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Election Upset Leaves Lab, Pathology Changes Up in the Air

With prospects for action on health care reform uncertain, other legislative vehicles now being considered by Congress may have to be tapped to advance clinical laboratory and pathology priorities.

The fate of comprehensive health care reform legislation passed by the House and the Senate is unclear, following Republican Scott Brown's victory in the Massachusetts special election, defeating Democratic candidate Martha Coakley and shifting the balance of power in the Senate by depriving Democrats of their filibuster-proof majority. Brown campaigned against the legislation, promising voters he would stop it from going forward.

The upset has also thrown into doubt what Congress will do on a host of significant Medicare payment policy changes affecting clinical laboratories and pathologists that are contained in the reform bills.

Physician fees: The fee update is frozen at 2009 levels through Feb. 28, blocking a 21.2 percent cut. *Continued on p. 8*

Lab Services Rolled Into New Medicare ESRD Bundled Payment System

Clinical diagnostic laboratory tests now separately billable to Part B for services to end-stage renal disease (ESRD) Medicare beneficiaries would be combined with other ESRD services, such as dialysis treatment and prescription drugs, into a single bundled payment to renal dialysis facilities under the impending switch to ESRD prospective payment.

Details of the new payment method, required by Congress under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), were published in a rule proposed by the Centers for Medicare and Medicaid Services (CMS), which aims to finalize it this year. The bundled payment would apply to dialysis facilities starting Jan. 1, 2011. It would be phased in using blended rates to Jan. 1, 2014, when payment would be based on 100 percent of the prospective payment (PPS) amount.

CMS proposes to implement a case-mix adjusted bundled PPS to replace the current basic case-mix adjusted composite payment system and the methods used to reimburse separately billable outpatient ESRD services. The ESRD PPS would combine payments for composite rate and separately billable services into a single base rate developed from claims data, including diagnostic lab tests. The payment system would be combined with required quality performance standards.
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INSIDE NIR

Medicare Spending Up, Even as National Health Spending Slows

Medicare spending continues to grow even as the growth in the nation's total health tab slowed, in part due to the economic recession, according to the latest annual report on national health spending from the Office of the Actuary at the Centers for Medicare and Medicaid Services.

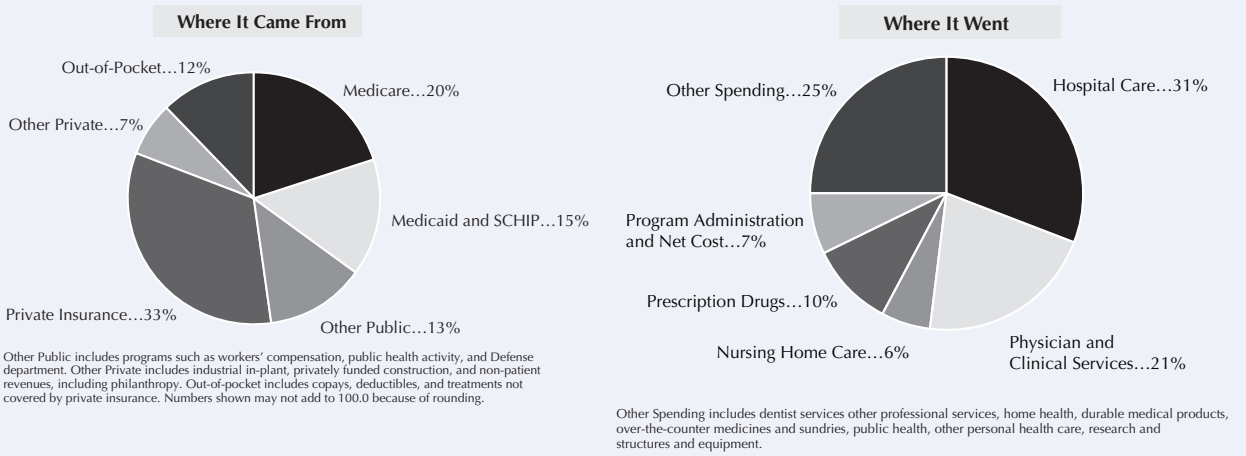
Medicare expenditures were up 8.6 percent in 2008, to a total of $469.2 billion, following growth of 7.1 percent in 2007.

- ❑ Fee-for-service (FFS) Medicare spending jumped 5.3 percent, compared with the growth rate of 3.8 percent in 2007, caused in part by accelerated spending for hospitals, the report said.
- ❑ Medicare managed care spending rose 21.3 percent, similar to the 22.1 percent growth in 2007, as more beneficiaries switched from traditional FFS to Medicare Advantage plans.
- ❑ Prescription drug spending increased 10 percent, to $51.5 billion.

