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Obama Era Promises New Initiatives in Health Care

The President-elect has ranked the economic crisis, energy policy, and expanding health care coverage as top three priorities for immediate action.

With a landslide victory in both the electoral and the popular vote and solid Democratic gains in the House and the Senate, President-elect Barack Obama is poised to deliver on his campaign pledge to work for health care reform.

Obama has put forth a comprehensive reform plan to expand health care coverage and access, but implementing it is expected to be incremental. The first legislative opportunity to fulfill part of that plan is reauthorization next year of the State Children's Health Insurance Program (SCHIP). Obama has proposed requiring that all children have health care coverage. To help achieve this, he backs lowering the eligibility threshold for SCHIP and also extending young people's eligibility on their parents' plans to age 25.

But the big question going into next year is what impact the financial crisis will have on Obama's new health initiatives. With the federal deficit approaching the $1 trillion mark, both his administration and the Congress will be under pressure to cut government spending, and Medicare has not escaped attention. *Continued on p. 6*

Medicare Physician Fees to Rise 1.1 Percent in 2009

Starting Jan. 1, pathologists and others paid under the Medicare Part B physician fee schedule will get on average a 1.1 percent increase in payments for covered services, the Centers for Medicare and Medicaid Services announced in a final rule released Oct. 30 and due to be published in the Nov. 19 *Federal Register*.

The conversion factor, used to translate a physician service's relative value units into a dollar amount, will be $36.0666, CMS said.

Congress authorized the 1.1 percent fee increase through 2009. Had lawmakers not intervened, physician payments were due to be cut by 15.1 percent under the statutory update formula, CMS noted.

Pathologists and others paid under the fee schedule also can receive an incentive payment of 2 percent of total allowed charges for successfully participating in the 2009 Physician Quality Reporting Initiative (PQRI).

The final rule added 52 new PQRI measures, for a total of 153. The total includes approved pathology measures for:

- ❑ Breast cancer resection pathology reporting: pT (primary tumor) category and pN (regional lymph nodes) category with histologic grade. *Continued on p. 2*

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Medicare Physician Fees, *from p. 1*

- ❑ Colorectal cancer reaction pathology reporting: pT (primary tumor) category and pN (regional lymph nodes) category with histologic grade.

New Incentives for E-Prescribing

In addition to the above payments, the rule implements new financial incentives Congress authorized for physicians who adopt e-prescribing. Those who use qualified electronic prescribing systems to send prescriptions to pharmacies can earn an incentive payment of 2 percent of their total Medicare-allowed charges during 2009, CMS said.

In all, the fee increase and the incentive payments would total a 5.1 percent increase in 2009 for physicians who qualify.

Qualified e-prescribing systems must be able to:

- ❑ Communicate with the patient's pharmacy.
- ❑ Help the physician identify appropriate drugs and provide information on lower cost alternatives for the patient.
- ❑ Provide information on formulary and tiered formulary medications.
- ❑ Generate alerts about possible adverse events, such as improper dosing, drug-to-drug interactions, or allergy concerns.

To earn the incentive payment, physicians must successfully report one of three codes, indicating either that:

- ❑ They did not prescribe any medications during the medical visit.
- ❑ They used e-prescribing for any medications prescribed during the visit.
- ❑ They did not use e-prescribing for a prescription because the law prohibits e-prescribing for the specific type of drug, such as a controlled substance.

Other Payment Issues

The final rule implements the congressionally mandated 1 percent increase in the ESRD (end-stage renal disease) composite rate and establishes a site-neutral base composite rate for both hospital-based and independent dialysis facilities.

- ❑ Total Medicare spending under the 2009 physician fee schedule is projected to be $61.9 billion, up 4 percent from the $59.5 billion projected for 2008.
- ❑ Medicare pays for more than 7,000 types of services based on the resources required to perform them.
- ❑ Approximately 980,000 physicians and nonphysician practitioners bill under the Medicare Part B physician fee schedule.
- ❑ Of this number, nearly 95 percent accept the fee schedule rate as payment in full for their services.

