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President Outlines Proposals To Expand Healthcare Coverage

One new proposal would expand the benefits of health savings accounts authorized under the Medicare reform law. Individuals who buy catastrophic coverage, as part of these accounts, could deduct 100% of the premiums from their taxes

In his State of the Union address on Jan. 20, President George W. Bush called for market-based reforms to help Americans obtain health insurance coverage suited to their specific needs, declaring that "a government-run system is the wrong prescription."

Mr. Bush urged Congress to work to control the rising cost of medical care and health insurance and to expand access to care. Toward these ends, he called for insurance-buying pools for small businesses, tax credits to help individuals purchase health insurance and liability reform to eliminate "wasteful and frivolous medical lawsuits." He also backed computerizing medical records to reduce medical errors.

The proposals reflect long-standing GOP priorities, and critics were quick to label them a "repackaging of old ideas." In the Democratic response, Sen. Tom Daschle of South Dakota said more tax cuts aren't the solution. He did not elaborate, focusing instead on the new Medicare drug benefit. He said the government should let Medicare negotiate lower drug prices directly with manufacturers and allow drug reimportation from Canada. For more on the growing problem of the medically uninsured, see the *Focus*, pp. 4-6.

New CLIA Survey Guidance Released

The CLIA lab regulatory program at the Centers for Medicare & Medicaid Services on Jan. 12 released updated surveyor guidelines that incorporate revised quality systems requirements that took effect last Apr. 24. The guidelines explain federal requirements for labs under CLIA (Clinical Laboratory Improvement Amendments) and are used by state surveyors to assess a lab's performance, based on those requirements.

Under the revised quality requirements, one set of quality standards was established for moderate and high-complexity testing and the frequency of quality control testing was reduced in most specialties and subspecialties (*National Intelligence Report, 24, 9/Feb. 24, '03, pp. 4-6*). Requirements for patient test management, quality assurance and QC were also reorganized to parallel the flow of specimens through the lab to help prevent errors and ensure accuracy and precision in the testing process.

In the updated guidelines, posted on the Web at *cms.hhs.gov/clia*, CMS has responded to comments by relaxing equivalent quality testing procedures allowed under the CLIA rules, said the agency's top CLIA official, Judy Yost.

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INSIDE *NIR*

Full compliance with the revamped quality rule won't be enforced until a lab completes its survey cycle. Surveyors will issue citations only for CLIA deficiencies that pre-existed the QC rule promulgated last year. Their main focus will be educational, to help labs understand the revised requirements. Action will be taken, however, if a serious risk of harm to patients or public health is discovered

New CLIA Survey Guidance, *from p. 1*

Labs may use less-frequent equivalent QC for quantitative, qualitative and semi-quantitative tests even for systems that lack internal/procedural controls. Equivalent QC will also be permitted for procedures with an extraction phase and for routine chemistry and hematology, but only for test systems with internal/procedural controls that monitor part or all of the analytic process.

CMS established a process that allows quicker evaluation and greater reduction in QC frequency for tests with more internal controls. By running internal controls and two levels of external controls daily:

- ❑ If labs show 10 days of system stability, they can cut external control frequency to monthly for tests with internal controls for the entire analytic process.
- ❑ If labs show 30 days of system stability, they can cut external control frequency to once a week for tests with internal controls for part of the analytic process.
- ❑ If labs show 60 days of system stability, they can reduce external control frequency to once a month for tests with no internal controls.

Labs must use more frequent QC than CMS requires if so instructed by test manufacturers, the agency notes. Also, if any internal or external control result is unacceptable during the evaluation or after frequency was reduced, the lab must repeat the control in question. If the second result is unacceptable, the lab must identify the problem, correct it and restart the evaluation process. CMS also set forth requirements for calibration verification, proficiency testing, analytic system quality assurance and competency assessment evaluation.

