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Democratic Leaders Roll Out Plans for Health Care Reform

Also to be added to the mix are reform proposals that President-elect Barack Obama advocated during his campaign, including requiring that all children have health care coverage, expanding Medicaid and SCHIP to reach more of the uninsured, and creating a new public plan for those who cannot otherwise obtain coverage.

Buoyed by strong gains in both the House and the Senate, Democratic leaders on key health committees this month have unveiled the plans they intend to push next year to reform health care and expand individual and family coverage and access.

Senate Finance Committee chairman Max Baucus (D-Mont.) on Nov. 12 released his blueprint for universal coverage, including a requirement that all individuals buy coverage from a choice of affordable private plans and public programs.

Sen. Edward Kennedy (D-Mass.), chairman of the Health, Education, Labor, and Pensions Committee, on Nov. 18 announced he has formed working groups on his panel to help craft health care reform legislation.

Rep. Pete Stark (D-Calif.), chairman of the House Ways and Means health subcommittee, predicted that action will likely center first on expanding coverage through the State Children's Health Insurance Program (SCHIP), which expires at the end of March, followed by a Medicare bill with a long-term physician fee fix. For more on the legislative debate shaping up, see the *Focus*, pp. 4-6.

INSIDE *NIR*

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The Election Outcome: What Does It Mean for Labs?

The shift in power in Washington due to the increased Democratic majority following this month's national elections portends legislative action next year on health care reform, but whether changes will be comprehensive or incremental remains a subject for speculation, said speakers at a Nov. 12 audio conference sponsored by the American Clinical Laboratory Association.

Regardless of the approach, a big unanswered question is how to cut spending and rein in the federal deficit and at the same time pay for expanding health care coverage and access as well as a host of Medicare changes, including an overhaul of the Medicare physician payment system to avert steep fee cuts in 2010 and subsequent years.

Lawmakers will be under strong pressure to seek health care spending cuts to offset reform costs, including a Medicare budget offset to pay for a long-term physician fee fix. So a top priority for the clinical laboratory industry is to protect the consumer price index update to the Part B lab fee schedule that Congress approved last year, said ACLA president Alan Mertz during the call-in. *Continued on p. 2*

The Election Outcome, *from p. 1*

Currently, lab fees are on track to receive the annual CPI update minus 0.5 percent from 2009 through 2012. The update for 2009 will be 4.5 percent. But labs had to sacrifice receiving the full update in exchange for congressional repeal of the Part B lab competitive bidding demonstration. This amounts to some $600 million over that period, Mertz pointed out. In arguing against any more cuts, he said, the industry can show that "we have already given at the office."

ACLA, along with other national organizations in the Clinical Laboratory Coalition, have long lobbied the case to Congress that lab spending, which makes up only 1.7 percent of Part B outlays, has already been targeted for cuts over the last two decades, despite the value of testing in influencing an estimated 70 percent of medical decision making (*see box*).

Congressional Curbs on Medicare Lab Fee Schedule

Payment rates under the Part B lab fee schedule are set at 60 percent of prevailing charges in the contractor's jurisdiction (62 percent for sole community hospitals providing 24-hour emergency services seven days a week). The rates are subject to an annual consumer price index update unless Congress says no and to maximum allowable payment limits.

CPI Update

1985	4.1%
1987	5.4%
1989	4.0%
1990	4.7%
1991	2.0%
1992	2.0%
1993	2.0%
1994	0.0%
1995	0.0%
1996	2.8%
1997	2.7%
1998-2002	0.0%
2003	1.1%
2004-2008	0.0%

National Payment Limits

The fee caps are set at a percentage of the national median of all local fee schedules and have dropped from 115 percent to the current level of 74 percent.

Jan. 1, 1986	115%
Apr. 1, 1988	100%
Jan. 1, 1990	93%
Jan. 1, 1991	88%
Jan. 1, 1994	84%
Jan. 1, 1995	80%
Jan. 1, 1996	76%
Jan. 1, 1998	74%

Tests capped after Jan. 1, 2001 are payable at 100 percent of the national median. To date, CMS has done so only for 12 diagnostic/screening Pap smear codes on the Part B lab fee schedule.

