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Major Lab Payment, Policy Changes Ahead Under New Comprehensive Health Care Reform Law

The reform law expands medical coverage to 32 million more Americans, with subsidies to help people obtain insurance, and seeks to improve patient outcomes. The estimated cost is $940 billion over 10 years, according to the Congressional Budget Office.

For clinical laboratories nationwide, the landmark health care reform bill (H.R. 3590) signed into law by President Obama on March 23 will usher in a big change to their Medicare fee update, a new five-year cut in fees, a demonstration on payment for complex molecular tests, and expanded coverage of testing for prevention and wellness.

As the broader reforms in the law roll out, labs will see the market for diagnostic testing and screening expand to nearly 95 percent of Americans who will be required to obtain medical coverage through their employer or from public and private programs, including new insurance exchanges for price and coverage comparison shopping. Large employers would have to offer employees health benefits or in some cases face penalties.

A With the insurance exchanges not due to be operational until 2014, the law creates a national high-risk insurance pool where individuals who might not otherwise be able to obtain medical coverage can get it. Also, starting in September, health insurers may no longer drop coverage when patients get sick, cap lifetime benefits, or deny children coverage for pre-existing conditions.For more on the lab changes, see the Focus, pp. 4-5.

Another Freeze on Physician Fees in Play; TC Pathology Protection Revived

Several legislative attempts to block an April 1 cut of 21 percent in Medicare physician payments are under way at press time as Congress prepares to adjourn March 29 for two weeks.

But in welcome news for certain independent clinical laboratories, the pathology "grandfather" protection, which expired last year, is restored for one year, retroactive to Jan. 1, 2010, under the Senate health care reform legislation that the House passed March 21 and the president signed March 23.

On the physician fee front, the new health care reform law does not address the Sustainable Growth Rate (SGR) update fix advocated by pathology and laboratory groups. The SGR, used to calculate the annual update, has triggered cuts for most of the past decade.

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Physician Fees, *from p. 1*
Currently, physician fees are frozen at their 2009 levels, blocking the 21 percent cut effective Jan. 1, 2010. The freeze expires March 31.The Senate jobs-related bill passed March 10 would extend the freeze through Sept. 30. But because the bill adds provisions to the underlying House measure, it has gone back to the House to reconcile differences. The outstanding issue between the two chambers is not the Medicare extenders but the offsets to pay for other parts of the bill, say industry sources.

With only a few days left to reconcile the differences before Congress adjourns, the House passed and sent to the Senate a separate bill with provisions to block the April 1 SGR cut and continue the freeze through April (H.R. 4213). In addition, Democrats in Congress are planning to introduce a bill that would provide a three- to five-year fix to the SGR.

Pushing for a Permanent Fix

While recognizing that an SGR fix will not be considered in the House reconciliation bill amending the new reform law, the American Medical Association (AMA) said in a statement that Congress must move quickly to repeal the SGR "which threatens access to care for senior and military families."

But the AMA also expressed support for the broader health care reform package in a March 19 letter to House speaker Nancy Pelosi (D-Calif.). "By extending coverage to the vast majority of the uninsured, improving competition and choice in the insurance marketplace, promoting prevention and wellness, reducing administrative burdens, and promoting clinical comparative effectiveness research, we believe that H.R. 3590 does, in fact, improve the ability of patients and their physicians to achieve better health outcomes."

Also in anticipation of the bill's passage, the College of American Pathologists (CAP) in a March 19 letter to Pelosi urged repeal of the SGR system and replacing it "with a fair, stable payment system that keeps pace with the rising cost of practicing medicine." CAP applauded the House for passing H.R. 3961, which would repeal the SGR in 2010 and establish a new update formula tied to growth in the gross domestic product at an estimated net cost of $210 billion over 10 years. But the change was not paid for, a sticking point with some senators who worry about the effect on the federal deficit. The Senate previously rejected an unpaid-for bid to repeal the SGR.

In the letter, CAP president Stephen N. Bauer, M.D., FCAP, also asked that Congress examine the value of an enhanced role for pathologists in coordinated care models, including the medical home and accountable care organizations. While welcoming the establishment of a Center for Medicare and Medicaid Innovation to evaluate new ways to promote coordinated care, improve quality, and reduce costs, "the legislation specifies a number of models to be examined, but makes no mention of diagnostic testing," he said.