CMS Announces HIPAA Standard Provider ID

The standard identifier for health plans is in the works, that for individuals is on hold, that for employers has been finalized with a compliance date of July 30, 2004 for all but small plans

The Centers for Medicare & Medicaid Services has adopted the National Provider Identifier (NPI) as the standard unique identifier for healthcare providers to use when filing and processing healthcare claims and other transactions. The standard identifier is required under HIPAA, the Health Insurance Portability & Accountability Act. CMS announced adoption of the NPI in a final rule published in the Jan. 23 *Federal Register* and effective May 23, 2005.

The NPI is a new number that will be assigned through the National Provider System which CMS is developing. It will replace all legacy identifiers now in use. Providers will be assigned only one NPI, and it will not change over time.

No action to apply for an NPI is required at this time. The system that will assign NPIs will be ready to accept applications after May 23, 2005. Providers may begin applying on that date. CMS will provide more information closer to the effective date.

All HIPAA covered entities must obtain NPIs. Providers are covered entities, CMS says, if they transmit any data in electronic form in connection with a transaction for which the HHS Secretary has adopted a standard. Use of NPIs in standard transactions will be required of all covered entities as of the following dates: for most providers, May 23, 2007; for small plans, May 23, 2008.

Outreach Labs Get Break Under Medicare 2ndary Payer Rules

Inside the Final MRL Medicare Reform Law

Hospital laboratories that perform outreach testing will now be treated the same as independent clinical labs when it comes to obtaining information on whether a beneficiary has another payer primary to Medicare. Under the Medicare reform law (P.L. 108-173), the government cannot require a hospital providing reference testing services (defined as those furnished without a face-to-face encounter with the beneficiary) to do more in this regard than it demands of independent labs.

Until now, such hospitals had to complete the lengthy Part A questionnaire for each beneficiary to determine whether Medicare was a secondary payer and had to update this information every 90 days. In contrast, requirements for independent labs are not spelled out in detail, but generally these labs must make only a good-faith effort to get this information.

"This levels the playing field," says attorney Steven Chananie with Garfunkel, Wild & Travis in Great Neck, NY, adding that outreach labs "should have a process to get physicians to provide insurance information, including whether Medicare is a primary or secondary payer." It's also important, he notes, for a lab to "affirmatively let physicians know it is relying on them" for this data.

Can outreach labs adopt the change without awaiting further guidance from the Centers for Medicare & Medicaid Services? Yes, according to some legal experts who regard the legislative language as "self-implementing." If so, the lab should notify its Medicare fiscal intermediary first, citing what the law permits. But attorney Peter Kazon with Mintz Levin in Washington, DC, advises waiting for guidance from CMS, which he expects will be issued within a few weeks. CMS reportedly is already working on it.

Congress Backs Transition To ICD-10 Coding System

Inside the Final MRL Medicare Reform Law

The Health & Human Services Secretary should accept a federal advisory panel's recommendation to adopt the ICD-10 coding system for disease classifications and initiate a proposed rulemaking on the matter as quickly as possible, says the House-Senate conference report that accompanied Medicare reform legislation (P.L. 108-173). Last November, the National Committee on Vital & Health Statistics (NCVHS) urged HHS to replace the 23-year-old, four-digit numeric ICD-9 system with the seven-digit ICD-10 for diagnosis coding and the inpatient share of procedure coding (*NIR, 25, 3/Nov. 10, '03, p. 8*). The switch would not impact use of the American Medical Association's CPT coding system.

Noting the limited reporting capabilities of ICD-9 "for today's needs and growth capacity for future needs," Congress said that ICD-10 would be able to keep up with modern medical advances, thus ensuring accurate reimbursement for emerging technologies and patient access to quality care. But providers and payers are worried about the cost and disruption of the changeover, though NCVHS has advised that any transition be phased-in over two years. The Rand Corp. (Santa Monica, CA) estimates that the switch would cost labs, hospitals and other providers from $425 million to $1.15 billion in the first year and $5-40 million per year thereafter to upgrade software and train code users.

focus on: Healthcare Reform

Pressure Building To Assure Healthcare Coverage For Uninsured

"It's a good time to raise an issue like this. Both parties are looking for something with juice. Both parties know it's the right thing to do, the problem is the political will to act"—former Kansas Sen. Bob Dole and GOP presidential candidate in 1996

With the federal budget deficit escalating due to tax cuts, spending for defense and homeland security and Iraq reconstruction costs, President George W. Bush said in his State of the Union address on Jan. 20 that he aims to hold the line on discretionary spending this year.

