G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 32nd Year of Publication

Vol. 11, Iss. 16, September 8, 2011

'Super Committee' Urged to Spare Medicare Lab Services

A broad coalition of lab professional groups, scientific societies, and lab companies is already on record opposing lab coinsurance and further lab fee cuts as part of a deficit-reduction deal.

"Reject further reductions in Medicare reimbursement to clinical labs and any beneficiary cost sharing for these services." The American Clinical Laboratory Association (ACLA) made that appeal in a recent letter to the Joint Select Committee on Deficit Reduction that begins deliberations this month.

The panel has scheduled a Sept. 8 meeting to establish operating procedures and a Sept. 13 hearing with Douglas Elmendorf, director of the Congressional Budget Office, as a witness on the history, drivers, and threats of the nation's debt.

The so-called "super committee," composed of six Democrats and six Republicans from the House and the Senate, is charged under the debt ceiling deal to find up to $1.5 trillion in savings over 10 years, beginning in 2013. Its recommendations are due by Nov. 23. If approved by a majority, they go to Congress for an up-or-down vote, with no amendments or filibuster, by Dec. 23. The president retains veto power over any legislation that passes.

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Medicare Increases Travel Allowance

The Medicare trip fee, payable when medically necessary for a laboratory technician to travel to collect a specimen from a nursing home or homebound beneficiary, has increased to $1.005 per mile or $10.50 on a flat-rate basis.

The Centers for Medicare and Medicaid Services (CMS) announced the fee increase in an Aug. 26 transmittal (No. 2283) to local contractors, with an effective date of July 1, 2011, and an implementation date of Nov. 29, 2011.

The previous travel allowance, in effect since the start of the year, was 96 cents per mile, with the mileage portion set at 51 cents and the personnel portion at 45 cents.

The new trip fee rate is due to an increase in the federal mileage rate announced by the Internal Revenue Service to 55.5 cents for the period from July 1, 2011, through Dec. 31, 2011, to help offset the rise in the cost of gas. The personnel portion is unchanged.

The fee increase represents a major win for the National Independent Laboratory Association (NILA), which had formally asked CMS to implement the new IRS rate to ease labs' pain at the pump (*NIR 11, 14/ July 28, p. 4*).

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'Super Committee,' *from p. 1*
Adding cost sharing for laboratory services in Medicare—through either a 20 percent coinsurance or a flat copayment per test —was one of the Medicare proposals reportedly on the table during negotiations leading up to the debt ceiling deal and the creation of the joint select committee (*NIR 11, 13/July 14, p. 1*).

'Super Committee' on Deficit Reduction

Members include three each appointed by Senate Majority Leader Harry Reid (D-Nev.), Senate Minority Leader Mitch McConnell (R-Ky.), House Speaker John Boehner (R-Ohio), and House Minority Leader Nancy Pelosi (D-Calif.)

Senate

Democrats: Patty Murray (Wash.), committee co-chair, Finance Committee Chairman Max Baucus (Mont.), and John Kerry (Mass.)

GOP: Jon Kyl of Arizona, Pat Toomey of Pennsylvania, and Rob Portman of Ohio.

House

GOP: Dave Camp (Mich.), Fred Upton (Mich.), and Republican Conference Chairman Jeb Hensarling (Texas). Hensarling will be "super committee" co-chair.

Democrats: Xavier Becerra (Calif.), James B. Clyburn (S.C.), and Chris Van Hollen (Md.).

In the letter, ACLA laid out a series of arguments for sparing Medicare lab services from the chopping block:

❏ Lab services have had no beneficiary cost sharing since 1984. Introducing coinsurance or a copay of 20 percent would hinder beneficiary access to needed and recommended testing. It would impose added out-of-pocket expenses (which, in the case of advanced molecular diagnostics for cancer and other serious diseases, could run into hundreds of dollars). It also runs counter to the emphasis Congress has given to prevention and wellness—this year, for example, by waiving cost sharing for most Medicare-covered screening services.

