leave it to the committees of jurisdiction to determine where to increase and cut spending.

For pathologists, a top priority is enactment of a permanent Medicare fee fix that does away with the Sustainable Growth Rate (SGR) update formula that will trigger deep payment cuts in the years ahead. In 2010, fees are scheduled to be cut by 21 percent under the SGR unless Congress intervenes.

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Medicare and Genetic Tests for Screening: What's the Evidence Needed for Coverage?

The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) will hold a May 6 public forum on the use of genetic screening tests to improve health outcomes for Medicare beneficiaries and the evidence needed to support Medicare coverage of such tests.

This is the second of two meetings that MEDCAC is conducting to obtain public input to guide Medicare coverage decisions relating to the uses of genetic (including genomic) testing by the beneficiary's treating physician to guide diagnosis and treatment. Genetic testing is defined as "any test performed using molecular biology methods to test DNA or RNA, including germline, heritable, and acquired somatic variations."

The first forum, held Feb. 25, focused on the use of genetic testing for diagnostic purposes (*NIR, 09, 3/Feb 9, p. 1*). The May meeting will be devoted to discussing screening tests that are used to identify an occult condition or state in an asymptomatic person or that lead to early detection of clinically inapparent disease. "Medicare currently does not have a national coverage decision for screening genetic tests," said the Centers for Medicare and Medicaid Services (CMS) in announcing the forum.

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Repealing the SGR and adopting a permanent Medicare physician fee fix would be costly—as much as $330 billion over 10 years. The House and Senate budgets set aside this amount in the reserve fund to finance a fix, though they disagree on how to account for the cost. The House plan would add it to the federal budget deficit, while the Senate plan would require that it be paid for, potentially through payment cuts to other providers or more short-term fixes to block the SGR from forcing further fee cuts. The Obama administration supports Medicare physician payment reform that is tied to rewards for quality and efficiency.

Clinical laboratories would see some gains in health care reform proposals being considered on the Hill, say industry sources. Expansion of coverage through public and private plans means more lab testing. Emphasis on prevention and wellness will increase the use of Medicare-covered screening tests for breast, colon, and prostate cancer, cardiovascular disease, diabetes, and other conditions. New Medicare financial incentives to physicians and hospitals to adopt electronic medical records, including test ordering and results reporting, will save money for labs. The economic stimulus law enacted this year provides $19.2 billion for these incentives and for investments in the health IT infrastructure.

For the lab industry, the key priority is to ward off any further reductions in Medicare lab spending that would be used to pay for increases elsewhere (*related story, p. 3*). While lab groups were successful last year in getting Congress to approve an annual Consumer Price Index (CPI) update to the Part B lab fee schedule over the next five years, starting Jan. 1, 2009, lawmakers required that the update be 0.5 percent less than the full CPI increase.

Some lab groups want to tap the reform effort to modernize the Medicare lab fee schedule. The American Society for Clinical Laboratory Science and the Clinical Laboratory Management Association are backing legislation that would use negotiated rulemaking to develop a single national lab fee schedule, adjusted for geographic practice cost differences.

Timeline for Crafting Legislation

No bills have been introduced at press time, but congressional health committee leaders have set a timeline for developing their health care reform proposals. In an April 20 letter to the president, Senate Finance committee chairman Max Baucus (D-Mont.) and Health, Education, Labor, and Pensions committee chairman Edward M. Kennedy (D-Mass.) said their committees will consider separate reform bills in early June. These measures will then be merged into a single bill for consideration on the Senate floor. Baucus has said he wants it done by the August recess.

The Finance committee on April 21 held the first of three roundtables to gather comments from stakeholders as it prepares a bill. The next roundtable, set for April 29, will examine legislative options, while sessions on health care coverage and reform financing will be held May 5 and May 14, respectively.

Baucus released a white paper last November with proposals for sweeping change, including an individual mandate to buy coverage, a national exchange where individuals could find coverage, improving health care quality, requiring employers to provide coverage for workers or pay into a fund, and creating a Medicare "buy in" for individuals age 55 to 64. Baucus has said taxing employer-sponsored health insurance should be part of the reform funding debate. In his white paper, he said the tax exclusion should not be eliminated, but could be capped.

On the House side, in a letter to Obama last month, the chairmen of the three House committees with jurisdiction over health care said they aimed to pass reform legislation by the August deadline. They pledged to coordinate their work with the Senate and the White House Office of Health Reform to ensure that reform is enacted. Signing the letter were Ways and Means chairman Charles B. Rangel (D-N.Y.), Energy

and Commerce chairman Henry A. Waxman (D-Calif.), and Education and Labor chairman George Miller (D-Calif.).

