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Congress Blocks Medicare Physician Fee Cut Again, to June 1

Lawmakers have kept physician fees in the deep freeze at 2009 levels since the start of this year while laboring to resolve differences over a long-term fix to the SGR formula that triggered the 21 percent cut for 2010.

President Obama on April 15 signed legislation (H.R. 4851) canceling a 21 percent cut in Medicare reimbursement following House and Senate approval of the bill earlier that day. The cut took effect April 1, but the bill blocks it retroactively to that date and continues the freeze on the physician fee update through May 31.

In response to enactment of the bill, the Centers for Medicare and Medicaid Services announced that claims with dates of service April 1 and later that were being held by Medicare contractors are being released for processing and payment. The statutory payment floors still apply and, therefore, clean electronic claims cannot be paid before 14 calendar days after the date they are received by contractors (29 calendar days for clean paper claims).

Physician groups and the AARP seniors' lobby continue to press Congress to adopt a permanent fix to the Sustainable Growth Rate (SGR) formula that has produced ever-deeper update cuts to physician fees since 2002.

Continued on p. 8

Obama Picks Berwick to Head CMS

President Obama on April 19 nominated Harvard professor Donald M. Berwick, M.D., a pediatrician and health policy expert, to be the next administrator of the Centers for Medicare and Medicaid Services (CMS), a post requiring Senate confirmation.

"Dr. Berwick has dedicated his career to improving outcomes for patients and providing better care at lower cost," Obama said in a statement. "That's one of the core missions facing our next CMS administrator."

CMS has been without a permanent chief since October 2006 when Mark McClellan resigned. Kerry N. Weems was acting head from 2007 to the end of the Bush administration. The current acting administrator is Charlene Frizzera.

If confirmed, as expected, Berwick will take the helm at CMS as the agency begins to implement sweeping changes mandated by the new health care reform law, including expansion of Medicaid, cuts in Medicare to slow spending growth, and a shift in Medicare from fee-for-service to alternative ways to pay for covered services. For details, see the *Focus, pp. 3-6.*

INSIDE *NIR*

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Health Care Reform Tightens the Squeeze on Lab Fee Updates

The long-term effect translates to a cut of 9 percent to 10 percent from the baseline of Medicare Part B laboratory spending, say industry sources.

In the marathon debate over comprehensive reform of the nation's health care system, clinical laboratories fended off the restoration of a 20 percent copay for their Medicare-covered services (abolished when the Part B lab fee schedule was established in 1984) and the introduction of an annual lab industry tax in the range of $7.5 billion.

But when all was said and done, labs had to absorb a new round of cuts in their annual update to the Medicare fee schedule to help pay for the final health care reform legislation—an estimated $10 billion over 10 years.

The hope is that the reform law's expansion of coverage to approximately 31 million more Americans and promotion of new prevention and wellness initiatives will generate increased utilization of laboratory services covered by Medicare and private health plans and help soften the blow to revenue.

This year, the lab fee update is at minus 1.9 percent under the current update formula, the consumer price index (CPI-U) minus 0.5 percent. This is the first time in the fee schedule's history that the update dropped into negative territory.

But next year, two big changes to the formula kick in under the reform law, the Patient Protection and Affordable Care Act (Public Law No. 111-148)—a productivity adjustment and an additional 1.75 percent cut.

Beginning in 2011 and subsequent years, the 0.5 percent reduction is repealed and replaced with a full productivity adjustment (currently estimated at 1.3 percent). However, this adjustment cannot reduce the fee schedule update below zero. The productivity adjustment is defined in the reform law as the 10-year rolling average of productivity gains in the general economy. This adjustment is projected to range between 1.1 percent and 1.4 percent over the next 10 years and is estimated to save Medicare $5 billion over 10 years, according to the Congressional Budget Office.

Also in 2011 and running through 2015, the CPI update is cut by 1.75 percent, contributing another $5 billion in savings to the Medicare lab spending baseline. However, unlike the productivity adjustment, this cut could push the update below zero. After 2015, only the productivity adjustment applies.

The fee update formula changes put continuing pricing pressure on labs, according to *Laboratory Economics*, with cuts of about 3 percent per year for the next five years.

In a media conference call earlier this month, Alan Mertz, president of the American Clinical Laboratory Association (ACLA), noted that all Medicare providers had to make concessions in order for the reform initiative to expand coverage and the industry stepped up to the plate to do its part. "We believe the expanded coverage will allow millions more Americans to get access to valuable diagnostic laboratory services, which we believe are the foundation to good health care and outcomes." In any year when the inflation update is 3 percent or more, labs will not feel a cut, and if this update is above that, labs will get an increase, he added.

focus on: *CMS Reorganization*

CMS Gets a Major Makeover
What Does It Portend for Labs and Pathologists?