❏ For labs, coinsurance or copayment means, in many cases, added costs for billing and collecting that typically exceed the amount due. "The volume of bills for small amounts would be over 215 million new bills to beneficiaries for an average of $6.20, with 70 million of those bills being for less than $2," ACLA said. "The cost of collection, and the ability of laboratories to collect, is uniquely difficult because they do not usually have a face-to-face encounter with the beneficiary that all other providers who bill patients have."

❏ The new costs will be "devastating" to thousands of smaller businesses that are often the sole provider of lab services to nursing home and homebound beneficiaries. These populations have high concentrations of "dual eligibles" (Medicare and Medicaid) for whom collection of the coinsurance or copay is unlikely. "While $6 lost per claim may not sound like a significant amount," ACLA said, "in fact, when the average claim is only $20, a loss of $6 per claim amounts to a 30 percent reduction in reimbursement to these labs—an amount that could swiftly put them out of business. Nursing homes could be left with no choice but to send beneficiaries by ambulance to the hospital for routine blood work, at considerable cost to Medicare."

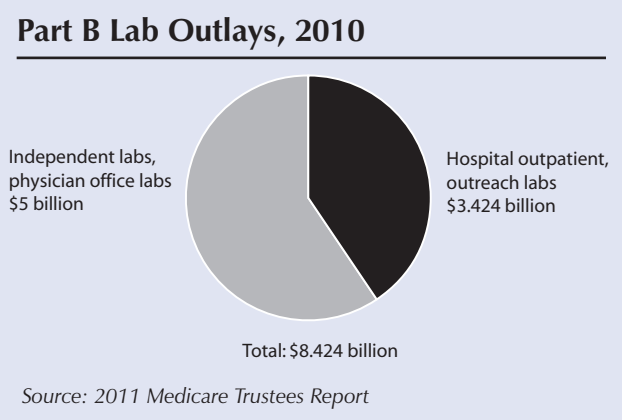
Over the past three decades, coinsurance or copays for lab services have been considered, ACLA noted, but have been rejected time and again by independent outside organizations, government agencies, and Congress.

ACLA also urged the joint select committee to spurn any further lab reimbursement cuts. "Payments have been reduced by about 40 percent in real (inflation-adjusted) terms over the past 20 years. And they are scheduled to decline by an additional 19 percent over the next 10 years under the health care reform law."

Since its debut, the lab fee schedule has been adjusted downward, lowering payment rates. National fee caps, first set at 115 percent of the national median of each affected test, have been trimmed to 74 percent. Congress has frozen the annual fee update in 12 of the years from 1985 to the present. Most recently, lawmakers changed the update formula based on the consumer price index, adding a productivity adjustment (but guaranteeing that this could never reduce the update below zero) plus a cut of 1.75 percent over the next five years.

In concluding, ACLA said that under lab coinsurance and fee-cutting proposals there is the potential for tens of thousands of jobs to be lost, particularly among smaller regional labs serving nursing home and homebound patients.

Part B Lab Spending Reaches $8.4 Billion in 2010



Medicare spending on Part B clinical laboratory services was up 4.6 percent to reach $8.424 billion in calendar-year 2010, according to data from the 2011 Medicare Trustees Report. This compares with a rise of 11.2 percent in 2009 to $8.049 billion and an anemic 2 percent increase between 2007 and 2008 (*NIR 10, 11/Sept. 9, p. 5*).

Of the total lab spending, $5 billion went to carrier labs (independent labs and physician office labs), an increase of 5.9 percent from $4.723 billion in 2009.

Intermediary labs (hospital lab outpatient and outreach) accounted for $3.424 billion, an increase of 2.8 percent compared with $3.331 billion in 2009.

Total Medicare spending in 2010 was $522.8 billion, up 2.7 percent from $509 billion in 2009. The number of beneficiaries increased by 2 percent to approximately 47.5 million compared with 46.3 million in 2009.

Part B lab services represented 1.6 percent of overall Medicare expenditures in 2010. Over the past five years, Part B lab expenditures have risen an average 5.9 percent per year, compared with an average rate of growth of 9.2 percent for total Medicare spending over the same time frame.