CMS also is changing how the budget neutrality adjustment is applied. In accord with a congressional directive, the adjustment will be applied to the conversion factor versus the previous policy of applying it separately to work relative value units. While CMS said the overall level of payments under the physician fee schedule would be maintained despite the change, the American College of Cardiology says services with a significant practice expense, such as imaging and in-office procedures, would get lower reimbursement, while services with more physician work elements, such as evaluation and management office visits, would have payments raised by more than 1.1 percent.

Worries Over the Future

Although physicians got a reprieve from the draconian cut of 15.1 percent triggered by the update formula, Congress specified that the conversion factors for 2010 and

subsequent years must be computed as if the 2009 increase and previous legislative actions to override the formula had never applied.

That's why the medical community, including the American Medical Association and the College of American Pathologists, have made it a top legislative priority next year to get Congress to enact a permanent physician fee fix to avert ever-steeper cuts beginning in 2010 and beyond. Medical groups have already signaled their commitment to work with Congress to devise an alternative to the Sustainable Growth Rate (SGR) system. The SGR sets a target rate for physician spending; when it is exceeded, the update is negative, as it has been for most of this decade, requiring Congress to block the fee cut and approve an increase instead. But since the SGR is cumulative, the short-term fixes only lead to the need for double-digit cuts in future years.

CMS Finalizes Anti-Markup Rules for Diagnostic Testing

In the final 2009 Medicare physician fee schedule, the Centers for Medicare and Medicaid Services announced that it will start applying anti-markup rules to diagnostic testing services (other than clinical lab services) billed by physicians and suppliers, as of Jan. 1.

The rules, to be published in the Nov. 19 *Federal Register*, limit how much Medicare can be billed for such testing when performed in a physician office or within a group practice. The agency had twice before proposed to apply the rules to such testing, but delayed action to get further comment (*NIR, 29, 6/Jan 14 '08, p. 8*).

CMS has now adopted, with some changes, the alternatives discussed in the proposed fee schedule rule in July for determining whether anti-markup provisions under the Stark self-referral rules apply to the technical component (TC) and the professional component (PC) of diagnostic testing services.

Under the first alternative, the provisions would apply in all cases where:

- ❑ The PC and the TC were purchased from an outside supplier, or
- ❑ The services were performed or supervised by a physician who does not share a practice with the billing physician or physician organization.

"Sharing a practice" is defined as a situation where the physician performs "substantially all" of his or her professional services for the billing physician or supplier. "Substantially all" means at least 75 percent of a physician's services. In these cases, the anti-markup rules would not apply.

Anti-markup restrictions on anatomic pathology services under the Stark self-referral rules are already in place.

For arrangements that do not satisfy the above, CMS advised, use the "site of service" alternative. The TC of diagnostic testing services performed in the office of the billing physician or other supplier would not be subject to the anti-markup rules.

"We believe that allowing billing physicians and other suppliers that cannot satisfy the first alternative to comply with the requirements of the second alternative on a case-by-case basis affords physicians flexibility while addressing our concerns regarding the ordering of unnecessary diagnostic tests," CMS said.

Spotlight on Genetic Testing in Front-Line Health Care

Against the backdrop of evolving federal policy, the nonprofit group, *Results for Life,* held an Oct. 28 briefing to answer three main questions on genetic testing: What is it, how does it work, and why does it matter? The group is composed of laboratory professionals, clinical labs, and test manufacturers.

The briefing, held in Washington, D.C., featured experts who discussed the science, economics, and policy issues surrounding genetic testing. The vast majority of genetic tests are used in front-line delivery to improve diagnosis and treatment for such conditions as HIV, cancer, and cardiovascular disease, *Results for Life* noted in a statement, while online direct-to-consumer genetic testing is a tiny segment the market.

Moderator John Iglehart, the founding editor of *Health Affairs* and the Washington correspondent for the *New England Journal of Medicine*, opened the meeting by noting that genetic testing is relatively new to health policymakers but in other respects has been an emerging field for many years.