For the first time in nearly 10 years, the Centers for Medicare and Medicaid Services (CMS) is undergoing a major in-house renovation to clear the way for implementing significant policy and payment changes mandated by the new health care reform law, the Patient Protection and Affordable Care Act (Public Law No. 111-148).

A New Chief for CMS: *Profile of President's Nominee*

Pediatrician Donald M. Berwick, nominated by the president to head the Centers for Medicare and Medicaid Services, brings considerable clout to the job of leading the agency in instituting reforms in its programs that insure nearly one-third of all Americans.

Berwick is founder and president of the Institute for Healthcare Improvement in Cambridge, Mass., and a professor at Harvard Medical School and the Harvard School of Public Health.

He is widely known for advising and working with hospitals and clinics nationwide to reduce medical errors, improve information sharing, and deliver quality care while reducing its cost. He summed up his philosophy at a recent conference held by his institute: "The best health care is the very least health care we need to gain the long, full, and joyous lives that we really want."

Berwick has extensive experience with government, serving as chair of the National Advisory Council of the Agency for Healthcare Research and Quality and as an elected member of the Institute of Medicine, serving on its governing council from 2002 to 2007. He also has served as vice chair of the U.S. Preventive Services Task Force.

In 1997 and 1998, he was appointed by President Clinton to the Advisory Commission on Consumer Protection and Quality in the Healthcare Industry.

In a March 24 notice in the *Federal Register*, CMS said the reorganization combines common core functions under common executive leadership. Four new centers are created, with deputy administrators who report directly to the top—the Center for Medicare; the Center for Medicaid, CHIP, and Survey and Certification; the Center for Program Integrity; and the Center for Strategic Planning—plus a new Office of External Affairs and Beneficiary Services (*see chart, p. 5*).

The reshuffling of programs and staff gives new prominence to program integrity and strategic planning, research, and demonstrations. It also aims to better coordinate the operations of the different units in carrying out the reform law's numerous overhaul provisions.

At this early stage in the reorganization's rollout, some key areas for clinical laboratories and pathologists already stand out, industry sources told *NIR*.

Program Integrity

The heightened role assigned to program integrity, which targets improper payments, fraud, and abuse, augurs more stringent oversight and enforcement actions. Providers need to remain vigilant about providing and billing for services in compliance with CMS requirements, these sources advised.

The new Center for Program Integrity combines oversight and enforcement in Medicare, Medicaid, and the state Children's Health Insurance Program (CHIP). Its work includes provider/contractor audits and policy reviews to identify program

vulnerabilities. The center's head is Peter Budetti, a former aide to Rep. Henry Waxman (D-Calif.), chair of the House Energy and Commerce Committee, known as a "hawk" on health care fraud and abuse issues.

Providers already are on notice that they are in for more scrutiny under federal probes. President Obama signed a presidential memorandum March 10 directing all federal departments and agencies to expand their use of payment recapture audits to locate and recover overpayments and underpayments. This initiative is expected to recover at least $2 billion over the next three years.

The audit model is based on Medicare's Recovery Audit Contractor (RAC) program for Part A and B services. Under the health care reform law, the RAC program is to be expanded to Medicaid, Part C Medicare Advantage, and Part D prescription drug plans by the end of this year. Under the RAC program, private contractors receive a contingency fee for the amount of improper payments they recover (*NIR 10, 6/March 25, p. 8*). The program has scored major recoveries from durable medical equipment suppliers and pegged high-utilizing beneficiaries for prepayment review. It recently gained approval to expand review of physician services, including units paid for blood transfusions, bronchosopy, intravenous hydration, and cancer drugs.

New Medicare Demonstrations

This is another area with long-term implications for clinical lab and pathology services. These demonstrations, set to start over the next few years, will test, evaluate, and implement alternative models for delivering and paying for coordinated care, including diagnostic and lab testing. The projects will test a mix of reimbursement methods: fee-for-service plus bonus payments for achieving quality performance standards as well as bundled payment for services per episode of care.

The new Center for Strategic Planning is charged with developing long-term plans and proposals for research and demonstrations required under the health care reform law. And by 2011, that law also requires CMS to form a Center for Medicare and Medicare Innovation to foster research-and-development initiatives.

Payment and Oversight

The reorganization assigns payment policy for covered clinical laboratory and pathology services to the new Center for Medicare, which acts as the CMS lead on issues affecting fee-for-service providers and suppliers, managed care plans under the Part C Medicare Advantage program, Part D prescription drug plans, and Medicare contractors.