House and Senate leaders acknowledge that the timetable is ambitious, and some observers continue to express doubts Congress will be able to meet it, given the politically charged trade-offs at issue. But Baucus and Kennedy emphasized that swift action is needed now in the face of rising health care costs, the growing number of the uninsured, and the need for payment incentives that reward the quality, not just the quantity, of care. A broad coalition of stakeholders, historically at odds over reform, agree and are eager to come to the table with their competing and complementary priorities. Stakeholders include health insurers, employers, state and local governments, and consumer groups.

But fissures are likely to emerge once the parties get down to the controversial details, including a public plan option to compete with private insurers, a coverage mandate for individuals, competitive bidding for Medicare manage care plans, and the spending trade-offs needed to pay for reform.

ACLA Spells Out Its Priorities for Health Care Reform

In anticipation of the upcoming debate in Congress over how to overhaul the nation's health care system, expand coverage, reward quality, and lower costs, the American Clinical Laboratory Association (ACLA) has released its major reform goals and proposed actions.

Laboratory testing services must be part of covered benefits in all health plans, ACLA says, since this testing is on the front line in preventing and treating diseases and other conditions. "Test results enable early detection and targeted therapy that, together, are changing the course of the most costly and damaging diseases—cancer, heart disease, HIV, and diabetes, among others."

Accordingly, ACLA says, health systems should "encourage appropriate utilization of clinical laboratory services by rewarding health care providers to institute care consistent with consensus clinical guidelines, especially for costly chronic disease." Toward this end, Medicare beneficiaries should continue to have full access to lab services without any copay.

Labs should receive "adequate reimbursement commensurate with the added value and savings they contribute to health care delivery," ACLA contends. In addition to earlier identification of health risks and disease, lab tests guide treatment, decreasing the severity and cost of subsequent health care interventions. While lab tests comprise less than 5 percent of hospital costs and about 1.6 percent of all Medicare costs, their findings influence as much as 60 to 70 percent of health care decisions, ACLA notes.

Accordingly, Medicare reimbursement for lab services should receive annual inflation updates. Lab services should continue to be billed directly to payers, with no bundling of payment into the physician office visit. Health plans should include a redesigned payment system for advanced diagnostic genetic and molecular tests that values these innovations and eliminates complex and outmoded reimbursement requirements.

ACLA also stressed that preventive and early diagnostic lab services should be a covered benefit in all health plans, and screening and wellness should be given equal importance with treating disease. This would replace the "silo" mentality in Medicare, ACLA says, and take into account these broad, crosscutting benefits to patients.

California Initiative Targets Shortages in Allied Health Ranks

California's Republican Gov. Arnold Schwarzenegger this month unveiled a $32 million effort to expand training in allied health professions to meet the state's rising demand as the population grows and ages.

The Allied Health Initiative aims to add thousands of allied health professionals, including laboratory and radiology technicians and technologists, pharmacy technicians, and dental hygienists, to the health care workforce over the next three years.

The initiative is a public-private partnership involving the state, schools, and hospitals, including the California Community Colleges, the University of California and California State University systems, and the California Hospital Association. It builds, the governor's office noted, on the 2005 Nurse Education Initiative, a five-year partnership that has increased registered nurse graduates by 54 percent by 2008.

Stimulus Money in the Pot

The $32 million tab for allied health training will be split, with the state contributing $16 million in federal stimulus funds and its partners contributing an equal amount in matching funds or in-kind contributions. Of the state's $16 million portion, $8 million comes from the Workforce Investment Act and $8 million from the American Recovery and Reinvestment Act. The state Labor and Workforce Development Agency is leading the initiative.

Shortages and Rising Demand

Over 60 percent of the health occupations in California are in allied health and are currently experiencing shortages, according to a Health Workforce Solutions study. Also, more than one million Californians will be 85 years of age or older by the year 2030, which will increase the demand for health care services.

To address this shortage, California will need to educate an estimated 206,000 additional health care professionals by 2014, according to the state Labor and Workforce Development Agency and the Employment Development Department.

Fall Startup Scheduled

Beginning this fall, the Allied Health Initiative will enroll more than 700 additional allied health students in 25 community colleges and the program will continue for three years. This will add to the more than 50,000 students currently enrolled in health occupation programs at the participating community colleges.

"In this difficult economy with high unemployment, health care is the only industry sector growing in California," the governor's office noted, "with 27,000 jobs created between January 2008 and January 2009, but still our hospitals and community clinics struggle with massive shortages."