This fiscal restraint is sure to please GOP conservatives as the party gears up for presidential and congressional electioneering, and may also explain in part why the President advanced only modest proposals on the problem of the growing number of medically uninsured and the rising costs of medical care and healthcare coverage.

There has been a steady crescendo of reports, mainly from foundations and public interest groups, urging Congress to address the ranks of the uninsured, the underinsured and those who fear becoming uninsured. In its report this month, the Institute of Medicine laid out four basic strategies to reduce the number of medically uninsured Americans, contending that any of them would be better than the status quo. The IOM urged policymakers to pick one and put it in place by 2010, rather than hold out for the "perfect" approach. In the view of the IOM, any of the strategies is workable if it yields coverage that is universal, continuous and affordable for those it covers and those who pay for it.

Most Democratic candidates vying to run against Mr. Bush have detailed plans to insure more Americans—mainly a mix of private and public reforms, while the GOP relies on market reforms to deliver affordable health insurance coverage tailored to an individual's or family's needs.

Millions Living On The Edge

In 2002, the U.S. Census Bureau notes in its latest annual Current Population Survey, the number of Americans without health insurance reached 43.6 million, or 15.2% of the total U.S. population—up 5.7% from the previous year's 41.2 million. While this rate is within the 14-16% range seen over the past decade vis-a-vis the total population, further increases are widely expected.

The uninsured get half as much healthcare as others, the IOM points out. They wait till they are sicker, when care is costlier and less effective. Further, the care available is often substandard. Consequently, they are sicker and shorter-lived, with 18,000 of them dying every year for lack of health insurance. According to IOM estimates, the additional work they could do with proper healthcare is worth $65-$130 billion a year, double the $34-$69 billion of additional healthcare services they would consume if insured.

Even Those With Insurance Are Anxious

Costlier healthcare, tighter benefits and an uncertain job market are raising anxiety too among middle-class Americans, a point politicians are expected to become increasingly sensitive to in this election year. To this key group of voters, affordable healthcare coverage is not a luxury, but a necessity. Kathleen Stoll of Families USA calls it a climate of "health insecurity." The effects are subtle and widespread, she adds, such as "job lock" which keeps people working below their potential just to hang onto health benefits.

Census data show that people with less household income, less education and less work experience are more likely to be without health insurance. In fact, the poor are least likely of all to have it—30.4% of those in poverty were uninsured in 2002 vs. 15.2% overall. But workers at all levels of the economy are losing health benefits, and many more are worried about losing them. In fact, workers in large companies now comprise a quarter of all the uninsured, the Commonwealth Fund said in October 2003. The ranks of the uninsured grew in 2002 mainly from people with jobs who lost their coverage, the Census Bureau noted. That trend, in which the share of Americans with employment-based coverage declined to 61.3% from 62.6%, is expected to continue as employers respond to rising healthcare costs by shifting costs to employees and reducing or canceling benefits.

Providers Are Losing Out Too

In a study supported by the Henry J. Kaiser Family Foundation, Jack Hadley and John Holahan of the Urban Institute (Washington, DC) estimate that in 2001, providers gave nearly $36 billion of uncompensated care to the uninsured (though 80% was subsidized through a maze of federal, state and local grants, programs and taxes). Hospitals gave $23.6 billion; clinics, $7.1 billion; and physicians, $5.1 billion.

Rural and inner city hospitals, which cannot shift uninsured patients to others, bore most of the cost, notes the IOM. In response, they cut costly services, such as HIV/AIDS, trauma and burn care, and reduced the number of beds, resulting in overcrowding of their emergency departments and diversions to other facilities. People with insurance can simply switch hospitals, unless it's an emergency or they're in a rural area.

Providers also are missing the opportunity to get paid for an estimated $34-$69 billion a year of additional care that the uninsured would obtain if insured. Those without health insurance get less preventive care, such as screening for breast, cervical or colorectal cancer. They also typically wait until later stages of illnesses to seek help, thus requiring more costly, less effective treatment.