Other highlights in the report:

- ❑ National health spending grew 4.4 percent in 2008, to $2.3 trillion, or $7,681 per person, the slowest rate of growth since the government began tracking expenditures in 1960. The rate was down from 6 percent in 2007, as spending slowed for nearly all health care goods and services, particularly for hospitals.
- ❑ Still, health care spending continued to outpace overall national economic growth. As a share of the gross domestic product, health spending reached 16.2 percent in 2008, up 0.3 percentage points from 2007.
- ❑ Health spending growth by state, local, and private sources slowed in 2008, while federal health spending accelerated, including a temporary 27-month increase in the federal Medicaid share, which shifted approximately $7 billion from states to the federal government for the last quarter of 2008.
- ❑ Private health insurance premiums grew 3.1 percent in 2008, down from a 4.4 percent growth in 2007. Benefit payment growth also slowed to 3.9 percent in 2008 from 4.8 percent in 2007. The recession had a big influence on these

The Nation's Health Care Dollar, Calendar Year 2008



Other Public includes programs such as workers' compensation, public health activity, and Defense department. Other Private includes industrial in-plant, privately funded construction, and non-patient revenues, including philanthropy. Out-of-pocket includes copays, deductibles, and treatments not covered by private insurance. Numbers shown may not add to 100.0 because of rounding.

Other Spending includes dentist services other professional services, home health, durable medical products, over-the-counter medicines and sundries, public health, other personal health care, research and structures and equipment.

Source: CMS Office of the Actuary, National Health Statistics Group.

downward trends: more individuals without jobs could not afford coverage, plan enrollments declined, plus there was a decline in the ratio of the net cost of private health insurance (the difference between premiums and benefits) to total private health insurance premiums.

- Out-of-pocket spending grew 2.8 percent in 2008, far below the growth rate of 6 percent in 2007. The decline was due to less personal spending for retail prescription drugs and for physician and clinical services.

The CMS report is posted at *http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage*.

Pathology Alert: CMS Proposes Rules for HIT Incentive Payments

Pathologists and other providers eligible for incentive payments for adopting certified electronic health record (EHR) technology have at lot at stake in how the government proceeds to define what they must do to qualify to receive the money.

One proposed rule would define "meaningful use" of certified EHRs and specify what providers would have to do to demonstrate such use, a prerequisite for receiving Medicare health information technology (HIT) incentive payments. A related rule would establish an initial set of standards to certify EHRs and standardize formats for exchange of EHRs among providers and between providers and patients.

The incentive payments and the initial standards are authorized by the American Recovery and Reinvestment Act of 2009 (ARRA). In approving new Medicare and Medicaid spending to help hospitals, physicians, and other health care providers adopt HIT, lawmakers set aside portions exclusive to physicians and hospitals. Physicians, for example, can receive up to $44,000 over five years for adopting computerized medical records. The payments to eligible hospitals can begin in October 2010, the Centers for Medicare and Medicaid Services (CMS) said; for other eligible providers, in January 2011.

For pathologists, the site of service makes a difference in qualifying for the incentive payments, without regard to any employment or billing arrangements. Independent pathologists are eligible, but hospital-based pathologists are excluded from directly receiving Medicare HIT incentives out of concerns over duplicate payments. They must seek their share of the money from the hospital's HIT payment.

An eligible professional who qualifies for both Medicare and Medicaid incentive payments may participate in only one program and must designate his or her choice. After this choice, the eligible professional may change the program selection only once during payment years 2012 through 2014. HIT incentive payments will be phased out over time, and Medicare payments will be reduced for those who do not use certified EHRs.

"Meaningful Use": A Definition in Progress

In a rule governing the HIT incentive programs, CMS proposes to define "meaningful use" in terms of a three-stage process that allows for criteria to be refined in line with developments in technology and providers' capabilities:

- Stage 1: Focused on collecting electronic health data in coded formats and reporting data usable for tracking key clinical conditions.

- Stage 2: Focused on advanced clinical processes to support coordination of care and exchange of information, including electronic transmission of diagnostic lab and imaging test results.
- Stage 3: Focused on improved outcomes, including decision support for national high-priority conditions, patient access to self-management tools, access to comprehensive patient data, and improving population health.

A "meaningful EHR user" would be defined as an eligible professional or hospital that, during the specified reporting period, demonstrates meaningful use of certified EHR technology in a form and manner consistent with certain objectives and measures presented in the regulation.

CMS proposes a single definition that would apply to eligible professionals participating in the Medicare fee-for-service and the Medicare Advantage EHR incentive programs as well as a definition that would apply to eligible hospitals and critical access hospitals. These definitions would serve as the minimum standard for eligible professionals and hospitals participating in Medicaid EHR incentives. States could request CMS approval to implement additional meaningful use measures, as appropriate, but could not request approval of fewer or less rigorous meaningful use measures than required by the federal rule.