Oversight of laboratory testing under the Clinical Laboratory Improvement Amendments (CLIA) is housed in the new Center for Medicaid, CHIP, and Survey and Certification.

Finally, the new Office of External Affairs and Beneficiary Services is the focal point for liaison with lab, pathology, other advocacy groups, and the states, along with media relations and communications with beneficiaries.

Ambitious Agenda for Demonstrations

In positioning CMS to achieve the long-term goal of shifting Medicare from paying

CMS Reorganization at a Glance

Office of the Administrator

Acting administrator,
Charlene Frizzera
Principal deputy administrator,
Marilyn Tavenner

Center for Medicare	Center for Medicaid, CHIP, and Survey and Certification	Center for Program Integrity	Center for Strategic Planning	Office of External Affairs and Beneficiary Services
Deputy administrator, Jonathan Blum Two deputy center directors *Responsible for fee for service, Medicare Advantage, prescription drug plans*	Deputy administrator, Cindy Mann Two deputy center directors *Handles policy and operations for the three programs in the title, plus CLIA lab oversight*	Deputy administrator, Peter Budetti Two deputy center directors *Combines previously separate Medicare and Medicaid anti-fraud and abuse groups*	Deputy administrator, Anthony Rodgers *Realigns the Office of Research, Development, and Information and the Office of Policy*	Office director, Teresa Nino Two deputy office directors *Responsible for communication with beneficiaries, the states, and advocacy groups*

Left intact are the following offices that report directly to the Administrator:
Clinical Standards and Quality,
Legislation,
the Actuary,
Equal Opportunity and Civil Rights,
Strategic Operations and Regulatory Affairs (to be renamed Executive Operations and Regulatory Affairs).

Source: BNA Medicare Report

primarily for volume to rewarding quality and efficiency, the health care reform law lays out a timeline for establishing mechanisms to develop and run numerous demonstration projects. Below are those of special interest to labs and pathologists.

2011

❑ Establish a Center for Medicare and Medicaid Innovation to test, evaluate, and expand different payment structures and methodologies. For the initial testing of the models, $5 million is provided; for possible expansion of the models, $10 billion is authorized for fiscal years 2011 through 2019.

❑ Begin a two-year demonstration project to pay for certain complex molecular diagnostic tests, up to a $100 million limit. Eligible hospital-based and independent labs would be allowed to bill Medicare Part B for these tests when performed within 14 days of a beneficiary's discharge.

2012

❑ Establish a shared savings program under which accountable care organizations (ACOs) that voluntarily meet quality thresholds can share in the cost savings they achieve for Medicare in coordinating Part A and Part B services. Participating providers would be paid via fee-for-service but would be eligible for bonus payments when meeting performance benchmarks.

ACOs would include groups of providers and suppliers with an established mechanism for joint decisionmaking, including practitioners in group practices, networks of practices, partnerships or joint ventures between hospitals and practitioners, hospitals that employ practitioners, and other groups as determined by the secretary of Health and Human Services.

- ❑ Launch the Medicare Independence at Home demonstration project. Under this model, physicians and nurse practitioners would manage home-based primary care for chronically ill beneficiaries and arrangements for care by specialists, when appropriate, to help improve the quality of life and reduce unnecessary hospitalization. The Medicare population that falls under the rubric of chronically ill accounts for about 80 percent of current medical expenditures but comprises only about 20 percent of beneficiaries. The demonstration is limited to a sufficient number of practices to accommodate 10,000 eligible Medicare beneficiaries.

Of special note for labs and pathologists is a stipulation in the health care reform law that one of the aims of the home-based primary care project is to reduce duplicative diagnostic and laboratory tests.

As part of the policy shift under this model, the College of American Pathologists (CAP) advocates that CMS conduct a demonstration project to evaluate the role of pathologist-initiated consultations on test selection and assisting in therapy management as a method to improve patient care and control costs.

The project would "focus on complex and costly genetic and other diagnostic tests that not only assist in the management of and diagnosis of disease, but also delineate an individual's unique responsiveness to preventive and therapeutic interventions."

Under current Medicare payment policies, pathologists are not compensated if they initiate consultation with a primary care doctor. The consult must be formally requested by the attending physician. "This may have made sense," CAP says, "when lab test results were considered routine and understood by most primary care providers, but this clearly is not the case today," given the evolution of molecular and genetic testing that has led to advances in personalized medicine (*NIR, 09, 13/July 13, p. 4*).

2013

- ❑ Establish a national Medicare pilot program to develop and evaluate bundled payment for medical services furnished per episode of care, including acute inpatient hospital services, physician services, outpatient hospital services, and post-acute care services.