"Pathologists are uniquely trained and positioned to assist in delivery system reform since diagnostic testing plays a central role in the direction and management of a patient's care in virtually all aspects of medicine, from prevention and primary care, to cancer, chronic disease, personalized medicine and public health," Bauer noted.

"In this context, pathologists not only ensure that patients get the right test at the right time, but they also protect the health care system against inappropriate requests for an ever increasing complex and expensive array of diagnostic testing."

Pathology 'Grandfather' Protection

The pathology "grandfather" protection, restored for all of 2010, allows qualified independent clinical laboratories to bill Medicare Part B directly for the technical component (TC) of pathology services to hospital inpatients and outpatients. Lab and pathology advocates hailed the restoration, saying it is needed to maintain quality testing and access to testing by Medicare beneficiaries, especially in rural areas where in-house hospital labs are scarce or underfunded.

Qualifying labs have not been paid for the TC service since the start of this year. The Centers for Medicare and Medicaid Services (CMS) advised them to hold TC claims for services furnished on or after Jan. 1, with the expectation that Congress would extend the grandfather protection *(NIR 10, 1/Jan. 11, p. 1).*

The protection applies to hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to eliminate these independent lab billings. Congress has repeatedly blocked the agency from going ahead with this policy change. CMS has repeatedly sought to end "grandfathered" TC billings, contending that the TC is paid through the hospital's inpatient diagnosis-related group and labs should seek reimbursement from the hospital, not the Part B program.

The protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The TC of pathology services includes anatomic services, cytopathology, and surgical pathology.

Labs on Track to Get Bids Back in CMS Demo Case

A California court on March 18 denied a request by the secretary of Health and Human Services (HHS) to dismiss a challenge filed by three clinical laboratories in the San Diego area against the now-aborted Medicare competitive bidding demonstration for Part B independent lab services.

The ruling is important, said Patric Hooper, an attorney with Hooper, Lundy and Bookman in Los Angeles, because it indicates that HHS will be forced to return the bid applications and not use the information contained in them to cut reimbursement for clinical laboratories. Hooper represents the plaintiffs in this case filed in 2008: Sharp Healthcare, Internist Laboratory, Scripps Health, the American Association of Bioanalysts, and the American Clinical Laboratory Association.

The court previously blocked the demo launch and Congress later repealed the authority for the project. But the plaintiffs continued their lawsuit to get HHS to return the bids and not use the information in any way. HHS countered that the lawsuit should be dismissed because, in part, "retention and anticipated analysis of the bid applications is within the secretary's general authority to make recommendations concerning Medicare operations." The government contended it could use the bids as long as proprietary data were not disclosed.

focus on: Health Care Reform

What's Ahead for Labs and Pathologists?
Key Provisions of the New Health Care Reform Law

Lab Fee Schedule Update

- ❑ No change in 2010. The update to the Medicare Part B fee schedule update is a cut of 1.9 percent under the current formula used to calculate the annual update: the consumer price index (CPI-U) minus 0.5 percent.

- ❑ 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 could not reduce the fee schedule update below zero.

- ❑ Also in 2011 and running through 2015, the CPI update is cut by 1.75 percent. This could result in an update below zero.

- ❑ After 2015, only the productivity adjustment applies.

Promotion of Preventive Services

The law eliminates cost sharing for preventive services that have an "A" or "B" rating by the U.S. Preventive Services Task Force (USPSTF) initially. This includes all services in the Medicare benefit. It also requires group health plans and individual health plans to expand their coverage of screening and early detection procedures.

Going forward, the USPSTF will be revamped to reflect broader representation. It will be charged with updating previous recommendations regarding clinical preventive best practices from government agencies, professional medical societies, patient groups, and scientific societies.

The Health and Human Services department (HHS) is instructed to plan and implement a national public-private partnership for a prevention and health promotion outreach campaign to raise public awareness of health improvement across the life span.

Complex Molecular Diagnostics Test Demonstration

A two-year $100 million demonstration project will be established for tests that analyze gene protein expression, topographic genotyping, or cancer chemotherapy sensitivity assays or that are billed using a Healthcare Common Procedure Coding System (HCPCS) code that is other than a "not otherwise classified" code. The project also applies to assays for which there is no alternative test with equivalent performance characteristics. HHS is to determine appropriate payment rates for the tests and report to Congress within two years after completion of the demonstration on its impact on access, quality, health outcomes, and expenditures.