Perhaps the most well-known are newborn screening programs run by the states and new tests for breast and colorectal cancer. But the field is dynamic, with molecular diagnostics now the fastest-growing segment of the clinical laboratory market, raising hopes for continuing advances in personalized medicine—tailoring treatment and therapy to an individual's genomic profile—to benefit patients and save health care dollars.

Yet, there is "massive confusion over what genetic testing is all about," said Alan Mertz, president of the American Clinical Laboratory Association. "How many people understand that genetic tests are the primary reason that people are no longer dying from HIV? How many understand that genetic tests are the reason that the survival rate for the most common form of childhood leukemia is now more than 80 percent versus 4 percent in the 1960s? These are well-established, real-time, real-world tests that are saving lives today and should not be overshadowed by media coverage of the online direct-to-consumer tests."

Policymakers and the news media must have a full and accurate understanding of genetic testing and its true impact, Mertz said, if they are to "knowledgeably address the policy questions that lie ahead regarding genetic testing … I am thinking of everything from future regulation to future reimbursement, along with privacy and validation."

Key Front-Line Genetic Tests

- A test that identifies genetic differences among patients in how their bodies metabolize warfarin, a common blood-thinning drug. Broad use of this test, which allows physicians to determine the most precise dosage for the patient, could reduce strokes by 17,000, bleeding episodes by 85,000, and costs by $1 billion annually.
- A test that identifies gene variation that leads to life-threatening side effects from certain colon cancer drugs, thus allowing physicians to bypass those drugs and select others.
- A test that identifies variations in the BRCA1 and BRCA2 genes that increase risks for breast and ovarian cancer, thus permitting preventive interventions.
- A genetic test that detects a leukemia-causing protein which can then be treated with a genomics-based drug—an approach that has boosted survival rates from 69 percent in 2001 to 89 percent today.

What Is Genetic Testing?

Sherri Bale, Ph.D., co-founder of Gene Dx, defined genetic testing as "the analysis of human DNA in any of its forms or related products (chromosomes, RNA, and proteins)." It is used

Advances in molecular diagnostics and other genetic testing innovations that are transforming the field include multiplex testing, genomic hybridization, and high throughput sequence analysis, said speakers at the briefing.

to detect disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes.

There are two main types of genetic tests, she noted: constitutional (tests for mutations that affect all cells in the body and have been there since conception) and acquired (tests for changes that affect only certain cells or cell types in the body and that occurred later in life).

Each type is further broken down to hone in on areas for intervention. Tests for constitutional mutations can be molecular (analysis of the DNA sequence in a patient for muscular dystrophy), cytogenetic (examining chromosomes in children who present with multiple anomalies, developmental delay, and autism), and biochemical (analyzing the quantity of a downstream product of the gene; for example, newborn screening with 20 specific tests mandated in all 50 states and over 4 million newborns being tested each year).

Tests for acquired disease, Bale continued, break down into molecular (for example, the KRAS gene test on tumor tissue from patients with colorectal cancer) and cytogenetic (Her-2/neu gene amplification in breast cancer to help select patients for chemotherapy or alternative therapies for those unlikely to respond).

Why Does It Matter?

Gail Vance, M.D., a professor in the Department of Medical and Molecular Genetics at Indiana University School of Medicine, noted that the mapping of the human genome, completed in 2003, has given physicians tools to understand the biological and disease variability of individual patients, opening the door to a new era of personalized medicine versus the "trial-and-error" medicine of the past.

Genetic tests are powerful in several ways, Vance said, enabling physicians to:

- Diagnose more precisely and select the appropriate treatment. For example, genetic tests identify DNA mutations of childhood leukemia, including the most common (acute lymphoblastic leukemia) and other subtypes that allow precise treatment and timing.
- Predict the risk of disease before symptoms occur. Variations in the BRCA1 and BRCA2 genes can identify greatly increased hereditary risk for breast and ovarian cancer, enabling physicians to monitor patients and start preventive measures, including surgery or chemotherapy.
- Manage disease more effectively. Patients on warfarin, an anticoagulant used to decrease the incidence of blood clots, require regular testing and other monitoring to adjust their dosage to prevent abnormal bleeding. These patients have highly variable responses to the drug, and variants of two genes, CYP2C9 and VKORC1, account for 30 percent to 50 percent of the variability. In 2007, the Food and Drug Administration changed warfarin labeling requirements to make clear that fast metabolizers may be more at risk.

