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Obama Signs SCHIP, Calls It 'Down Payment' on Reform

On the broader health care reforms expected to be debated, congressional Democratic and Republican leaders have assembled teams to spearhead their efforts, but the Obama administration needs to find a champion for its proposals following the withdrawal of Tom Daschle's nomination to serve as HHS Secretary.

President Barack Obama on Feb. 4 signed into law a reauthorization and expansion of the State Children's Health Insurance Program (SCHIP) that will extend health care coverage to 11 million children in low-income families.

At a signing ceremony, Obama hailed the new law as a "down payment" on his pledge to provide health care coverage to all Americans as a key part of his economic recovery blueprint.

Renewal of SCHIP is an initial victory for the Obama administration and congressional Democrats in their ambitious agenda for overhauling health care. Their next political test is economic stimulus legislation, which includes new funding for health information technology (HIT).

Investment in HIT has bipartisan support, and pending bills agree to spend some $20 million to promote adoption of HIT, including Medicare and Medicaid incentive payments to hospitals, physicians, and other providers.

For an update on these and other policy developments on the health care front, see the *Focus*, pp. 4-5.

INSIDE *NIR*

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Medicare and Genetic Testing: What's the Evidence for Coverage?

The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) this month will hold the first of two public forums on the use of genetic testing to improve health outcomes for Medicare beneficiaries and the evidence needed to support Medicare coverage.

Each meeting will examine a separate use of genetic testing, defined as "…any test performed using molecular biology methods to test DNA or RNA, including germline, heritable, and acquired somatic variations."

The first forum, scheduled for Feb. 25, will discuss and gather input on the types of evidence on which to base Medicare coverage decisions relating to uses of genetic (including genomic) testing by the beneficiary's treating physician to guide diagnosis and treatment. The second forum, tentatively set for May, will focus on screening tests used to identify an occult condition or state in an asymptomatic person.

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Who's Calling the Shots in Congress on Health Care Reform?

The shape and pace of health care changes hinge greatly on the positions held by the Democratic and GOP reform teams, the personalities of the protagonists, and the people confirmed to head key agencies involved in reform, including CMS and the FDA.

Democratic and Republican leaders in the House and the Senate have put together their teams to guide the legislative debate over health care reform. The latest to join the lineup is the House GOP. Minority leader Rep. John Boehner (Ohio) on Feb. 4 named members of a task force, led by Roy Blunt (Mo.), to develop health care reform options.

"Health care costs are too high, access is too limited, and American families and small businesses are looking to their leaders in Washington for free-market solutions, not a government-dominated health care bureaucracy," Boehner said.

Blunt said, "Through this working group, Republicans will develop real solutions to improve our health care system by putting patients before paperwork and frivolous lawsuits."

In addition to Blunt, task force members are Reps. Joe Barton of Texas, Judy Biggert of Illinois, Charles Boustany of Louisiana, Ginny Brown-Waite of Florida, Michael Burgess of Texas, Dave Camp of Michigan, Nathan Deal of Georgia, Phil Gingrey of Georgia, Wally Herger of California, Lynn Jenkins of Kansas, Howard McKeon of California, Tim Murphy of Pennsylvania, Tom Price of Georgia, Paul Ryan of Wisconsin, and John Shadegg of Arizona.

In the Senate, GOP minority leader Mitch McConnell (Ky.) last month named his pick to lead the party's health care reform efforts. They are Michael Enzi (Wyo.), ranking minority member of the HELP Committee, Charles Grassley (Iowa), ranking minority member of the Finance Committee, and Orrin Hatch (Utah). Judd Gregg (N.H.) had been on the team but has since become the president's nominee for Secretary of Commerce.

"Republican ideas will be critical to developing bipartisan health care legislation that is fully paid, does not expand government bureaucracies like Medicaid, and ensures we get better value for every dollar we spend on health care," Enzi said.

On the Senate Democratic side, 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 and a Medicare buy-in for individuals between the ages of 55 and 64.