Lab fees have been steadily reduced since the switch to the fee schedule payment method in 1984. Congress cancelled the CPI update in 12 of the 15 years since 1994, while in this decade, it allowed an increase only once, in 2003, when fees rose 1.1 percent. In a further squeeze on lab spending, national payment limits on lab tests have gone from 115 percent to 74 percent of the national median.

FDA Regulation of Lab-Developed Tests

A participant in the call-in asked whether the Democratic control would mean further regulation of genetic and other laboratory-developed tests (LDTs). Currently, the Food and Drug Administration regulates the analyte-specific reagents (ASRs), the ingredients of LDTs, and a category of genetic and other LDTs known as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). The latter expansion of oversight has been highly controversial in the lab industry since it could affect frequently performed tests for cancer and other life-threatening conditions and stifle innovation in fast-changing technologies.

The current head of the FDA Office of In Vitro Diagnostic Device Safety and Evaluation, Steven Gutman, Ph.D., has said the agency has no interest in regulating all LDTs and is only focused now on the IVDMIA category, noted Peter Kazon, counsel with Alston and Bird (Washington, D.C.) and outside counsel to ACLA. But Gutman retires at the end of this year, and Alberto Gutierrez, Ph.D., the office's current deputy director of new product evaluation, is slated to succeed him.

Nonetheless, Kazon, together with other speakers, cautioned that much depends on who takes the helm at the FDA in the Obama administration and this is not likely to shape up until next year. Other political

commentators have predicted that the Democratic sweep in Congress will usher in a more vigorous oversight role across all federal agencies, including the FDA.

But the FDA is already stretched thin for oversight, observed Chris Jennings, president of Jennings Policy Strategies Inc. and a former senior health care advisor to President Bill Clinton. "The FDA is so underfunded that it will have to prioritize its resources, especially for food and drug safety, and allocate them to areas where it looks to the public eye that the agency is not doing enough to assure safety."

Changing of the Guard on Capitol Hill

Jason DuBois, ACLA vice president for government relations, presented a "drill-down" on the national election results impacting lab industry legislation. Many familiar friendly faces remain in the upcoming 111th Congress, he said, though there were some upsets.

For example, DuBois noted, Sen. Gordon Smith (R-Ore.) a co-sponsor of the Kennedy proposal to require premarket review of LDTs, lost his bid for re-election, so if Kennedy opts to reintroduce a bipartisan bill, he would have to shop for another GOP co-sponsor. Also leaving Congress is Rep. Phil English (R-Pa.), a long-time backer of increasing the Medicare specimen collection fee and a co-sponsor of legislation to do that (H.R. 1501). The bill's Democratic co-sponsor, Gene Green (Tex.), did win re-election. The specimen collection fee has remained at $3 per beneficiary encounter for over two decades.

Further, provisions of the Genomics and Personalized Medicine Act (S. 976), introduced by Barack Obama, are likely to resurface in his proposals for health care reform, political analysts say. These include additional studies on the role of federal regulation in genetic testing and an emphasis on tapping comparative effectiveness research to evaluate federal health care payment policy in supporting improved clinical outcomes, not just the quantity of services furnished.

Waxman to Head Energy and Commerce Committee

Rep. Henry A. Waxman (D-Calif.) on Nov. 20 won his bid to become chairman of the House Energy and Commerce Committee, unseating John D. Dingell (D-Mich.), the longest serving member of the House, first elected in 1955. The House Democratic Caucus, bucking the seniority system that typically governs committee assignments, endorsed Waxman by a secret ballot vote of 137-122.

Waxman had been the top Democrat on the House Oversight and Government Reform Committee since 1997, known for his vigorous grilling of the Bush administration and investigations of federal agency accountability, including the Food and Drug Administration's oversight role in assuring drug and device safety.