Personalized medicine addresses the main concerns underlying health care reform, Vance said, by reducing overutilization and inappropriate care, cutting costs because less is spent on care shown to have no benefit for the individual patient, and assuring patient safety against adverse drug reactions and other potentially threatening side effects.

NPI Advisory

Out-of-Jurisdiction Screening Mammograms, Diagnostic Services

Effective Dec. 1, the Centers for Medicare and Medicaid Services will establish an exception to the standard reporting of the national provider identifier (NPI) on certain Medicare fee-for-service claims for purchased mammography screening and diagnostic services (Change Request 6237, Oct. 31, 2008).

CMS noted that a billing provider may purchase certain Medicare-covered services from another provider. In this case, the billing provider must not only report its own NPI (as the billing provider), but also annotate the claim with the performing provider's NPI. However, when the performing provider is located in a contractor jurisdiction different from that of the billing provider, the contractor will not have a record of the performing provider's NPI. In this instance, the billing provider may annotate its own NPI as the performing provider's NPI in order for the claim to be adjudicated by Medicare. The billing provider is responsible for documenting the performing provider's NPI in the clinical records for auditing purposes.

The above reporting convention had not previously been established for out-of-jurisdiction mammography screening and diagnostic services, CMS said. Thus, it has added the following new policy: "When a provider bills for [these services] that have been purchased from a provider in another contractor jurisdiction, the billing provider must, in addition to reporting its own NPI on a paper or electronically submitted Medicare claim (as the billing provider), also report its own NPI as the performing provider and annotate the claim with the name, address, and ZIP code of the performing provider." The term "provider" means "physician or other supplier" if the context requires alternative reading.

Obama Era, *from p. 1*

Obama and congressional Democratic leaders have already singled out Medicare managed care for payment reductions. Medicare Advantage plans get on average 12 percent to 15 percent higher rates than traditional Part B fee-for-service providers for comparable services to beneficiaries. The Democratic plans would eliminate this differential and pay plans at the same rate as fee-for-service. But this has already run into resistance from the health insurance industry and from GOP lawmakers.

Analysts also predict that the Obama administration will usher in a more activist, expansionist role in oversight by all federal agencies, including the CLIA lab program and the Food and Drug Administration's role in regulating lab-developed tests.

The higher pay was an incentive established in 2003 by the GOP-controlled Congress to revitalize the Medicare managed care market, which collapsed in the late 1990s when health plans dropped out of Medicare+Choice, the predecessor to Medicare Advantage, saying they were losing money, and thousands of beneficiaries were left to scramble for other coverage. The added pay was necessary, supporters said, to entice health plans to enter and remain in the Medicare market.

In another major Medicare area, Democrats would seek savings by allowing the program to use its volume purchasing power and negotiate prices directly with drug manufacturers under the Part D prescription drug benefit.

Industry analysts also predict that the Obama health care agenda will emphasize comparative effectiveness, an approach to evaluate which medical procedures benefit patients, but this will entail cooperation with physician groups on the guidelines. Obama has sponsored legislation (S. 976) to advance genomics and personalized medicine, including studies of medical outcomes.

♦ Medicare Coverage *Advisory*

Major Changes Ahead for 'Welcome to Medicare' Physical

Effective Jan. 1, the initial preventive physical examination covered by Medicare Part B has been expanded and the annual deductible is waived, though beneficiaries remain liable for the 20 percent copay, the Centers for Medicare and Medicaid Services has alerted its contractors (Change Request 6223, Oct. 17, 2008).

The baseline checkup by a physician must include measurement of vital signs, a review of the beneficiary's medical and social history, plus potential risk for depression and decreased functional ability / safety. The physician also is to provide education, counseling, and referral to other Part B preventive services, including a brief written plan (such as a checklist) for obtaining them. The services include lab screening and other diagnostic procedures for colorectal and prostate cancer, cervical and breast cancer, and cardiovascular disease.