HIT incentive payments will be phased out over time, and Medicare payments will be reduced for those who do not use certified electronic health records that allow them to electronically communicate with others.

Proposed Initial Standards for Certified EHR

An interim final regulation (IFR) with comment period, issued by the Office of the National Coordinator for Health Information Technology (ONC), sets initial standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security in the exchange of EHR data among providers and between providers and patients.

The rule describes standard formats for clinical summaries and prescriptions; standard terms to describe clinical problems, procedures, laboratory tests, medications and allergies; and standards for the secure transportation of this information using the Internet.

Under the ARRA statute, the government is required to adopt an initial set of standards for EHR technology by Dec. 31, 2009. The interim final rule will go into effect 30 days after publication in the Jan. 13, 2010 *Federal Register*, followed by a 60-day public comment period. A final rule will be issued in 2010.

ESRD Bundled Payment System, *from p. 1*

In 2007, there were about 591 hospital-based and 4,330 freestanding ESRD facilities furnishing outpatient dialysis services to nearly 330,000 Medicare patients, CMS said. The total cost was $9.2 billion, including the dialysis service and other ESRD-related items such as drugs.

Single Payment Rate

Currently, Medicare pays for certain dialysis services under a partial bundled rate, referred to as the composite rate. Payments for composite rate services represent about 60 percent of total Medicare payments to ESRD facilities. The remainder of

Medicare spending for dialysis services is for separately billed items such as drugs, but may also include laboratory services, supplies, and blood products.

Under the proposed rule, CMS said, facilities would receive a base bundled payment rate of $198.64 in 2011 for all services related to a dialysis session—including the services in the current composite rate as well as items, including oral drugs, that are billed separately. The proposed base rate was derived from 2007 claims data for both composite rate and separately billable services and updated to reflect projected 2011 prices.

The prospective payment (PPS) would be adjusted for case-mix factors such as the patient's age, gender, body size, and time on dialysis. A special case-mix adjustment would apply to pediatric patients. Additional adjustments to the payment rate would be made for specific conditions or co-morbidities that have a significant impact on a course of treatment. More information is available on the CMS Web site at *www.cms.hhs.gov/ESRDPayment/*.

ACLA Comments

In comments to CMS on the proposed rule, the American Clinical Laboratory Association (ACLA) said its principal concern was how the agency would define which laboratory tests are included in the bundled payment. The statute requires that diagnostic lab tests now included under the composite payment rate and furnished to individuals in the treatment of ESRD be included in the bundled payment. CMS proposes to define such tests as tests that are separately billable by ESRD facilities as of Dec. 31, 2010, as well as lab tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients and billed by independent labs.

ACLA supports including in the proposed bundle those lab tests separately billed by ESRD facilities; however, it does not support the inclusion of all lab tests ordered by MCP physicians, who often serve as the patient's primary care provider. This would "capture a universe of tests that are wholly unrelated to the treatment of ESRD," ACLA said.

ACLA urges CMS to develop a list of laboratory tests related directly to the treatment of ESRD to ensure that the costs of providing those services are captured completely and accurately in the bundled payment, while those services not directly related to ESRD treatment would continue to be paid separately to the independent lab.

Specifically, ACLA supports the Kidney Care Council's proposed list of approximately 50 lab tests that represent approximately 95 percent of all tests ordered by dialysis facilities and approximately 95 percent of total lab revenue. The approximately 5 percent of lab tests ordered for ESRD beneficiaries that are not directly related to ESRD treatment would include, among others, prostate-specific antigen, oncology tests, thyroid tests, drug screens, and therapeutic drug levels for certain medications. Such tests should continue to be billed directly by the lab to Medicare when ordered by either the MCP physician or another physician regardless of where the specimen is drawn, ACLA said.

Facilities Affected by Switch to ESRD Bundled Payment

Type	
Freestanding	4,330
Hospital-based	591
Ownership	
Large dialysis organization	2,987
Regional chain	753
Independent	550
Unknown	160
Hospital-based	471

(includes facilities not reported to have large dialysis organization or regional chain ownership)

Medicare Claims Advisory

CMS Clarifies Billing Rules for Drug Screening Codes

The Centers for Medicare and Medicaid Services has issued guidance on how clinical laboratories should bill four drug screening codes on the Medicare lab fee schedule from Jan. 1 of this year through March 31, 2010. Further direction on the billing rules will be provided by April 1, CMS said.