% of U.S. Adults Screened In 1997-1998

	Uninsured	*Insured*
Cancer Screening		
Mammography in past 2 yrs	68%	89%
Pap test in past 3 yrs	80	94
Cardiovascular Risk Reduction		
Hypertension	80	94
Cholesterol	60	82

Source: Henry J. Kaiser Family Foundation

Time To Act?

Since former President Bill Clinton's sweeping plan for universal healthcare coverage collapsed, the conventional wisdom has been that only incremen-

"It isn't just a matter of taking care of the uninsured—it's a matter of the enlightened self-interest of everyone. Everyone's interests are at stake here, it's not just a matter of doing good for those less fortunate"—Harvey Feinberg, president, Institute of Medicine

tal or round-the-edges change is politically viable at the federal level. And until now, developments have reinforced that view. Coverage has been expanded only by two major initiatives—SCHIP or the State Children's Health Insurance Program under the Clinton Administration, and the Medicare prescription drug benefit under the Bush Administration. For Congress to even consider new initiatives to cover the uninsured, "you almost had to get Medicare off the agenda first," says David Colby, deputy director of the Robert Wood Johnson Foundation's healthcare group.

With the persistent federal deadlock, some states have grappled with the problem, most notably smaller states like Vermont and Maine which have mandated different versions of universal coverage. California last year enacted a measure requiring small businesses with 50 employees or less to offer health benefits, but even this modest advance could be imperiled as the state struggles to manage its multi-billion-dollar deficit and businesses within the state clamor for relief or threaten to move elsewhere, further eroding the revenue base. And state Medicaid programs, once a major vehicle for expanding care to low-income families but now battered by rising deficits, are cutting back on benefits, while pleading for federal help.

The President's call for more tax breaks to bring healthcare coverage to more Americans appears to hinge on the prospects for wider recovery in the job market. "People need jobs, usually, to get health insurance," says John Holahan, director of health policy at the Urban Institute. The President's refundable tax credit would help an estimated additional four million Americans get insurance, his Administration projects. The value of the credit—up to $1,000 for individuals, $3,000 for families—is the same as that in Mr. Bush's $89 billion proposal last year, reports Vicki Kemper in the *Los Angeles Times*.

Among the Democratic presidential candidates, Sen. John Kerry (D-MA), the favorite coming out of Iowa, has proposed an $895 billion plan that would, among other things, reimburse employee health plans for catastrophic costs and create a version of the federal employees plan for use by individuals and private employers, large and small.

Meanwhile, Senate Majority Leader Bill Frist (R-TN) says the problem of the uninsured is his top healthcare priority. Frist led the creation of a task force on the uninsured last fall, chaired by Judd Gregg (R-NH), head of the Senate Health, Education, Labor & Pensions Committee. The task force aims to issue a report in the first quarter of this year. In the GOP-dominated House, hearings are likely to be held on the President's proposals, political analysts predict, and legislation could pass on tax incentives, association health plans and perhaps healthcare vouchers.

But the overall consensus among congressional staff and Washington insiders is that despite talk about the uninsured, there will be little substantive action until after the November elections. However, 2005 could be a different story.

"Covering the uninsured will be an issue during the election," says Stuart Butler of the Washington-based Heritage Foundation. "It will force commitments that will carry through next year," just as commitments in the 2002 midterm elections presaged passage of the Medicare prescription drug benefit in 2003.

♦ QUESTION *of the* M·O·N·T·H

Our independent lab qualifies for the lab-to-lab referral exception to Medicare's direct billing rule. We refer a lot of tests to other labs that bill us at rates well below Medicare lab fee schedule rates. When we bill Medicare in turn, the program has always reimbursed us at fee schedule rates. Now our compliance officer says there is a memo from Medicare to the effect that, as of this Apr. 1, we may bill only what we paid for those tests. Is that correct?