As head of Energy and Commerce, Waxman is in a position to generate legislation as well as conduct oversight hearings. He is expected to continue to pursue his interests in federal regulatory policy as well as focus on health care reform, lowering Medicare drug costs, energy independence, and global warming. Though Waxman and Dingell clashed over auto emission standards and other environmental issues, both are long-time advocates of universal access to health care. Waxman also will enjoy a receptive ear in the White House. His former chief of staff, Phil Schiliro, has been named Obama's liaison to Congress.

focus on: Health Care Reform

New Political Dynamics Propel Push for Health Care Overhaul

With the election of Barack Obama as president and the sizable gains in Democratic majorities in the House and the Senate, the political winds are blowing in favor of action on health care reform in the 111th Congress, which opens in January, many political analysts agree.

But others caution that it won't be easy. Health care will be competing with other priorities—the soaring federal deficit, bailouts of the financial sector and the credit crunch, two wars, and an economic downturn—so action may get delayed until 2010. Reforming the health care sector is a massive undertaking, they point out, involving 16 percent of the national economy and providing tens of millions more Americans with coverage options.

Bold health care reform initiatives have failed in the past, notably the universal coverage plan put forth by Hillary Rodham Clinton that went down in flames in 1994. Since then, lawmakers have taken more politically palatable incremental steps to cover more of the uninsured, for example, through creation of the State Children's Health Insurance Program (SCHIP) and expansion of Medicaid.

Strong Support Shown for Overhaul

Now, the political odds are mounting behind bolder measures. With voters in the November elections ranking health care among their top concerns, congressional Democratic leaders have pledged to make reform a top agenda item next year.

Comprehensive reform also has widespread support in the private sector among a broad coalition of business, labor, senior citizen, and consumer groups. While they have been at odds over specifics in past reform debates, they have now united to issue a joint call to lawmakers to tackle the issue sooner rather than later, warning that rising costs threaten worker and retiree coverage and benefits as well as access to hospitals and physicians.

The health insurance industry has also signaled its backing for change. The leading trade group, America's Health Insurance Plans, said Nov. 19 it would drop pre-existing condition restrictions in exchange for a national mandate that all Americans obtain health care coverage.

Key Senators Jump In

In the Senate, there has been a flurry of activity over the last two weeks to get health reform plans on the table, without waiting for Obama to introduce the proposals he championed during his campaign.

Finance Committee Chairman Max Baucus (D-Mont.) on Nov. 12 released his ambitious blueprint to reach universal coverage, including a requirement that all individuals obtain health care coverage.

Edward Kennedy, chairman of the Health, Education, Labor, and Pensions (HELP) Committee, on Nov. 18 announced that he has formed three working groups on his

panel to draft reform proposals. The groups will concentrate on three areas:
- ❑ Prevention and public health, chaired by Tom Harkin (D-Iowa)
- ❑ Health care quality, led by Barbara Mikulski (D-Md.)
- ❑ Insurance coverage, led by Hillary Rodham Clinton (D-N.Y.)

On Nov. 19, a bipartisan group of senior members of the Finance and HELP Committees, including Baucus, Kennedy, and the ranking Republicans—Charles Grassley (Iowa) and Mike Enzi (Wyo.), respectively—met to discuss the process for tackling health care reform next year. They later issued a statement urging other senators to support "comprehensive health care reform that includes access to effective coverage, quality care for all, and measures to control rising costs."

Daschle Pick for HHS Gets Wide Welcome

Senate health leaders on both sides of the political aisle hailed the news that President-elect Obama has tapped former Sen. Tom Daschle to head the U.S. Department of Health and Human Services, saying his many years of legislative experience well equip him to work with Congress on health care reform. Business and provider interests joined in the praise, also citing his service on Capitol Hill.

Although no formal announcement had been made at press time, Democratic officials said Nov. 19 that the offer was made and accepted.

Daschle represented South Dakota in the House and the Senate for 26 years. He begin his tenure in the Senate in 1986 and served as its Democratic leader for 10 years, where he was a leading proponent of health care reform. He was defeated for re-election in 2004.

Daschle is an adviser to the law of Alston and Bird and a Distinguished Fellow of the Center for American Progress. He has written extensively on health care reform, including advocating more reliance on comparative effectiveness research with establishment of a federal board to advise on drugs and treatments that should be covered.

How Far, How Fast?