Over the next 10 years, 2011-2020, the annual growth in total Medicare spending will slow to an average of 6 percent per year, the trustees' report said. This is based on scheduled physician payment reductions, which Congress is not likely to allow, and on other savings expected from new care delivery and payment models authorized under the health care reform law, the trustees noted, but cautioned "specific outcomes cannot be assessed at this time."

focus on: Medicare Payment Policy

CMS Unveils Bundled Payment Initiative: Wave of the Future for Labs, Pathologists?

The Centers for Medicare and Medicaid Services (CMS) has high hopes for its new initiative to reimburse services, including clinical laboratory and pathology services, via a bundled payment per episode of care.

Four payment models are to be tested, giving doctors, hospitals, and other health care providers new incentives to coordinate care for patients in the hospital and after discharge. Two of the models specifically roll clinical lab and pathology reimbursement into the bundled payment.

CMS spelled out details of the initiative in the Aug. 25 *Federal Register* and invited providers to apply to run one or more of the model programs. "By bundling payment across multiple services, providers will have a greater incentive to coordinate and ensure continuity of care across settings, resulting in better care for patients," the agency said in a fact sheet. "This can reduce unnecessary duplication of services, reduce preventable medical errors, help patients heal without harm, and lower costs." Participants also can share in savings achieved under their programs.

To sweeten the invitation, CMS noted that providers will have "great flexibility in selecting conditions to bundle, developing the care delivery structure, and deciding how payments will be allocated among those participating."

In this initiative and in others aimed at coordinating care such as through accountable care organizations, clinical labs and pathologists will play a crucial role in achieving better outcomes for patients and cost efficiencies for Medicare by selecting only the appropriate testing for disease prevention, treatment, therapy, and monitoring and ruling out unnecessary and duplicative services. An estimated 70 percent of medical decisionmaking derives from clinical lab and pathology data.

Choices Among Four Models

Three of the four broadly defined models of care involve a retrospective bundled payment arrangement, with a target price (target payment amount) for a defined episode of care, while the fourth would establish a single, prospectively set bundled payment. While all offer the prospect of sharing in savings, they also present the risk of losses when spending targets are breached.

❑ Model 1

The episode of care is defined as the inpatient stay in a general acute-care hospital. Medicare would pay the hospital a discounted amount based on rates under inpatient prospective payment. The minimum discount would rise from 0 percent for the first six months to 2 percent in the third year. Pathology and other physician services would not be included in the episode of care and would be paid separately under the Medicare fee schedule. Hospitals and physicians may share gains arising from better coordination of care.

❏ **Models 2 and 3**

In Model 2, the episode of care includes the inpatient stay and post-acute care and ends, at the applicant's option, either a minimum of 30 or 90 days after discharge, while in Model 3, the episode of care begins at discharge from the inpatient stay and ends no sooner than 30 days after discharge.

In both Models 2 and 3, the bundle would include pathology and other physicians' services, care by a post-acute provider, related readmissions, and other services proposed in the episode definition such as clinical laboratory services; durable medical equipment, prosthetics, orthotics, and supplies; and Part B drugs. The target price would be discounted from an amount based on the applicant's historical fee-for-service (FFS) payments for the episode. While the discount to Medicare is to be proposed by applicants, CMS would require for Model 2 a minimum discount of 3 percent for a post-discharge episode of 30 to 89 days or 2 percent for an episode 90 days or longer. Payments under both models would be made at the usual FFS rates, and any reduction in expenditures would be paid to the participating providers to share.

❏ **Model 4**

CMS would make a single, prospectively determined bundled payment to the hospital that would encompass all services furnished during the inpatient stay by the hospital, physicians, and other practitioners. Physicians and other practitioners would submit "no-pay" claims to Medicare and be paid by the hospital out of the bundled payment.