No. Like many others who read it, your compliance officer is mistaken about the memo, Change Request 2919 (dated Oct. 31, 2003), from the Centers for Medicare & Medicaid Services. You may bill Medicare the same as always. A CMS official told us the point of the memo is to remind carriers that CMS policy is to pay a lab the fee schedule rate for tests, even if a lab paid another lab less to perform them. This applies only to hospital and independent labs, however, not to physician office labs.

CMS issued the memo after getting complaints from labs that carriers were demanding they file claims showing what they paid reference labs. Carriers were then reimbursing them only for that amount if it was below the fee schedule rate. These carriers were incorrectly applying a policy in Publication 100-04, Chapter 1, Section 30.2.9, "Payment to Physicians for Purchased Diagnostic Tests—Claims Submitted to Carriers." This policy applies to pathology services. If a physician purchases the technical component (TC) of a referred service from an outside lab, Medicare will pay the lower of the billing physician's fee schedule amount or the price paid for the TC. On the Medicare claim, the physician must identify, among other things, the amount the supplier charged, net of discounts.

♦ REGULATORY W·A·T·C·H

CBC Billing: Responding to an inquiry from *NIR*, the Physicians Regulatory Issues Team at the Centers for Medicare & Medicaid Services is working to clarify how laboratories should bill Medicare for a complete blood count with automated differential when results are abnormal or inconclusive and a manual differential is then performed. The issue surfaced after CPT 85023 (automated CBC with manual differential) was discontinued at the start of 2003, leaving many labs unsure how to bill correctly for the procedures. And lab billing consultants have differed over the issue (*NIR, 25, 4/Nov. 25, '03, pp. 5-6*).

The team, which works to reduce the Medicare regulatory burden on physicians, held a conference call with agency stakeholders on whether labs should be allowed to bill for an instrument-flagged manual differential, even if a physician doesn't specifically request it. Many participants in the call were reluctant to allow such billing, citing the potential for fraud and abuse, says William Rogers, MD, who heads the team. Rogers told *NIR* the team is still working on the issue.

Lab-To-Lab Referrals: Though CMS set April 1 of this year as the effective date for changes to facilitate Medicare payment to labs that do business across different carrier jurisdictions, only part of those changes will be ready by that time (*NIR, 25, 3/Nov. 10, '03, p. 5*). CMS plans to send a revised change request to contractors with a "a better implementation effective date," says CMS official Joan Proctor-Young.

Ernst & Young Accused Of Abetting False Claims Submission

The case underscores that hospital outpatient lab billings remain a key compliance risk area under government scrutiny

The national accounting firm of Ernst & Young should pay more than $900,000 in fines for advising hospitals to bill for certain hematology indices that were neither medically necessary nor ordered by physicians, according to a complaint filed Jan. 5 by the U.S. attorney's office in Philadelphia, PA. The government alleges that E&Y's advice caused nine hospitals to submit more than 200,000 false claims to Medicare from 1991 through 1997.

Ernst & Young denied the charges, stating: "Our work was fully consistent with professional standards and coding guidelines at the time. We received a flat fee for the consulting work and in no way shared in or benefited from reimbursements received by the hospitals."

The government says that E&Y told the hospitals they could boost Medicare revenue by adding separately billed indices to complete blood counts (CBCs), such as red cell distribution width, mean platelet volume, red blood cell histogram, platelet histogram and white blood cell histogram.

The allegations are based on "charge description master" reviews that E&Y conducted for "optimization of outpatient reimbursement" at four hospitals, as well as outpatient lab reviews the firm did for five hospitals that were under the gun for improper lab claims based on advice from Metzinger & Associates (which later settled).

washington WATCH

HHS Report Backs More Screening

Though providers are making strides in quality improvement, the U.S. health system continues to lag in providing preventive care, according to the first annual federal quality report released late last month by the HHS Agency for Healthcare Research & Quality.

Noting that some 95% of the $1.4 trillion spent in the U.S. on medical services each year goes to treatment and only 5% to preventing disease, the report concludes that the Nation neglects opportunities to stop diseases such as heart attacks, cancer and diabetes before they begin.

One example cited: only 53% of people age 45 and younger have had their cholesterol checked in the past two years, even though such screening can often prevent heart attacks and other coronary afflictions.

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