CMS has used its authority to exclude outpatient lab services from the outpatient prospective payment system and pay for these services via the Part B lab fee schedule. But this could change, industry sources speculate, depending on how the agency designs the pilot. Regulations to implement the demonstrations as well as the other numerous provisions in the health care law will take a long time to be written and are sure to generate controversy, according to the Congressional Research Service. In many instances, rules must be proposed before becoming final while in other cases, CMS has discretion to make changes via policy directives.

New Curbs Imposed on Physician-Owned Hospitals

The health care reform law makes major changes to the exception under the Stark self-referral statute that allows physicians to refer Medicare patients to "whole hospitals" in which they have an ownership or investment interest.

The law bans new physician-owned hospitals in Medicare after Dec. 31, 2010, and limits the growth of certain "grandfathered" physician-owned hospitals. It imposes significant restrictions that cap the hospital's aggregate physician ownership and, with certain narrow exceptions for high Medicaid hospitals, prohibit expansion of the number of operating rooms, procedure rooms, or beds.

Physician-owned hospitals also must meet new Medicare reporting requirements as well as extensive disclosure requirements to its patients, on the hospital's Web site, and in any public advertisements.

Medicare Claims Advisory

Lab Reasonable Cost Payment Extended for Rural Hospitals

The new health care reform law extends reasonable cost payment for outpatient clinical laboratory tests furnished by hospitals with fewer than 50 beds in qualified rural areas for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011. This payment method was first authorized by Congress for a two-year period beginning July 1, 2004, and has been repeatedly extended since.

Section 3122 of the reform law reinstitutes reasonable cost payment through June 30, 2011, but for some hospitals, this could affect services performed as late as June 30, 2012, said the Centers for Medicare and Medicaid Services (CMS) in Change Request 9873 (April 2, 2010).

Hospitals that qualify under Section 3122 need take no action, CMS added. They will receive reasonable cost payment for an entire year, starting with their cost reporting period beginning on or after July 2, 2010. Medicare contractors use the Medicare Zip Code File to identify qualified rural areas. A qualified rural area in the context of the change request is one with a population density in the lowest quartile of all rural county populations.

Interest Rate to Drop for Medicare Overpayments, Underpayments

Effective April 23, 2010, the rate of interest that Medicare will pay you for claims that were underpaid, or collect from you for claims that were overpaid, has dropped to 10.875 percent, down from the rate of 11.25 percent in effect from Jan. 25 to April 22 of this year. The highest rate in the past decade was in early 2001, 14.125 percent, but for most of the years since, the rate has hovered between 11 percent and 12 percent. Medicare regulations provide for assessing interest at the higher of the current value of funds rate (1 percent for calendar year 2010) or the private consumer rate fixed by the Treasury. Upon notification from the Treasury of the new private consumer rate at 10.875 percent, the Centers for Medicare and Medicaid Services announced the quarterly update to the interest rate in Change Request 6653 (April 16, 2010).

Congress Blocks Medicare Physician Fee Cut, *from p. 1*

The American Medical Association in an April 16 statement said, "Repeated delays and continued uncertainty combined with the fact that Medicare payments, even without the 21 percent cut, have not kept up with the cost of providing care to seniors demonstrates the need for a permanent solution to this annual problem. Congress must now turn toward solving this problem once and for all through repeal of the broken payment formula that will hurt seniors, military families, and the physicians who care for them. It is impossible for physicians to continue to care for all seniors when Medicare payments fall so far below the cost of providing care."

While lawmakers have expressed support for fixing the SGR system, they are divided over how to do it and pay for it. The Senate has approved an extension of the fee update freeze through Sept. 30, but the House has yet to act on it. The Congressional Budget Office estimates that a permanent fix would have a net cost of $210 billion over 10 years. The debt ceiling law allows $82 billion to pay for it without budget offsets, but that still leaves a big balance to finance. Conservative senators on both sides of the aisle have insisted thus far that the SGR fix be fully paid for and not add to the deficit *(NIR 10, 7/April 8, p. 2).*

• Upcoming G-2 Events •

Webinar (2 p.m. – 3:30 p.m. Eastern)

April 30
Changing the Playing Field: What Does Health Care Reform Mean for Labs and Pathologists?

Conferences

June 2-4
Lab Outreach 2010: Building the Value Equation for Your
Hyatt Regency Baltimore on the Inner Harbor, Baltimore

Oct. 13-15
Lab Institute 2010
Crystal Gateway Marriott
Arlington, Va.

Dec. 8-10
Laboratory Sales and Marketing 2010
The Venetian Las Vegas
Las Vegas

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