At the Health, Education, Labor, and Pensions (HELP) Committee, chairman Edward Kennedy (Mass.) has assigned members to three working groups to write their version of health care overhaul:

- ❑ Jeff Bingaman to lead the HELP committee's working group on insurance coverage. He replaces Hillary Rodham Clinton, now secretary of state.
- ❑ Tom Harkin (Iowa) to lead the group on prevention and public health.
- ❑ Barbara Mikulski (Md.) to lead the group on health care quality.

Kennedy has also asked Christopher Dodd (Conn.) to serve as his chief deputy for health care reform.

In the House, the leading Democrats for reform are Henry Waxman (Calif.), chairman of the Energy and Commerce Committee, and Pete Stark (Calif.), chairman of the Ways and Means health subcommittee. Stark has introduced two bills for universal health care coverage, based on Medicare as a model (*NIR, Vol. 09, Iss. 1/Jan 12, '09, p. 2*).

Push for Personalized Medicine in Health Care Reform

Clinical laboratory and pathology groups are gearing up to lobby for emphasis on personalized medicine in the health care reform debate that is expected to begin this year on Capitol Hill. Their overarching focus, say industry sources, is to educate members of Congress on the crucial role that lab testing plays in 70 percent of medical decisions and the need to encourage innovation in testing technologies that tailor treatment and therapy to the patient's genomic profile.

Lab-developed tests (LDTs) make up a significant portion of the rapidly expanding genetic testing market, and the American Clinical Laboratory Association and the College of American Pathologists are among those who oppose additional federal oversight. Existing regulation is sufficient to ensure quality and safety, they say, noting that LDTs are regulated by the Centers for Medicare and Medicaid Services at the highest level of CLIA complexity, while the Food and Drug Administration regulates analyte-specific reagents (ASRs) used in LDTs as well as a category of widely used LDTs called in vitro diagnostic multivariate index assays (IVDMIAs). Additional oversight, the groups warn, could stifle innovations in molecular diagnostics that tailor treatment and therapy to patients with cancer, heart disease, diabetes, and other chronic conditions.

But controversies have erupted recently over LDTs that could lead to tighter oversight by the FDA and CMS. Biopharmaceutical giant Genentech (South San Francisco, Calif.), a developer of cancer drugs, has filed a citizen petition with the FDA, asking that all LDTs 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 also asked the FDA to initiate enforcement action against any clinical lab or company selling or making claims about LDTs without sufficient analytical and clinical evidence.

Quest Diagnostics (Madison, N.J.) ran into problems with its Vitamin D testing using a test it developed in-house as an alternative to an FDA-approved test. The company last December sent letters to thousands of physicians offering to provide free retests for patients who may have received questionable results. Vitamin D testing volume has soared as medical studies have called widespread attention to vitamin D deficiency and linked it to some infectious diseases, cancers, cardiovascular disease, and autoimmune disorders.

Quest said the problems were related to reagent preparation and, in some cases, to less than strict adherence to rigorous operating procedures for the test, a company spokesperson noted, and the problems were limited to a specific time period and only affected some of Quest's labs. Less than 10 percent of Quest's Vitamin D tests from early 2007 through mid-2008 were flagged for retesting.

Despite these controversies, industry sources see no sign on the horizon of legislative zeal to subject LDTs to tighter regulatory controls. But the Obama administration is expected to show great interest in advancing the role of genetic testing, including LDTs, in personalized medicine as part of overall health care reform. While in the Senate, Obama introduced the bipartisan Personalized Medicine Act (S. 976), which required Congress to solicit outside expert advice before further regulation of genetic testing. The bill called for an Institute of Medicine study to identify oversight gaps to be filled and recommend a decision matrix to guide federal risk-based ranking of genetic testing.

focus on: Health Care Reform

Congress Moves on Health Coverage, System Overhaul

While the 111th Congress is gearing up to tackle reform of the nation's health care system—an effort broadly backed by industry, business, and consumer groups—it has already expanded health care coverage for children in poor families and is working on an economic stimulus bill that includes new financial incentives to spur health care industry adoption of health information technology (HIT).