Pundits are divided over how the scope and speed of the reform effort will play out, given the worsening economic crisis. Some say the cascade of grim economic news leaves little room to maneuver on health care. GOP and conservative Democrats have expressed alarm over the rising federal deficit and want to push for curbs that would slow health care spending growth.

Other commentators think the economic crisis strengthens the case for acting boldly to break the partisan deadlock that has doomed health reform initiatives in the past. Lawmakers have been hearing from business interests that health care is a big part of their economic woes, as large and small employers struggle with rising coverage costs while sales and profits fall. Providers too have raised concern about the impact on patient care as workers and retirees are increasingly at risk of losing coverage and being forced into the ranks of the uninsured.

Analysts who anticipate fast and broad legislative action interpret Obama's selection of Senate veteran Tom Daschle to be Health and Human Services Secretary as a clear sign the new administration intends to follow through energetically on campaign pledges for health system overhaul (*see box*).

Shared Responsibility

In expanding health care coverage and access to services, the proposals outlined by Obama and Baucus build on the current system of shared responsibility among employers, individuals, and government, but with added features. These include:
- ❑ Barring insurers from denying coverage based on pre-existing conditions.
- ❑ Establishing a national exchange to help individuals and groups shop among an array of affordable private insurance options.
- ❑ Creating within the exchange a new government-run plan similar to that enjoyed by members of Congress and federal employees. It would be open to all who cannot obtain coverage elsewhere.

- ❑ Providing tax credits to help small businesses provide coverage to their employees.
- ❑ Expanding SCHIP and Medicaid to cover more of the uninsured by lowering eligibility thresholds and loosening restrictions on states.

On the latter point, Baucus would have SCHIP include all uninsured children in families with incomes at or below 250 percent of the poverty level ($44,000 for a family of three). This would raise the income limit in about half the states. He would make Medicaid available to those below the poverty level ($17,600 for a family of three), giving at least 7 million more people access to the program. Further, he proposes a Medicare buy-in for persons age 55 to 64 who cannot get into a public insurance program or a group health plan.

Obama and Baucus part company, however, over the issue of an individual mandate. Baucus would require that all individuals—not just children as Obama has advocated—obtain health insurance coverage when affordable options are available through employers or the insurance exchange. The likely vehicle for enforcement would be the tax system.

Still, important details remain to be worked out, especially the costs of the proposals and how to pay for them, along with provisions to increase the quality of care, including use of comparative effectiveness measures in evaluating payments for services and incentives for industry adoption of health information technology and electronic health records.

Medicare Managed Care Reforms

The Medicare Advantage (MA) program has already been singled out by Obama and Democratic leaders for payment reductions to help pay the tab for health care reform. They propose eliminating the higher pay rates that MA plans receive and instead reimburse the plans at the same level as traditional Part B fee-for-service for comparable services to beneficiaries. The higher MA rates were approved in 2003 by the GOP-controlled Congress to encourage private health plans to enter and remain in the Medicare market.

The MA program offers Medicare beneficiaries a range of coverage options: HMOs, PPOs, private fee-for-service (FFS) plans, and special needs plans. Of the total 44.85 million Medicare beneficiaries, 10.2 million are enrolled in MA plans, of which some 2.28 million are in private FFS plans.

MA plans are paid an average 113 percent of traditional Medicare, according to policy analysts at the Medicare Payment Advisory Commission. Reducing the rate to 100 percent of Part B fee-for-service would save $62 billion over five years and $169 billion over 10 years, the commission found. The savings could go to help pay for physician fee increases and possibly other goals, such as SCHIP expansion.

Private FFS plans will get an average 16.6 percent more under Medicare in 2008 than traditional FFS providers, for a total of $2.5 billion, according to a Commonwealth Fund study released Oct. 21. The study estimates that payments to these plans will amount to $1,248 per beneficiary more than traditional FFS for each of about 2 million enrolled.

GOP leaders and the managed care industry oppose MA rate cuts, arguing that the higher payments are needed to offer more benefits and lower cost sharing to seniors and that enrollees express satisfaction with their plans. Still, managed care plans are bracing for some degree of cutbacks, insiders acknowledge, saying the only question is how the reductions would be phased in.