Background

The bundled payment initiative has been launched by the Center for Medicare and Medicaid Innovation, housed within CMS and established by the health care reform law to study payment and delivery alternatives to traditional FFS medicine under which Medicare makes separate payments to providers for the services they furnish to beneficiaries for a single illness or course of treatment.

It is based on research and previous demonstration projects that suggest bundled payment methods have tremendous potential for wider application, CMS noted. For example, a Medicare heart bypass surgery bundled payment demonstration saved the program $42.3 million, or roughly 10 percent of expected costs, and saved patients $7.9 million in coinsurance while improving care and lowering hospital mortality.

Deadlines for Bundled Payment Applicants

Organizations interested in applying must meet the following deadlines:

❏ Model 1: Submit a nonbinding letter of intent no later than Sept. 22 and a completed application by Nov. 4, 2011.

❏ Models 2, 3, and 4: Submit a nonbinding letter of intent no later than Nov. 4, 2011, and a completed application by March 25, 2012. Applicants that wish to receive historical Medicare claims data to develop well-defined episodes and discount proposals based on the experience of providers in their area must complete a Research Request Packet by Nov. 4 as well.

For more information about the various models and the initiative itself, go to *www.innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html*.

New Gains for Women's Preventive Services

Under a new federal rule, women's preventive health services, including clinical laboratory tests that screen for certain diseases, must be covered by private health insurers with no charge for copayments, coinsurance, or deductibles (*see box*).

The requirement implements a provision of the health care reform law (the Patient Protection and Affordable Care Act or PPACA). It affects group and individual health insurance policies with plan years beginning or after Aug. 1, 2012. It does not apply to "grandfathered" health plans that began before PPACA was enacted in 2010 and that meet criteria for not making many changes.

The new coverage was announced in an interim final rule published in the Aug. 3 *Federal Register* by the Centers for Medicare and Medicaid Services, the Labor Department's Employee Benefits Security Administration, and the Internal Revenue Service, which adopted guidelines recommended July 19 by the Institute of Medicine. The IRS also issued a separate rule amending excise tax regulations.

Services to be covered with no cost sharing

- Screening for gestational diabetes
- Human papillomavirus screening
- DNA testing for women 30 and older
- HIV screening and counseling
- Sexually transmitted infection counseling
- Contraception
- Well-woman visits
- Breast-feeding supplies and support
- Domestic violence screening

"Millions of women will be positively affected" by the end of cost sharing, said Howard Koh, assistant secretary for health in the U.S. Department of Health and Human Services (HHS), during a press briefing.

"This puts forward a national standard for the first time that will have broad impact," he said. "Some 88 million people will be in nongrandfathered plans by 2013, of which about 34 million will be women ages 18 to 64, and new plans are being created all the time."

A recent study cited by HHS officials found that each year more than half of women avoid or delay key preventive care because of cost, which hurts public health and drives up health care costs. On average, women need to use more preventive services than men, yet women typically earn lower incomes than men and are often less able to pay, Koh noted.

Mayra Alvarez, director of public health policy in the HHS Office of Health Reform, said during the briefing that the new rule would result in a "very small increase" in premiums, since most employer plans already cover the services.

But America's Health Insurance Plans, which represent about 1,300 insurers covering about 200 million people, said the rule "would increase the number of unnecessary physician office visits and raise the cost of coverage."

The administration also released an amendment allowing religious institutions that offer insurance to their employees the choice of whether to cover contraception. Plans may use reasonable medical management to help define the nature of the covered service, and they have the flexibility to control costs and promote efficiency by such methods as imposing cost-sharing payments for branded drugs if a generic version is available and safe.

Update on Revalidating Your Medicare Enrollment

"Wait till you hear from your Medicare Administrative Contractor (MAC)." That's the word from the Centers for Medicare and Medicaid Services (CMS) to providers and suppliers whose Medicare enrollment status must be revalidated under new risk-screening criteria.

The advice applies to clinical laboratories, pathologists, and others who enrolled in the program prior to March 25, 2011. "Do not submit your revalidation until notified to do so," said CMS. "You will receive a notice to revalidate between now and March 2013."