Comprehensive health care reform bills have been unveiled in the House and the Senate, and the lineup of key Democratic and Republican players in the reform effort is clear (*related story, p. 2*). But President Barack Obama will have to find a new shepherd for his reform plans. Tom Daschle, his choice for Secretary of Health and Human Services and designated lead architect for reform, withdrew his nomination on Feb. 3, saying he did not want his controversial tax problems and ties to health care groups to become a distraction to Obama's reform agenda.

After being nominated, it came to light that Daschle, a former Senate Democratic majority leader, owed back taxes and penalties of more than $140,000 from 2005 to 2007 related to use of a car and driver provided by a firm he advised. He paid the amount owed last month, but this was not enough to quell the growing chorus of criticism on Capitol Hill.

Update on the Legislative Agenda and Outlook

SCHIP Reauthorization and Expansion

President Obama on Feb. 4 signed legislation (H.R. 2) reauthorizing the State Children's Health Insurance Program (SCHIP), preserving health care coverage for 7 million children in low-income families and extending coverage to 4 million more. The House earlier that day passed the bill. The Senate approved it Jan. 29.

The law gives the program a 4.5-year reauthorization and funding of $32.8 billion, raised by increasing federal tobacco taxes to $1 from 61 cents. It expands SCHIP to families with incomes up to 300 percent of the federal poverty level ($42,000 for a family of four in 2008) and allows states to drop a five-year waiting period required of legal immigrant children and pregnant women who seek public coverage.

SCHIP was created in 1997 to provide coverage to uninsured children from families whose incomes are too high to qualify for Medicaid and too low to afford private coverage. The previous Congress twice passed a five-year, $35 billion expansion of SCHIP but failed to override the presidential vetoes that followed. A short-term extension of the program was approved through this March 31. SCHIP received $40 billion in federal funds over 10 years through 2007, according to government figures.

Meantime, the U.S. Department of Health and Human Services reported Jan. 26 that some 7.4 million children were enrolled in SCHIP in 2008, a 4 percent increase over the previous year, and the rising trend is expected to continue into 2009, said acting HHS secretary Charles Johnson, "with unemployment numbers rising and the economy struggling to regain momentum."

Enrollment data, compiled by the Centers for Medicare and Medicaid Services and based on state reports, show that 7.4 million children were enrolled in SCHIP at some point during federal fiscal year 2008, compared to 7.1 million for fiscal 2007. During 2008, 334,616 adults were covered with SCHIP funds.

Health Information Technology

Economic stimulus legislation being considered in the Senate at press time contains a range of new incentives to further adoption of health information technology (HIT) by health care providers aimed at reducing operating costs and improving the quality of care, including prevention of medical errors.

The Finance Committee on Jan. 27 approved its portion of the stimulus package (S. 1), including Medicare and Medicaid funding for HIT. The measure is similar to legislation passed by the House (H.R. 1) on Jan. 28. President Obama also backs HIT adoption as a vital infrastructure investment in reforming health care.

Both the full Senate package (which includes Finance Committee provisions as well as those from the Appropriations Committee) and the House version dedicate a total of about $20 billion to the broad development and implementation of HIT, according to a Jan. 30 report by the Congressional Research Service.

Part of the money would be used as incentive payments to spur HIT adoption by hospitals, physicians, and other providers, but the payments would be phased out over time, and Medicare payments would be reduced for providers who do not use certified electronic health records that allow them to electronically communicate with others.

Both the House and Senate bills would dedicate $1.1 billion for comparative effectiveness research, $600 million to strengthen the health workforce by training primary care providers and helping pay medical school expenses for those in the National Health Service Corps, and $500 million to repair and improve National Institutes of Health facilities.