The project, slated to start in July 2011, would allow hospital-based and independent clinical labs to bill Medicare directly for certain complex molecular diagnostic tests performed within 14 days of a beneficiary's discharge, beginning July 1, 2011 *(NIR 09, 21/Nov. 23, p. 4)*. Under current Medicare rules, if a lab performs testing on blood or tissue samples collected by a hospital for inpatients and outpatients within the 14-day period, it must be paid by the hospital through its inpatient diagnosis-related group (DRG) payment, rather than a direct payment from Part B.

The College of American Pathologists (CAP) says further modifications to the demonstration authority are warranted. Although this provision in the law was expanded to cover all laboratories, including hospitals, academic medical centers, and independent facilities, "the criteria to unbundle payment from the DRG and qualify for more favorable payment is decidedly tilted toward a small number of commercial labs. For instance, the requirement that only 'unique' tests qualify mainly promotes proprietary test monopolies, regardless of the test's clinical effectiveness. As a result, the provision in its current form falls short of providing a level playing field" for all competitors.

Payment for New Lab Tests

HHS is required to convene a public meeting on how to determine payment levels for new lab tests under Medicare, including a discussion of payment reform for such tests. HHS will submit a report to Congress summarizing the meeting, including recommendations for legislative or regulatory action.

Independent Payment Advisory Board

The law creates a 15-member Independent Payment Advisory Board (IPAB) with significant authority with respect to Medicare payment rates. Beginning in 2014, in any year in which the Medicare per capita growth rate exceeds a target growth rate, the IPAB would be required to recommend Medicare spending reductions. The recommendations would become law unless Congress passed an alternative proposal that achieved the same level of budgetary savings.

Subject to some limitations—hospitals, for example, would be exempt until 2020—the IPAB could recommend spending reductions affecting Medicare providers and suppliers, as well as Medicare Advantage and prescription drug plans. In years in which the IPAB would not be required to make recommendations, it would have to submit an advisory report. Every two years, the board would make recommendations on slowing the growth of private health expenditures.

The American Medical Association, CAP, and a host of other groups have raised concerns with this provision, arguing that it shifts responsibility for Medicare coverage and payment decisions historically made by Congress to an unelected body in the executive branch. The groups say the current process provides an open and transparent legislative means to air important policies on health care services.

Insurance Market Reforms

Beginning this year, private health insurers can no longer deny coverage when policyholders get sick, impose a cap on lifetime plan benefits, or deny children coverage for pre-existing conditions. Also, young people can be covered under their parents' plan until age 26. In 2014, the ban on coverage denial for pre-existing conditions will be extended to adults.

Medicare Claims Advisory

Medicare Travel Allowance Reduced for 2010

The Centers for Medicare and Medicaid Services (CMS) has revised downward the Medicare travel allowance payable to cover the costs of collecting a specimen from a homebound or nursing home beneficiary.

The change is to be implemented by contractors on April 5 but is effective as of Jan. 1 of this year (CMS Change Request 6864, March 19, 2010).

The new trip fees for the billing codes are:
— P9603, 95 cents per mile

— P9604, $9.50 flat rate per trip

The fees are 50 cents lower than the rates that CMS announced in the Medicare labfee schedule update for 2010 (Change Request 6657): $1 and $10, respectively (NIR 10, 1/Jan. 11, p. 5).

Medicare contractors have discretion to pay for travel to collect a specimen on either a per mile basis or a flat rate per trip.

The per mile code, P9603, is used where the average trip to the patients' homes is longer than 20 miles round trip, and it is to be prorated in situations where specimens are drawn from non-Medicare patients in the same trip. The per mile rate for 2010 is computed using the federal mileage rate of 50 cents per mile plus an additional 45 cents per mile to cover the technician's time and travel costs. Contractors are allowed to establish a higher per mile rate in excess of the minimum 95 cents per mile if local conditions warrant.

The flat rate per trip code, P9604, is based on a study of the fixed and variable costs of operating an automobile. This study is conducted on an annual basis for the Internal Revenue Service. Many contractors have a local policy to pay based on a flat rate only, CMS noted, "because of audit evidence that some laboratories abused the per mileage fee basis by claiming travel mileage in excess of the minimum distance necessary for a laboratory technician to travel for specimen collection."