According to recent statistics from the California Labor Market Information Division and Federal Bureau of Labor Statistics, California only has 65 percent of the medical lab technologists and 62 percent of the radiation technologists and technicians of the national average per 100,000 people.

California Not Alone in Facing Shortages

More than half of clinical laboratories struggle to hire personnel, and the vacancy rate for medical technologists is the highest, at over 10 percent, according to the *2009 Wage and Vacancy Study* conducted by the American Society for Clinical Pathology.

Sixty-three percent of laboratories face increased competition for qualified staff as the primary challenge in filling vacancies. Other hiring challenges include salary and job location. Thirty-three percent of survey respondents reported low compensation as a recruiting problem, while 28 percent said applicants were unwilling to relocate.

The most difficult positions to replace are medical technologists (MT) at the staff level, at 63 percent and medical laboratory technicians (MLT), at 38 percent. The highest MT vacancy rate was 10.4 percent, primarily in the East North Central and Far West areas of the United States. Laboratory assistants also reported a high vacancy rate, 8.8 percent, primarily in high-volume testing labs (26.3 percent). Histotechnicians also rated among the highest in vacancies, at 8 percent. The survey showed MLTs with a 6.4 percent vacancy rate. The highest MLT vacancies were in outpatient clinics, reference labs, and high-volume testing labs.

CAP Presents Its Priorities for Comparative Effectiveness Research

The aim of CER is to evaluate health care tests and treatments to determine significant advantages or disadvantages. The findings would help patients make better decisions about the health care they need and help physicians focus on the best tests and treatments for individual patients.

The new federal priority on competitive effectiveness research (CER) should "recognize the central role that laboratory testing and diagnostics play in minimizing the burden of disease, enhancing patient safety, and promoting patient-centered and personalized care," the College of American Pathologists (CAP) told the Federal Coordinating Council on CER. This research got a boost of $1.1 billion in the economic recovery legislation enacted earlier this year.

Speaking for CAP at the council's first public listening session, held April 14, David Witte, M.D., Ph.D., FCAP, said, "The goal of the health care system should be to provide accessible quality health care to patients. This requires getting the right test, to the right patient, in the right time, to provide the right care." Witte, who chairs the CAP Patient Safety and Performance Measures committee, also provided guidelines for CER development:

- Any organizational entity that evaluates clinical effectiveness must be independent, objective, transparent, and inclusive.
- Priorities should be based on consensus criteria derived from input provided by providers, patients, payers, purchasers, and researchers.
- Pathologists and the pathology community should have substantial and central representation on the determining body because of their critical role in medical decisions.

In an April 13 letter to the Institute of Medicine, CAP urged the IOM committee on CER to recognize the laboratory's essential role and presented areas that should have the highest priority for research funding allocated to the Health and Human Services secretary by the economic stimulus law. The IOM will submit a consensus report to Congress and HHS by June 30, 2009, with recommendations for spending more than $400 million in CER funds.

Medicare and Genetic Tests, *from p. 1*

Medicare Part B generally does not cover screening services for beneficiaries, but during the last 25 years, Congress approved coverage for certain screenings, including mammography, glaucoma, pelvic exam and Pap test, diabetes, lipids, colorectal cancer, and prostate cancer. Until this year, only Congress could approve Part B coverage of screening tests, but as of Jan. 1, CMS has authority to cover new services, via the Medicare national coverage decision process, that are recommended by the U.S. Preventive Services Task Force (Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275).

In advance of the May forum, CMS said it wants MEDCAC's recommendations on "whether screening genetic testing changes the natural history and/or reduces the complications of the disease and alters morbidity/mortality." The agency also wants the committee to identify current data deficiencies that warrant further research.

"An example of a genetic test suggested for screening use," CMS noted, "is detection of the homozygous presence of e4 allele of the APOE gene (also expressed as APOE e4/e4). This genetic characteristic has been shown in published studies to be associated with an elevated risk of developing Alzheimer disease (Odds Ratio 2.1 (95% CI, 5.1-11.9)b)."

Issues for MEDCAC Screening Forum

CMS has raised specific questions on which it wants MEDCAC's advice:

1. Are there differences in the desirable characteristics of evidence about screening genetic tests versus those of screening tests in general?

2. What are the desirable characteristics of evidence for determining the analytical validity of screening genetic tests?