Health Personnel Shortage

The economic stimulus legislation is being eyed by the American Society for Clinical Pathology as a vehicle to address the growing shortage of clinical laboratory personnel as part of funding for the overall health professions workforce. The society noted that the Senate Appropriations Committee is working on its portion of the stimulus package, with a proposed $600 million to the Health Resources and Services Administration for scholarships, loan repayment programs, training program grants for equipment, and activities to foster cross-state licensure agreements. The funding includes specific programs such as the Title VII Scholarships for Disadvantaged Students, the Title VII Faculty Loan Repayment, and the Title VIII Nursing Loan Repayment and Scholarships.

Modernizing the Lab Fee Schedule

Health care reform legislation is a vehicle of choice for an initiative to devise an alternative to the Medicare Part B laboratory fee schedule, backed by the American Society for Clinical Laboratory Science and the Clinical Laboratory Management Association. In the previous Congress, they were instrumental in getting legislation introduced to use negotiated rulemaking to rebase payment rates in line with advances in clinical practice and changes in market factors (*NIR, 29, 20/Aug 13 '08, pp. 4-6*). The fee schedule, based on 1983 prevailing charges, has not been subject to a fundamental updating since then, the groups say.

Medicare and Genetic Testing, *from p. 1*

In a Jan. 29 Web posting, the Centers for Medicare and Medicaid Services presented a range of issues on which it wants MEDCAC's advice, including:

- ❑ Are the desirable characteristics of evidence for diagnostic genetic testing different from those of diagnostic testing in general?
- ❑ What are the desirable characteristics of evidence for determining the analytical validity of genetic diagnostic tests?
- ❑ Beyond aspects of analytical validity considered above, are there meaningful differences in the desirable and/or necessary characteristics of evidence about the effect of genetic testing on outcomes for the three testing paradigms below?
  - —Diagnostic assessment: for example, testing for the variant of the gene HD associated with Huntington's disease.
  - —Prognostic assessment: for example, assessment of gene expression in tumor tissue to evaluate likelihood of distant recurrence in patients with early-stage breast cancer.
  - —Pharmacogenomic assessment: for example, testing for variants in the K-ras gene indicating absent response to certain chemotherapy for colorectal cancer (e.g., cetuximab).
- ❑ For each type of outcome below, how confident are you that methodologically rigorous evidence on the outcome is sufficient to infer whether diagnostic genetic testing improves patient-centered health outcomes?
  - —Changes in physician-directed patient management.
  - —Indirect or intermediate health care outcomes, for example, changes in laboratory test results such as hemoglobin or time to achieve a target value.
  - —Direct patient-centered health care outcome, for example, mortality, functional status, adverse events.
- ❑ Does the age of the Medicare population present particular challenges that may compromise the generation and/or interpretation of evidence regarding genetic testing?

The planned MEDCAC public forum in May will focus on uses of genetic tests in screening and their application to Medicare beneficiaries. Further clarification of specific issues that CMS wants this session to consider will be available later, the agency said.

The American Clinical Laboratory Association weighed in with its views in comments submitted to MEDCAC on Jan. 29. "Differences in the types and uses of tests strongly suggest that it would be both difficult and inappropriate to develop a single national coverage decision that can apply to all genetic testing. The current approach allows local carriers or Medicare Administrative Contractors to make these determinations at least initially. The medical directors are able, in most instances, to review the documented research and make a decision about the value of the test based on that information … While it may be useful to develop an approach by which CMS can be consulted when necessary, the current approach appears to be the best one for the time being."

There are more than 1,600 different diseases for which genetic tests are available, ACLA pointed out, and these tests use various methodologies and are done for different purposes. "These tests should be considered on a case-by-case basis, rather than a one-size-fits-all approach applicable to all genetic tests. MEDCAC and CMS should look at a variety of factors in determining what level of evidence is appropriate for any given test." There is a broad spectrum of evidence that could be considered in evaluating diagnostic tests other than randomized clinical trials that take years to show results, ACLA added. "Retrospective reviews, in lieu of prospective clinical trails, can more rapidly determine the utility of a diagnostic procedure without adversely affecting incentives to develop beneficial new tests."