What's New

The changes, required by the Medicare Improvements for Patients and Providers Act passed last July (MIPPA, Public Law 110-275), include:

- ❑ **Extended Eligibility:** The eligibility period for the baseline exam has been extended from six months to 12 months following a beneficiary's Part B enrollment. Those who enrolled in 2008 but have not yet had the exam can have it in 2009 as long as it is done within 12 months of their initial enrollment.
- ❑ **More Required Services:** Added to the benefit as mandatory services are measurements of an individual's body mass index and, with the individual's consent, end-of-life planning. The latter is defined as verbal or written information regarding (1) an individual's ability to prepare an advance directive in case an injury or illness causes the individual to be unable to make health care decisions and (2) whether or not the physician is willing to follow the individual's wishes as expressed in the advance directive.

CMS has assigned a *new HCPCS code* for billing the "Welcome to Medicare" physical—*G0402*. As a result, codes G0344, G0366, G0367, and G0368 will no longer be valid for dates of service starting Jan. 1.

- ❑ **Screening EKG Optional:** The screening electrocardiogram is no longer a required service as part of the exam, though it may be performed as an optional, one-time service obtained as a result of a referral for additional screening, educational, and counseling services covered by Part B.

The new screening EKG codes are G0403, G0404, and G0405. Contractors are to recognize these codes only once in a beneficiary's lifetime. The new codes, CMS said, are similar to codes G0366, G0367, and G0368, except that the EKG is no longer "performed as a component of the initial preventive exam" but is an optional one-time-only screening as the result of a referral from the exam.

For the Record: In the Oct. 27 issue, the chart on Medicare preliminary pricing of new 2009 CPT lab codes (p. 3) incorrectly reported the crosswalk recommended by the American Society for Microbiology for new code 87905. The correct crosswalk should read: "82657, Enzyme cell activity, nonradioactive substrate, each specimen, minus 87176, Homogenization, tissue, for culture."

New Guidance From CLIAC on Good Lab Practices

The CLIA program has opted not to create a specialty for genetic testing, and the guidance is intended to help lab personnel better understand how current CLIA requirements apply to this testing.

Clinical laboratories can look forward to new guidance on molecular and genetic testing now that the Clinical Laboratory Improvement Advisory Committee (CLIAC), which advises the government on CLIA scientific and technical matters, has adopted a workgroup report on good lab practices in this rapidly expanding area of medicine. The report, adopted at the panel's September meeting in Atlanta, will be published in the CDC *Morbidity and Mortality Weekly Report* later this year or in early 2009.

The report offers guidance on heritable conditions, the new CLIAC chair, Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science, told *NIR*. Another workgroup will be organized to report on biochemical and somatic diseases.

The soon-to-be-available report discusses preanalytic, analytic, and postanalytic phases of testing, including best practices in providing user information about services offered; informed consent and confidentiality; test requests; specimen submission, handling, and referral; test authorization; performance verification and control procedures; proficiency testing; test reporting; retention of records and specimens; and personnel competencies and training.

Upcoming G-2 Events

AUDIO CONFERENCES

Nov. 25 (2:00 – 3:30 Eastern). ***Coding and Reimbursement for Molecular Diagnostics: Practical Planning and Preparation for 2009***
Don't risk Medicare and other payer denials. Get up to speed on coding updates along with coding and billing guidelines to ensure you receive fair and accurate payment for molecular testing services.

CONFERENCES

Dec. 10-12, 2008. ***LabCompete: Laboratory Sales & Marketing Conference, How to Win the Battle for Market Share in Today's Health Care Market,*** Hyatt Regency, Scottsdale, Ariz.

Feb. 2-4, 2009. ***Business & Financial Strategies for Molecular Diagnostics: Expanding the Platform for MDx Lab Growth and Profitability,*** Hyatt Regency Pier Sixty-Six, Fort Lauderdale, Fla.

To register or get more details on the above, go to www.g2reports.com or call 800-401-5937, ext. 2.

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