The codes affected are:

—CPT 80100	Drug screen, qualitative; multiple drug classes chromatographic method, each procedure
—G0430	Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure
—CPT 80101	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class
—CPT 80101QW	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class
—G0431	Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class

Billing Instructions

From Jan. 1, 2010 through March 31, 2010, when performing a qualitative drug screening test for multiple drug classes using chromatographic methods, CPT 80100 is the appropriate code to bill.

New test code G0430 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 do not use chromatographic methods, new test code is the appropriate code to bill.

New test code G0431 is a direct replacement for CPT 80101. However, CMS is delaying this replacement until April 1, 2010.

Similarly, from Jan. 1, 2010 through March 31, 2010, when performing a qualitative drug screening test for a single class of drug, regardless of the testing methodology, those labs that do not require a CLIA certificate of waiver should bill the new test code G0431. Those labs that do require a CLIA certificate of waiver should continue to use CPT 80101QW to bill.

Background

For the 2010 Medicare lab fee schedule, CMS created new codes G0430 and G0431. When these were introduced at the annual public meeting during 2009, members of the lab industry expressed concern about how these new codes would be described and when they should be billed.

It came to CMS's attention that some companies were using questionable billing practices concerning CPT 80100 and 80101. Also, 80100 describes only chromatrographic testing for the presence of drugs, which left certain labs unable to bill accurately when this type of testing was performed but the chromatographic method was not used. Therefore, CMS created new G codes to operate in place of and alongside existing CPT 80100 and 80101.

Medicare Claims Advisory

Interest Rate To Rise for Medicare Overpayments, Underpayments

Effective Jan. 25, 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 increased to 11.25 percent, from the rate of 10.875 percent in effect since Oct. 22, 2009. At the start of 2009, the rate was 11.75 percent, the same since April 18, 2008. The highest rate in this decade was in early 2001, 14.125 percent, but for most of the decade 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 2010) or the private consumer rate fixed by the Treasury. The Centers for Medicare and Medicaid Services announced the quarterly update to the interest rate in Change Request 6652.

Update on Policy Changes for Medicare Advance Beneficiary Notices

CMS has revised instructions to Medicare contractors regarding changes to the use of the Advance Beneficiary Notice (ABN). The new guidance is contained in Transmittal 1894, effective April 5, 2010. It replaces Transmittal 1840, dated Oct. 29, 2009 (*NIR, 09, 20/Nov. 9, 2009, p. 7*).

The new transmittal provides guidance on using one new and one revised modifier to distinguish between voluntary and required uses of the ABN. The ABN alerts beneficiaries that they may be financially liable for an item or service that Medicare is likely to deny. The transmittal also clarifies general noncovered charge instructions for institutional claims and relocates certain benefit-specific information in their associated chapters of the Medicare Claims Processing Manual.

Changes in Billing Modifiers

Starting April 1, 2010, CMS will introduce the following:

- The modifier, –GA, will be redefined to mean "Waiver of Liability Statement Issued, as Required by Payer Policy." It is only to be used to report 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.

Since March 1, 2009, Medicare has recognized as valid only its revised single-page ABN (CMS-R-131), as well as a version tailored to clinical laboratory use (*NIR 09, 4/Feb. 23, p. 5*). The ABN is formatted to help a beneficiary match a listed or checked service, the reasons Medicare may not pay, and the estimated cost of the service. It should be kept for five years from discharge or completion of the delivery of care when there are no other applicable requirements under state law.

Election Upset, *from p. 1*

Congress is expected to grant a modest increase in 2010. The Senate reform bill would grant a 0.5 percent increase; the House bill would replace the current update formula and allow a 1.2 percent increase.

Lab fees: The 2010 update was cut 1.9 percent. The Senate bill would leave this intact but alter the formula in 2011, translating to continuing cuts. The House bill would alter the formula in 2010, for a total cut of 2.7 percent (*NIR 10, 1/Jan.11, p. 1*).

Pathology 'grandfather' protection: This has expired, but the House has approved a two-year extension; the Senate, a one-year extension. The protection allows independent clinical labs to bill Medicare separately for the technical component of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999. Meantime, the Centers for Medicare and Medicaid Services, anticipating some legislative action, has advised providers to hold claims if possible or they may continue to submit claims, which may be reprocessed later if and when the protection is extended (*NIR 10, 1/Jan. 11, p. 1*).

Upcoming G-2 Events

Webinars

Jan. 26

How Do You Know How Well You're Doing? Measuring Quality in the Clinical Laboratory

Feb. 2

Keeping the Government Off Your Doorstep: Essentials of an Effective Lab Compliance Program

Times: 2:00 p.m. – 3:30 p.m. (Eastern)

Conferences

April 14-16

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

Register before March 5 to save $100!!

June 2-4

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

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