Contractors are not required to search their files to either retract payment or retroactively pay claims; however, they are to adjust claims that are brought to their attention.

CMS Issues Instructions on Billing for Drug Screening

Clinical laboratories that bill Medicare for drug screening should take special note of the latest guidance from the Centers for Medicare and Medicaid Services (CMS), effective April 1 (Change Request 6852, March 19, 2010).

The codes affected are:
— CPT 80100 Drug screen, qualitative; multiple drug classes chromatographic method, each procedure

Medicare Claims Advisory

— CPT 80101, 80101QW Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

— G0430, G0430QW Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure

— G0431, G0431QW Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

When performing a qualitative drug screening test for multiple drug classes using chromatographic methods, the appropriate billing code is CPT 80100. The new test code G0430, introduced in the 2010 Medicare lab fee schedule, was created to limit the billing to one time per procedure and to remove the limitation of the method (chromatographic) when this method is not being used in the performance of the test. As a result, when performing a qualitative drug screen test for multiple drug classes that does *not* use chromatographic methods, G0430 is the appropriate code to bill. Labs certified for waived testing only use G0430QW.

New test code G0431 is a direct replacement for CPT 80101. When performing a qualitative drug screening test for a single class of drug, regardless of the testing methodology, this code is to be used. Labs certified for waived testing only use G0431QW. Effective April 1, CPT 80101 will no longer be covered by Medicare and CPT 80101QW will be deleted.

Change Coming April 1 in Modifiers for Advance Beneficiary Notice

Starting April 1, 2010, the Centers for Medicare and Medicaid Services (CMS) will introduce one new and one revised billing modifier to distinguish between voluntary and required uses of the advance beneficiary notice (ABN). The ABN alerts Medicare beneficiaries that they may be financially liable for an item or service that Medicare is likely to deny.

- The modifier GA is redefined to mean "Waiver of Liability Statement Issued, as Required by Payer Policy." It is only to be reported when a required ABN was issued for a service. It should not be reported in association with any other liability-related modifier and should continue to be submitted with covered charges. However, Medicare systems will now deny these claims as a beneficiary liability (rather than subjecting them to possible medical review), and the beneficiary will have the right to appeal this determination.
- The modifier GX, "Notice of Liability Issued, Voluntary Under Payer Policy," is to be used to report when a voluntary ABN was issued for a service. Providers may use this to provide beneficiaries with notice of their liability for services excluded from Medicare coverage by statute. In these cases, GX must be submitted with noncovered charges only and will be denied by the Medicare contractor as a beneficiary liability.

The CMS instructions are presented in Transmittal 1921 (Change Request 6563), which makes technical corrections to Transmittal 1894 issued earlier this year *(NIR 10, 2/Jan. 25, p. 7).*

Providers Are in for More Scrutiny in Federal Probes

The president's memo directs the Office of Management and Budget to develop guidance within 90 days on steps that executive departments and agencies must take to comply with the new requirements.

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. The initiative is expected to recover at least $2 billion over the next three years.

The audit model is based on the Recovery Audit Contractor (RAC) program used by Medicare. Under the RAC program, private contractors are responsible for analyzing program payments and identifying where payments were improper due to waste, abuse, or fraud. The contractors receive a contingency fee for the amount of improper payments they recover.

The Centers for Medicare and Medicaid Services launched the RAC program as a demonstration project in 2005 in California, New York, and Florida. It eventually expanded to South Carolina, Arizona, and Massachusetts and ran until 2008, resulting in recovery of more than $1 billion. Congress then made it permanent. It is expected to cover all 50 states by the end of 2010. In addition to RAC, provider claims are subject to review via correct coding and medically unlikely edits and audits by the Comprehensive Error Rate Testing program.

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Webinar (2 p.m. – 3:30 p.m. Eastern)

March 31

IT and the New Pathology Enterprise: Applying Informatics to Compete and Win

April 20

Building a High Performance Sales Team: Fundamentals to Catapult the Growth of Your Outreach Program

Conferences

April 14-16

Putting MDx to the Test: How Your Lab Can Capitalize on Molecular Diagnostics
Hyatt Regency Cambridge
Cambridge, Mass.

June 2-4

Lab Outreach 2010: Building the Value Equation for Your
Hyatt Regency Baltimore on the Inner Harbor, Baltimore, Md.

Oct. 13-15

Lab Institute 2010
Crystal Gateway Marriott
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