3A. Beyond aspects of analytical validity, are there meaningful differences in the desirable and/or necessary characteristics of evidence about the effect of genetic testing on outcomes? If yes, please consider question 3 separately for each paradigm:

- — Early detection of disease in an asymptomatic person
- — Early treatment of disease (before signs or symptoms are apparent)

3B. What comparative data are needed on alternative strategies for screening?

4. For each type of outcome below, how confident are you that methodologically rigorous evidence is sufficient to infer whether or not screening genetic testing is effective for the prevention or early detection of illness or disability? For each lettered outcome type, assign a number from 1 to 5 to indicate your vote. A lower number indicates lower confidence; a higher number indicates higher confidence.

- — Additional (confirmatory) diagnostic procedure
- — Survival
- — Other patient-focused health care outcomes, *e.g.*, functional status, incidence of adverse events

5. What are the desirable measures of the cost-effectiveness of screening genetic tests for the prevention or early detection of illness or disability?
Consider ranking (1=lowest thru 3=highest) the below (a-c) options and/or identify other measures that would be appropriate.

- —Quality-adjusted life years (QALYs) gained due to screening?
- — Decreases in incidence of illness or disability or net gains in other patient-focused health care outcomes?

—Net changes in lifetime costs of illness or disability?

6. What are the desirable methodological characteristics of studies of cost-effectiveness for screening genetic tests for the prevention or early detection of illness or disability?
7. Are there ethical issues particular to screening genetic testing that may alter the methodologic rigor of studies of genetic testing? Please discuss the existence, relevance, and impact of such issues.
8. Does the age of the Medicare beneficiary population present particular challenges that may compromise the generation and/or interpretation of evidence regarding genetic testing? Please discuss the existence, relevance, and impact of such challenges.

OIG Faults Medicaid Lab Payments for Dual Eligibles

Medicaid programs in eight of 11 states surveyed spent a total of $1.3 million in potential improper payments for clinical diagnostic laboratory services provided on an assignment-related basis to dual eligibles in fiscal years 2005 and 2006, the HHS Office of Inspector General (OIG) said in an April 15 memo to the Centers for Medicare and Medicaid Services (CMS).

Dual eligibles are beneficiaries who are enrolled in Medicare Part A and/or Part B and also are entitled to some Medicaid benefits. When Medicare is liable for payment of 100 percent of a dual eligible's clinical lab services, no payment should be made by the recipient's state Medicaid program, the OIG noted. As of January 2006, there were more than 6 million dual eligibles nationwide.

For the study, the OIG selected 10 states with the highest Medicaid payments for all clinical lab services for dual eligibles: California, Florida, Illinois, Ohio, Mississippi, New Jersey, New York, North Carolina, Tennessee, and Texas. Washington state was added based on discussions with CMS officials. Only Illinois, Mississippi, and New Jersey were found to have made no improper payouts.

Over half of the potential improper payments corresponded to five CPT codes, the OIG said. One of these codes accounted for almost 30 percent of the potential improper payments identified.

Code	*Total Potential Improper Medicaid Payments*	*Percentage of Total*
36415, Venipuncture	$379,065	29%
85025, CBC	166,457	13
80053, Comprehensive Metabolic Panel	57,981	5
81000, Urinalysis, nonautomated with microscopy	50,884	4
87536, HIV-1, quantification	49, 771	4
Others, all remaining procedure codes	582,568	45
Total	$1,286,726	100

Citing the study results, the OIG noted to CMS that "opportunities exist to educate state Medicaid programs on this policy." The OIG made no recommendations, and CMS had no comment.

♦ Medicare Claims *Advisory*

Lab NCDs: In the latest quarterly update of the laboratory national coverage determinations (NCDs), effective April 1, the Centers for Medicare and Medicaid Services announced a series of changes to eight of the 23 NCDs established under negotiated rulemaking (Change Request 6383). It adds numerous ICD-9-CM codes to be covered under seven of the NCDs, including partial thromboplastin time, prothrombin time, serum iron studies, blood glucose testing, lipids testing, gamma glutamyl transferase, and fecal occult blood. It also modifies the NCD for blood counts by adding a few ICD-9 codes that do not support medical necessity.

Interest Rate: Effective April 16, the rate of interest that Medicare will pay you for claims that were underpaid—or collect from you for claims that were overpaid—is 11 percent, down from 11.375 percent in effect since Oct. 22, 2008, CMS announced. The highest rate in this decade was in early 2001, at 14.125 percent. Medicare rules provide for assessing interest at the higher of the current value of funds rate (3 percent for calendar year 2009) or the private consumer rate fixed by the Treasury Department. The Medicare effective date for the new private consumer rate was announced in CMS Change Request 6240.

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