The staggered time frame for revalidations, CMS said, "will allow MACs to process them in a timely fashion and allow providers to take advantage of innovative technologies and streamlined enrollment processes now under development. Updates will be shared with providers as these efforts progress."

Providers who enrolled on or after March 25, 2011, are not affected. They have already been screened under the new criteria and need not revalidate at this time, CMS said.

CMS earlier this year imposed tighter screening on providers and suppliers in Medicare, Medicaid, and the state Children's Health Insurance Program, using its discretionary authority under the health care reform law (*NIR 11, 3/Feb. 10, p. 1*). The aim, CMS said, is to keep "bad actors" out by switching from pay-and-chase enforcement to preventing possible payment of fraudulent claims.

Newly enrolling and revalidating providers and suppliers are placed in one of three tiers—limited, moderate, and high, each representing the level of risk to Medicare posed by the particular category. This determines the degree of screening the MAC uses to process enrollment information.

Histocompatibility laboratories and pathologists are among those ranked as limited fraud risk, subject only to license verification and database searches to confirm Social Security numbers, tax delinquency, and any exclusions by the Office of Inspector General.

Independent clinical laboratories are ranked as moderate fraud risk, subject to the same scrutiny as limited risk entities, plus unscheduled site visits. CMS noted that "while these labs are subject to surveys under the Clinical Laboratory Improvement Amendments (CLIA), there are nonetheless a number of potentials for fraud, not the least of which is the sheer volume of service and associated billings generated by these entities."

When You Hear From Your MAC

When your MAC notifies you that it is time to revalidate, you have 60 days from the date of the contractor's letter to submit complete enrollment forms. Failure to respond in a timely and complete manner may result in deactivation of Medicare billing privileges.

Upon notice, you can update enrollment, either online using the Provider Enrollment, Chain, and Ownership System (PECOS), or through the mail.

Additionally, all institutional providers (excluding physicians and nonphysician practitioners) will have to pay a $505 enrollment fee for calendar-year 2011.

Medicare Increases Travel Allowance, *from p. 1*

NILA also forwarded several letters and e-mails to CMS officials, urging them to adopt the new rate quickly, "as this is important to labs whose technicians must travel daily to collect specimens."

Why the gap between the effective dates of the fee increase and its implementation? CMS is required to give contractors 90 days from release of the transmittal to update their systems to process claims at the new rate.

Laboratories that experience problems with carriers paying the new rate are asked to contact NILA by telephone at (314) 241-1445 or e-mail at nila@nila-usa.com.

Once carriers make the update, clinical labs will be able to resubmit any claims that have been processed since July 1, 2011, at the lower rate to have them reprocessed at the new higher rate. Contractors are responsible for paying for the new rate within their current operating budgets. To date, CMS said, it has not received any comments from carriers claiming they cannot pay the new rate.

The trip fee billing codes are P9603 (per mile; used when the average trip is longer than 20 miles round trip) and P9604 (flat rate). The modifier LR is used to indicate round-trip travel. Under either code, when one trip is made for multiple specimen collections, the fee is prorated among specimens collected for Medicare and non-Medicare patients.

Upcoming Events From G2

Conferences

Sept. 23
Molecular Diagnostics—Fall 2011
W San Francisco
San Francisco

Oct. 19
Lab Leaders Summit 2011
Come for the summit and stay for Lab Institute
Ritz-Carlton Pentagon City
Arlington, Va.

Oct. 19-21
Lab Institute 2011
Crystal Gateway Marriott
Arlington, Va.

Dec. 12-14
LabCompete: Laboratory Sales & Marketing
Sheraton Wild Horse Pass Resort
Chandler, Ariz.

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 G2 Compliance Report (ISSN 1524-0304) is published by G2 Intelligence, 1 Phoenix Mill Lane, Fl. 3 , Peterborough, NH 03458-1467 USA. Tel: 800-401-5937 or 973-718-4700. Fax: 603-924-4034. Web site: www.G2Intelligence.com.

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