♦ Medicare Claims *Advisory*

CMS Issues Correction on Home PT/INR Monitoring

Medicare contractors are to implement, as of Feb. 9, a correction to instructions for paying for prothrombin time (PT/INR) monitoring for home anticoagulation management. The change involves adding ICD-9 diagnosis codes that were inadvertently omitted from the original implementation (*NIR, 29, 20/Aug 13 '08, p. 7*). The codes are for "phlebitis and thrombophlebitis" in the 451.0-451.9 series, "other venous embolism and thrombosis" in the 453.0-453.3 series, and "pulmonary embolism and infarction" in the 415.11-415.19 series.

The Centers for Medicare and Medicaid Services last year expanded the national decision (NCD) of PT/INR for home anticoagulation management to encompass more beneficiaries on warfarin therapy. The NCD previously was limited to beneficiaries with mechanical heart valves who are on warfarin. Under the expanded policy, coverage includes home monitoring by beneficiaries with chronic atrial fibrillation or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) who are on warfarin.

Coverage requirements specify that the treating physician must prescribe the monitor and the home testing, and all of the following must be met:

- ❑ The patient must have been anticoagulated for at least three months prior to use of the home device;
- ❑ The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated correct use of the device prior to its use in the home;
- ❑ The patient continues to correctly use the device in managing anticoagulation therapy after home monitoring has begun; and
- ❑ Self-testing with the device should not be done more than once a week.

The PT/INR monitoring NCD applies to claims with dates of service on or after March 19, 2008 (CMS Change Request 6313). Applicable HCPCS codes will continue to be used for claims processing. Their descriptors are:

G0248..... Demonstrate use home INR monitoring
G0249..... Provide INR test meter/equipment
G0250..... MD INR test review interpret management

This NCD is distinct from, and makes no changes to, the prothrombin time clinical laboratory NCD at Pub. 100-03, section 190.17 of the NCD Manual.

Interest Rate for Overpayments, Underpayments

Effective Jan. 23, the rate of interest that Medicare will pay you for claims that were underpaid—or collect from you for claims that were overpaid—is 11.375 percent. This is the same level in effect since Oct. 22, 2008 (*NIR, 30, 2/Oct 27 '08, p. 7*). The rate was 11.125 percent from July 24 through Oct. 21 of last year. From April 18 through July 23, it was 11.375 percent. At the start of 2008, the rate was 12.5 percent. The highest rate in this decade was in early 2001—14.125 percent.

Medicare regulations provide for assessing interest at the higher of the current value of funds rate (3 percent for calendar 2009) or the private consumer rate fixed by the Treasury Department. The Centers for Medicare and Medicaid Services announced the new private consumer rate in Change Request 6239 (Jan. 23, 2009).

American College of Physicians Releases HIV Screening Guidance

ACP guidelines differ from those of CDC, which recommend routine HIV screening only until age 64 unless the HIV prevalence in the patient population is known to be less than 0.1 percent.

In the Jan. 20 issue of the *Annals of Internal Medicine*, the American College of Physicians (Philadelphia) released new guidance urging doctors to begin routine HIV screening of patients at age 13, regardless of whether they engage in risky behaviors. The guidelines do not include an upper age limit because 20 percent of people living with HIV are older than age 50.

The ACP guidance is based on an evaluation of HIV screening guidelines developed by the U.S. Preventive Services Task Force and the Centers for Disease Control and Prevention (CDC), but differs from the task force, which recommends routine screening only for patients at high risk of the virus. But it has been noted that many patients do not know about risky behaviors or do not inform their physicians if they do engage in risky behaviors.

"Although risk-based screening has been recommended for more than 15 years, evidence from the CDC and Veterans Affairs indicate that almost half of patients are identified late in the course of disease, when they will no longer receive the maximum benefit from antiretroviral therapy," conclude the authors of the ACP guidelines.

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