♦ Medicare Coding *Advisory*

CMS Adopts New G Codes, Fees for Prostate Cancer Biopsies

The codes are to be used for specimens obtained by the clinician under new CPT code 55706, Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance.

Four new Medicare G codes for prostate needle saturation biopsies have been adopted for use starting next year, the Centers for Medicare and Medicaid Services announced in the final 2009 physician fee schedule rule published in the Nov. 19 *Federal Register* and effective Jan. 1.

And in a major change in course, CMS has decided to establish the payment rates for these codes, instead of letting local carriers, fiscal intermediaries, and Medicare Administrative Contractors set the prices as the agency had previously proposed (*NIR, 29, 18/Jul 9 '08, p. 6*).

The new codes are:

- G0416, Surgical pathology, gross and microscopic exam for prostate needle saturation biopsy sampling, 1 to 20 specimens.
- G0417, 21 to 40 specimens.
- G0418, 41 to 60 specimens.
- G0419, greater than 60 specimens.

These procedures are currently reported with CPT 88305, Surgical pathology, gross and microscopic examination, which is billed by the physician for each core sample taken. Patients requiring a prostate needle saturation biopsy sampling generally have 30 to 60 specimens taken. CMS says that paying individually for each core sample submitted "grossly overpays for the pathologist interpretation and report for this service." The average total payment for evaluation of samples from such a biopsy ranges from $3,000 to $6,000, depending on the number of specimens taken. (CMS specifically alerted providers that 88305 will continue to be recognized for surgical pathology services unrelated to the new biopsy codes.)

In deciding to set the fees for the new G codes, CMS noted that all commenters favored this approach. CMS calculated the fees using a complex formula by analogy to the current relative value units (RVUs) of two existing codes, CPT 88304 and 88305. The assigned values are shown below.

Code	*Work RVU*	*PE RVU**	*Malpractice RVU*	*Total*	*Fee***
G0416	3.09	13.96	0.54	17.59	$634.41
—TC	0	12.14	0.30	12.44	$448.67
—26	3.09	1.82	0.24	5.15	$185.74
G0417	5.86	27.26	1.06	34.18	$1,232.76
—TC	0	23.71	0.60	24.31	$876.78
—26	5.86	3.55	0.46	9.87	$355.98
G0418	10.30	46.56	1.80	58.66	$2,115.66
—TC	0	40.50	1.03	41.53	$1,497.84
—26	10.30	6.06	0.77	17.13	$617.82
G0419	11.61	55.86	2.16	69.63	$2,511.32
—TC	0	48.60	1.23	49.83	$1,797.20
—26	11.61	7.26	0.93	19.80	$714.12

Source: CMS. *Transitional 2009 nonfacility fee. **Total RVUs x 2009 conversion factor of $36.066. Unadjusted for geographic practice cost variations.

CMS Picks New MAC for New England States

Providers, Beneficiaries Affected

- ❑ *1,717,303 Medicare fee-for-service beneficiaries as of July 2007.*
- ❑ *219 Medicare hospitals as of December 2007.*
- ❑ *79,712 physicians and other medical practitioners as of July 2007.*

The Centers for Medicare and Medicaid Services on Nov. 19 announced that it has selected National Heritage Insurance Corp. (NHIC), based in Hingham, Mass., to handle combined Medicare Part A and Part B claims processing for clinical laboratories, pathologists, and other health care providers in Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.

This is the 10th of 15 competitively bid A/B contracts that CMS will award in the transition to the Medicare Administrative Contractor (MAC) system by 2011, replacing fiscal intermediaries and carriers. As the MAC for the New England states (Jurisdiction 14), NHIC will assume full responsibility for A/B claims processing by May 2009, CMS said. The contract has an approximate value of $176 million over five years. The workload accounted for 4.2 percent of national Medicare fee-for-service claims as of September 2007.

NHIC has been serving Part A and B providers in all the above states except Rhode Island. As the new MAC, the company will take over claims payment work now performed by three fiscal intermediaries and two carriers.

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